Factors that impede the adoption of TQM in Professional Scientific Organisations

Volume I

Jane Elizabeth Pearse

A thesis submitted in partial fulfilment
of the requirements of the University of Brighton
for the degree of PhD

September 1997

Centre for Management Development
The University of Brighton

ABSTRACT

Author: Jane Elizabeth Pearse

Title: **Factors that impede the adoption of Total Quality Management in Professional Scientific Organisations**

This thesis reports on the implementation of TQM in the unusual environment of two Professional Scientific Organisations. An action research case study was concluded in the first organisation which had implemented an unconventional form of TQM. A corroborating case study was conducted in the other which had implemented "traditional" TQM.

The dissimilar approaches made little difference to the experiences of the organisations. Both moved to a more harmonious working environment. Less gain was made in the tangible aspects of operations. Complicating influences to the success of TQM were identified. These included inconsistencies in management commitment, the resistant mindset of the scientists, poor communication, the complex and variable nature of the work, the unusual relationship between organisation and client, economic constraints, and the design of work itself.

This study is of significance to the body of knowledge on quality management because it looks at TQM in the context of organisations that provide a "product" that has major implications for the well-being of man and the environment - the safety testing of new drugs and other chemicals. TQM is studied in the presence of Good Laboratory Practice, a potent and extensively used level of quality compliance rarely discussed in the literature.

The research has looked at the dynamics of the organisations, the practical difficulties that have been encountered, the immediate relevance of quality improvement upon the actual processes and systems of the organisation, and the influence of the people in the organisation on its success or otherwise.

The contribution to knowledge lies in the understanding of the influence of management styles and the scientific mindset on TQM implementation, increased understanding of the validity and application of measurement techniques in relation to the regulated nature of the business of a PSO and the identification of conflicting, complicating and destructive impediments that influence the implementation of TQM in PSOs.

CONTENTS

CONTENTS

CONTENTS

CONTENTS

CONTENTS

CONTENTS

LISTING OF TABLES AND FIGURES

LISTING OF TABLES AND FIGURES

LISTING OF TABLES AND FIGURES

Page

LISTING OF TABLES AND FIGURES

Chapter 9 : BioFarm Case Study - Technical Improvement Survey - Phlebotomy

Chapter 10 : Corroborative Case Study

Page

LIST of APPENDICES

Numbering of Appendices is consistent with chapter numbering

LIST of APPENDICES

Published Works

Pearse JE (1997) "Does fraud in science influence the 3Rs?", Animal Technology, 48(1), 7-16

ACKNOWLEDGEMENTS

DECLARATION

While registered as a candidate for the degree for which this submission is made, the author has not been a candidate or enrolled student of any other university or professional institution

No material in this thesis has been used in any other submission for an academic award

Jane E Pearse

CHAPTER 1
INTRODUCTION TO THE RESEARCH

Introduction

The purpose of this chapter is to provide an overview of the research and introduce the research aims, scope, methodology, context and the form of the thesis.

This thesis describes a case study of two commercial organisations engaged in the business of toxicology, that is safety testing of chemicals (drugs, pesticides, food additives, industrial chemicals etc.) that have the potential to cause damage to man or the environment. The focus of the research project was the intent of these organisations to implement Total Quality Management (TQM) and their experiences of that process in their novel environment.

To provide an indication of the business style and focus of the companies, the label of Professional Scientific Organisation (PSO) has been applied to the organisations.

1.1 Definitions

Because this research crosses the boundary of management and science, and in some areas is looking at improvement of scientific processes, it is sometimes impossible not to use appropriate technical terms to describe elements of the work. Where possible, terms have been explained at the first instance of use and the author has tried to avoid the jargon of the industry. However, because a number of terms, particularly those relating to the scientific disciplines, may not be familiar to the reader, they are explained in the Glossary of Terms.

The following four definitions have been proposed and applied to this research:

1.1.1 Professional Scientific Organisations

Professional Scientific Organisations (PSOs) are independent commercial, public or private organisations that derive their main income as a "contractor" of scientific services (i.e. services in a scientific discipline the conduct of which is dependent upon the qualification, skills, knowledge, social and professional standing of its employees) to industry. PSOs do not manufacture any tangible product. Their tangible output will generally be an expert report, released from a "responsible scientist", conveying the results of scientific/technical work that has been conducted within, or under the control of the PSO on behalf of a third party, often referred to as "the Sponsor". The total product is generally a complete service which includes provision of all resources (facilities, materials and staff) to conduct the work, in addition to consultancy, design, project management and reporting.

1.1.2 Total Quality Management

Total Quality Management is a form of long-term strategic management directed towards increasing an organisation's competitive advantage through commitment of all employees to meet the needs of the customer. It is a process that requires critical evaluation of all facets of the way that an organisation is managed. TQM requires breakthrough in the traditional resistance to change to facilitate continuous improvement directed towards making the organisation more responsive, flexible and adaptive to the demands of the market place.

1.1.3   Action Research

An eclectic approach of a researcher to facilitate a change, intended to address a jointly perceived problem, in a collaborating organisation (the client).   The research aims to contribute both to practical concerns of people (including people in organisations) and to the research goals, via joint collaboration within a mutually acceptable ethical framework.   It is characterised by

> 1.*The immediacy of the researcher's involvement in the action*

> 2.*The intention of both parties to be involved in the change*

Action research has a clear conceptual framework which is acceptable to the researcher and which may have to be imposed on the research on the initiative of the researcher himself. (Rapoport, 1970: 499)

1.1.4   Good Laboratory Practice

Good Laboratory Practice (GLP) is concerned with the organisational processes and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported.   Adherence by laboratories to the principles of Good Laboratory Practice ensures the proper planning of studies and the provision of adequate means to carry them out.   It facilitates the proper conduct of studies, promotes their full and accurate reporting, and provides a means whereby the integrity of studies can be verified. (Department of Health, 1989: 2)

3

1.2   Organisational context of the research

The majority of this work, a major action research case study, was conducted at BioFarm Laboratories (BFL) where research activity and data collection spanned the period between 1989 and 1994. The organisation was a medium sized enterprise, established for just under twenty years, employing around 600 staff and with a turnover in the order of £20 million per year. The business of BFL is as a PSO in biomedical toxicology, that is safety testing of chemicals (drugs, pesticides, food additives, industrial chemicals etc.) that have the potential to cause damage to man or the environment. This work is performed on behalf of a "Sponsoring" company and is performed to meet the requirements of governmental authorities worldwide.

A second organisation, SciTec Europe (STE), engaged in the same business and a direct competitor of BFL, was used to corroborate and compare findings. This organisation was used because of

> a) the similarities in profile to that of BFL and
>
> b) because it shared with BFL a common problem (the need to improve quality) with a common solution (implementation of TQM).

Research at SciTec was conducted in the first half of 1993.

Because of the potentially controversial nature of this work, pseudonyms and/or codes have been used for the companies and individuals who participated.

1.3   Background to the research

The growth of TQM in the UK from the mid 1980s through to the early 1990s is now well documented. At that time there was a growing body of evidence indicating that organisations were recognising TQM as increasingly relevant to their survival in an ever more competitive market place (Oakland, 1989; Lascelles and Dale, 1989; Cook and Blaxter, 1991). The majority of the application of TQM and its field of applicability was reported as being in manufacturing industry. However, Professional Scientific Organisations, working in a specialist service market, were no less zealous than manufacturing organisations in their desire to increase their competitive advantage and grasp a greater market share in the process. Some looked to TQM as a potential means of achieving these objectives. The problem was that TQM did not have a

proven track record in the service sector and there was little evidence that it had even been tried in the somewhat specialist area of regulatory toxicology. The growing body of TQM practitioners advocated that it was applicable to any business sector and suggested that its relevance and use would be no less valid in the professional scientific market than in manufacturing.

In the late 1980's BioFarm Laboratories (BFL) and SciTec Europe (STE) both took the decision to adopt TQM. The decision of BFL to follow the route to TQM had not been made easily or rapidly. There had been wide debate amongst senior managers some of whom saw TQM as unwelcome hype and argued that being professional scientists, their work was always conducted to the highest standards. Others allowed that the company needed to do *something* to improve quality and TQM appeared a feasible candidate.

At this stage, the researcher was one of a small group of senior managers at BFL involved in the discussions. As part of an advanced management development programme requiring the conduct of an organisation based project, a study was conducted into the validity of TQM to the business of the company and the feasibility of implementation. That work, which galvanised the decision of BFL to implement TQM, provided the foundation for this thesis. There were a number of unanswered questions worthy of deeper consideration, the first of which was *"Is it actually possible for TQM to be successful in an organisation such as a PSO when its own basis is so firmly grounded in manufacturing industry?"*.

Turning to the literature in search of answers, the dearth of relevant publications on TQM implementation in scientific service environments was quickly evident. From the middle of the 1980s there was a noticeable increase in publications which addressed the development and management of TQM as a corporate survival strategy (Rieker,1987; Boghossian,1988; Foster and Whittle,1989; Lorenz,1989). These writers acknowledged that the desire of organisations to adopt this "tool for survival" had resulted in an extensive growth in TQM consultancy which, at the time of commencing this research, appeared not to be matched by much real growth in understanding of the

difficulties that can be encountered by the wide variety organisations attempting to implement programmes of quality improvement. Many of the consultants and much of the literature presented the successful case study and "how to introduce TQM" in a manufacturing environment and failed to take cognisance of the potential difficulties of introducing radical companywide change into a variety of different business environments.

During the early 1990s, the impact and significance of TQM to business success resulted in greater research interests and consequently a marked expansion in the body of knowledge of implementation strategies for TQM. There has been exponential growth of literature on quality management. In addition to the journals and books specialising in the subject, it was noted that professional institutes were publishing articles on Quality Management in their specialist field. Although most publications focused on TQM in manufacturing industry, there was a growing recognition of the potential of, and need for, TQM in the service sector. Gummerson (1989; 83) notes that in comparison with manufacturing industry, there had been a widespread focus and little research into development of generally accepted techniques and measures for service industries. Where reports have been published on TQM in service industries, the predominant subject organisations tend to be in transportation services, banking, public services and telecommunications.

Literature which relates to the field of regulated science and professional service organisations remains scarce. In 1989 a survey of the literature failed to identify any publications with direct relevance to the implementation of TQM in a scientific research environment and since then Price and Gaskill (1990) have published on their observations and methodology for implementation of TQM in research and development in the petrochemical industry and conclude that there are special challenges when applying TQM to a research environment. A joint symposium of the American College of Toxicology and Society of Quality Assurance (1991) resulted in the production of a number of articles linking Good Laboratory Practice, the guiding quality principles for professional scientific organisations conducting toxicology, with TQM.

At the outset of this research few authors had examined the real issues underlying the failures of quality programmes. Lascelles and Dale(1989), Atkinson (1990), James (1991), and Macdonald (1993), all consider reasons for failure of TQM but take very little cognisance of the underlying difficulties that might arise because of differences of, for example, company and individual culture, the specialised nature of an organisation's business, profile of a workforce, or past experience of an organisation. Ritsema *et al* (1992) fill some of this gap with their work on the quality management and professional service organisations where they recognise the relevance of the professional culture to the adoption of quality management and describe the tensions that exist between the client, the organisation and the professionals within the professional organisation.

Taylor and Pearson(1994) have published on Total Quality Management in Research and Development. They report upon a case study of successful implementation of TQM in a large complex Research and Development laboratory. The importance of this work is that it identifies a fundamentally different approach to TQM which Taylor and Pearson claim significantly increases the chances of unchallenged adoption of TQM in an R&D organisation. Taylor and Pearson propose an approach which convinces scientists of "proof of the need" (Taylor and Pearson, 1994: 27) for improvement rather than modifying the "traditional" approaches to suit the organisation. Until the publication of this case study, there had been very little published empirical research on factors that influence successful application of TQM by organisations staffed by those of the scientific persuasion. From the researcher's earlier work and unstructured observations at BFL, it seemed that there were a host of potential factors that could lead to success, failure or masking of the impact of TQM which were worthy of investigation. One of the shortfalls that was perceived of much of the published work on TQM was the tendency to present the surface level picture - the tools and techniques, the systems and the strategies and the theory rather than getting to the deeper levels and looking closely at reality. In this research interest lies in practical application and what actually happens and why things happen in the organisation when such a process is adopted.

1.4 Aims of the Research

The aim of this research was to develop an understanding of factors which may influence adoption of Total Quality Management by Professional Scientific Organisations. This broad aim can be broken down into more specific areas. These were to

1. Evaluate the quality related activity of the organisation to assess the degree of success or failure that implementation of an unconventional form of TQM could have upon the business performance and upon the organisation community

2. Observe the effects of implementing TQM on the individuals within the organisation.

3. Understand how the mindset of the professional scientist influences the implementation of TQM.

4. Identify external and internal variables which complicate the assessment of progress.

5. Assess the applicability of the tools and techniques of TQM in the context of the work conducted by a PSO.

1.5 The Research Framework and Timing of Activities

The framework of this project is relatively complex because of a) the extended time frame with activities spreading over the period from 1989 to 1993, b) the total organisation base and c) because research activities were differently conducted in two organisations. A diagrammatic presentation of the framework and timing of activity, is provided by the Figures 1.1 (research phases and the relationship of activity at BioFarm to SciTec) Figure 1.2 (conceptual framework of case study of BFL) and Figure 1.3 (timeframe of research activity)

This project required intervention by the researcher in an organisation to facilitate (the introduction of TQM at BioFarm Laboratories) and assess the effect of that change on the people, systems and organisation through use of a variety of measuring rods. Part of the assessment process involved work at the second subject organisation, SciTec

8

Europe, to corroborate and compare findings from BFL. The need to combine change activity with empirical work led to the selection of an Action Research approach.

Figure 1.1   Research Framework
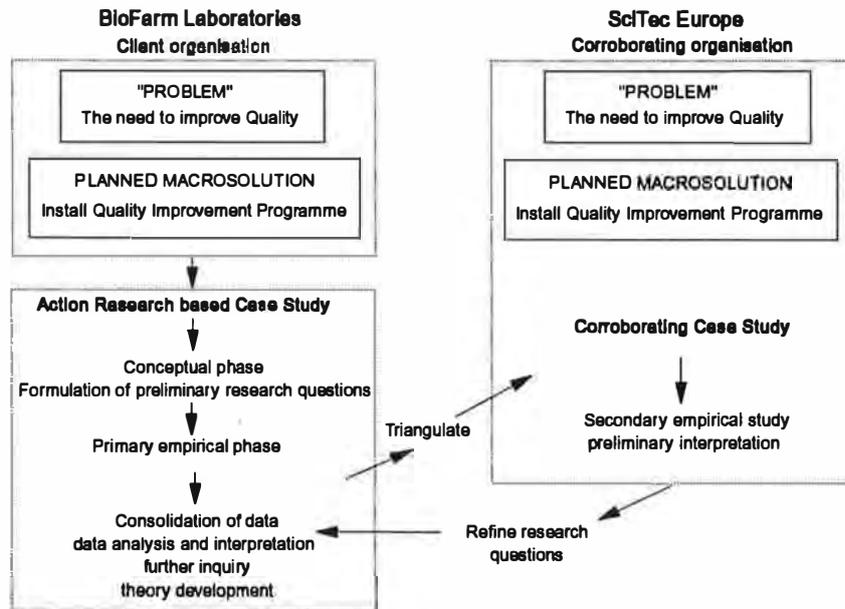
Figure 1.2   Conceptual model of the Action Research case study of BioFarm
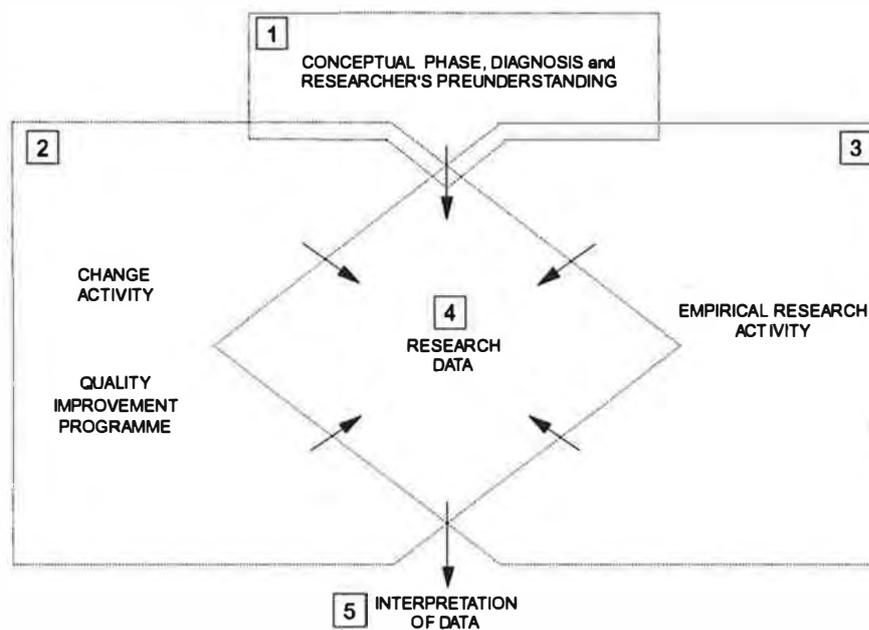
Figure 1.3   Timing of research and intervention activities
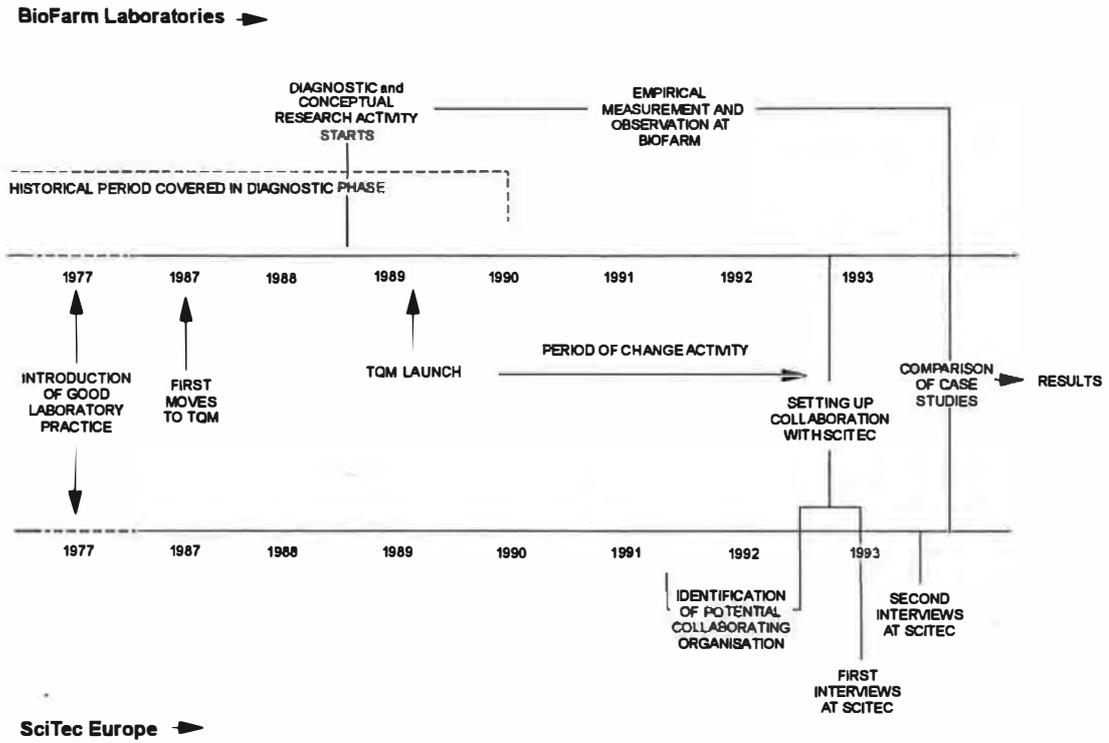
1.7   Overview of thesis

From this chapter forward the content of this thesis is arranged as follows

Chapter 2   Review of the literature on Total Quality Management.

This chapter provides a contextual review of the literature on quality management. Commonly used terminology are explained and the links between differing hierarchical levels of quality are discussed. A brief overview of the origins and proponents of quality management is given to provide a historical perspective of recent thinking. TQM is discussed in the context of other schools of management theory and initiatives followed by a review of the literature of immediate relevance to this research.

Chapter 3   Background : Professional Scientific Organisations

The first part of this Chapter looks at Professional Scientific Organisations, what they are, where they are, what they do and the general characteristics. The nature of such organisations (specifically biological contract research companies) are discussed in the context of their role and development in the social and business environment. Mintzberg's model of a Professional Bureaucracy is used to describe the organisation of a PSO.

The second part of the chapter looks at the origins and need for regulations for the testing of new chemicals. The development and acceptance of Good Laboratory Practice is discussed and an outline description of its principles is provided.

Chapter 4   Selection of Organisations and Comparative Profiles

In this Chapter the basis of the selection of the subject organisations is presented. A comparative profile of BFL and SciTec is presented.

Chapter 5   BioFarm Laboratories - Organisation and Quality Systems

This is a major chapter reporting upon the data gathered in the diagnostic phase of the research. The chapter provides an in-depth profile of BFL. The organisation structure and function, the reporting structure, the product and processes and the management of quality are considered. The

11

discipline of Good Laboratory Practice is visited again as it represent the hub around which quality in the organisation has been understood and evolved.

A window is opened onto the quality culture in the organisation, the systems in place, the development of those systems to manage quality, and the climate for change within the organisation. Finally, the move to adopt TQM (in the form of the Quality Improvement Programme) is discussed and the characteristics of QIP described.

Chapter 6 Methodology Overview

This chapter provides an overview of the methodology selected for this research. Selection of Action Research is discussed and the nature of the action research framework is described and justified. The relationship between the researcher and the subject organisations of this research are considered in the context of the chosen methodology. The basis for selection of the two subject organisations is presented. The methods used for facilitating organisational change and the techniques used to measure it are described. Finally, the methodological implications for researchers-as-employees conducting inquiry in a directly competing organisation are considered.

Chapter 7 BioFarm Case Study - Management Reactions

This Chapter provides a report and discussion of the participant observation activity at BFL. The interviews with senior managers and surveys into their perception of the BFL's standing in the context of quality management are reported.

Chapter 8 BioFarm Case Study - Measurement Results

The results of four surveys that provided measurement rods to supplement and provide quantification of the progress of QIP are reported in this Chapter.

Chapter 9   BioFarm Case Study - Technical Improvement Survey

This Chapter reports on an example of the type of improvement engendered in the technical operations of BFL.

Chapter 10 Corroborative case study : SciTec Europe

This Chapter describes the background to the need for a corroborating case study and the basis for identification and selection of SciTec as the subject organisation. It explains what was emerging out of the research at BFL to be investigated further at SciTec, and finally presents the findings and discussion of the interviews.

Chapter 11 Development of Models

Three models developed out of the finding presented in Chapters 5,7.8 and 10 are proposed and discussed.

Chapter 12 Synthesis of results and discussion

This Chapter provides a synthesis of the key research activity. The major findings on the influence of the scientific mindset, the validity of measurement and impediments to TQM are discussed. The importance of the findings are identified and explained and related back to the literature.

Chapter 13 Summary and recommendations

The major findings of the research are summarised. The implications for professional scientific organisations and other similar types of organisation are presented. Shortfalls in the research model are considered and recommendations for further work are made.

Appendices   Numbered according to the chapter to which they relate.

Glossary of Terms

References

Bibliography

CHAPTER 2
REVIEW OF THE LITERATURE
QUALITY AND
TOTAL QUALITY MANAGEMENT

Introduction to Chapter

This chapter provides a contextual review of the literature on quality management. Commonly used terminology are explained and the links between differing hierarchical levels of quality are discussed. A brief overview of the origins and proponents of quality management is given to provide a historical perspective on recent thinking. TQM is discussed in the context of other schools of management theory and initiatives followed by a review of the literature of immediate relevance to this research.

Organisation of Chapter

The sections in this Chapter are organised as follows:

2.1 Definitions

The development of quality management has been presented as an evolutionary process starting with inspection, then Quality Control to Quality Assurance and ultimately to Total Quality Management (Foster and Whittle, 1989; Dale and Plunkett, 1990). The term "quality" and various terms used to describe the different stages of evolution of quality management are frequently misunderstood with definitions used interchangeably, inconsistently and without general agreement on the meaning. As Garvin (1988: 6) notes, *"Quality is a slippery concept, easy to visualise yet exasperatingly difficult to define"*. He presents the case for better understanding if quality is to assume a strategic role, purporting that the problem is one of coverage with commentators from four different disciplines, philosophy, economics, marketing, and operations management each having a different vantage point. Since 1988, the problem has not eased as even more disciplines have entered the fray.

2.2.1 Definitions - Quality

The word "quality" traditionally signified "excellence" with products made from the finest materials or service of the "highest class". Over time the definition has evolved to describe the ability of a product or service to meet the requirements of the customer. The principle of managing or improving quality assumes that quality, as an entity, can be defined and measured; there are difficulties with this assumption. For example, Deming (1982) recognises that one man's definition of quality, and thus what he will measure, may not be the same as that of another man. Deming sees quality as non-static and measurable on more than one scale, i.e. each characteristic of a product can represent a scale with an associated quality level. Shewart (1931) recognised the difficulty of determining the future and changing needs of the customer.

> *"The difficulty in defining quality is to translate future needs of the user into measurable characteristics, so that a product can be designed and turned out to give satisfaction at a price the user is willing to pay"*

Most definitions of quality are generics open to a range of interpretation. Garvin (1988) proposes five principal approaches to defining quality into which most definitions fit. These are

1. Transcendent
2. Product-based
3. User-based
4. Manufacturing based
5. Value-based

Persig (1974: 240) provides an example of a transcendent definition

> *"Quality is neither mind nor matter, but a third entity independent of the two .... even though quality cannot be defined, you know what it is"*

According to this view, quality is synonymous with innate excellence. It is both absolute and universally recognisable, a mark of uncompromising standards and high achievement. An implicit assumption of the transcendent view is that there is something timeless and enduring about works of high quality, an essence that rises above changes in tastes or style. Occasionally the transcendent approach equates quality with *fine quality* and rejection of mass production. But more often it claims that quality cannot be defined precisely but that it is a simple, unanalysable property we learn to recognise only through experience. The difficulty with the view is that it offers little practical guidance. To argue that the hallmark of quality is intensive effort and honesty of purpose says little about how quality products differ from lesser products. In fact, at its most primitive, this definition offers little more than whatever quality consists of, managers will know it when they see it.

Product-based definitions view quality as a precise and measurable variable. Differences in quality thus reflect differences in the quality of some ingredient or attribute possessed by the product. An example could be two evening dresses, one with more sequins on it than the other. This approach lends itself to a vertical or hierarchical ranking of quality and goods can be ranked according to how much of the desired attribute they have. An unambiguous ranking is only possible if buyers rank attributes in the same order. Because higher quality implies more of the desirable attribute, and it costs money to provide more of the attribute, then higher quality goods will be more expensive. Because quality reflects the presence of a measurable attribute,

it can be assessed objectively and is based on more than just preferences. Whilst the objective nature of the approach is an important strength, it also has limitations. A one-to-one correlation between two product attributes does not always exist. Sometimes high quality products are simply different, their attributes being based on entirely different concepts. An example of a product based definition is provided by Abbott (1955)

> *"Differences in quality amount to differences in the quantity of some desired ingredient or attribute."*

Juran's user-based definition of *"fitness for purpose or use"* (Juran,1967) implies that the supplier is aware of the customers intentions for the "product". Again, it is the explicit and implicit needs of the customer that have to be met. This definition has been adopted and described in ISO 8404 (BS4478, 1987) as

> *"The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs."*

The ISO/BS description goes some way to broadening the scope of Juran's definition and emphasises the totality of considerations which, together, satisfy all needs, whether expressly stated or taken for granted.

The extended breadth of the influence of quality is presented by Ishikawa (1985) in his statement

> *"Quality means quality of work, quality of service, quality of information, quality of process, quality of direction, quality of people, including workers, managers and executives, quality of company, quality of objectives."*

This statement, taken out of the context, appears deficient in that Ishikawa has failed to describe the attributes of quality. Certainly he adds weight to the notion that quality is not restricted to the output, but should be pervasive with impact extending to the "soft" elements of an organisation.

Feigenbaum (1991) provides a "manufacturing-based" definition which extends to include the attributes of a user-based definition. It names the key divisions of a business which have a critical role to play in the achievement of quality. He defines quality as

> *"The total composite product and service characteristics of marketing, engineering, manufacture and maintenance through which the product and service will meet the expectation of the customer"*

The following "user-based" definition cited by Dale and Cooper (1992) focuses on adding value to the product or service:

> *"the attributes of a product and/or service which, as perceived by the customer, make the product/service attractive to them and gives them satisfaction"*

User-based definitions are rooted in consumer preference, starting from the premise that quality lies in the eyes of the beholder. Individual consumers are assumed to have different needs or wants, and the goods that best satisfy their preferences are those that are regarded as having the highest quality. This is an idiosyncratic and highly subjective view of quality. The user-based definition goes beyond the manufacturing-based definition of "conformance to the requirements" to suggest that the customer is the judge of quality and that all customers do not share a common perception.

Meeting Crosby's concise "manufacturing-based" definition of quality as *"conformance to specification"* (Crosby, 1970) assumes that *the specification* is adequately descriptive of all of the characteristics of a product or service. If the specification is lacking or does not meet the needs of the customer, then it follows that the outcome may not be quality (Price,1990). The customer's specifications may not always be exactly and explicitly known and thus a product or service may tend to meet the internal specifications of the supplier rather than the customer.

Whilst not stated in the definitions provided so far, there is an underlying logic that suggests that a "quality" product or service will be delivered on time and at a price that the customer is willing to bear. It is apparent that delivery of a quality product or service in the marketplace does not, on its own, guarantee either sales or business success; failure to meet any of the criteria will detract from the performance of an organisation. To this end, quality must be placed in the context of the business environment where customers expect "value for money" and companies require return on their investment. The car manufacturer, Ford of Europe endorse the importance of the customers' perception of value for money with this "value-based" definition

> *"Quality is defined by the customer. The customer wants products and services that throughout their life meet his or her needs and expectations at a cost that represents value."*

The value-based definitions take the ideas of user and manufacturing-based one step further. They define products in terms of costs and prices. Thus a good quality product is one that provides conformance and performance at an acceptable price.

Looking at the definition of quality of a professional organisation, where the output (the product) has very few tangible elements albeit that there are some tangible characteristics eg, the toxicologist writes reports, the actual service is advice and information based upon knowledge and expertise of a professional. In this case the foregoing definitions appear inadequate in that they are generally describing quality of a tangible entity. Ritsema, Broekhuis and Gruisen (1992: 28) propose a definition of professional quality which recognises the continuous and sometime paradoxical interchange which is a characteristic of the relationship of professional and client.

> *"The whole properties and characteristics of a professional service which is relevant to meeting the specifications agreed upon in a continuous tuning process between the clients and the professional concerning the effort and expected end result; the quality standards in the professional field involved have been incorporated here as the self evident needs of the client and the professional"*

A key difference between the former definitions with that of Ritsema *et al* is that the customer of the service (the client) has potential to shape the output to their own view of quality; this view may not match the perception of the professional providing the service. A client's satisfaction with a service does not necessarily mean that the service is of quality and conversely, a client's dissatisfaction may not mean that the service was not of quality. It is this difference in the perception of quality which provides a starting point for divergence of quality improvement in professional scientific organisations to that of manufacturing and service organisations.

2.1.2 Definitions - Inspection

ISO 8402 - *Activities such as measuring, examining, testing, gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.*

Inspection and Quality Control are often taken to be the same thing and commentators may chose not to differentiate them. Inspection can be regarded as the fundamental level at which a product's conformance to the specification can be examined. The inspection process does not add value to a product or service and tends to be an unrecoverable cost of production. It occurs at completion of a process or part of a process and is concerned with detection of products that do not meet the specification and "sentencing" those items for rework or disposal.

2.1.3 Definitions - Quality Control (QC)

ISO 8402 - *The operational techniques and activities that are used to fulfil requirements for quality*

The basis of quality control is detection of problems through inspection. It is an "after the fact" activity (Bell, McBride and Wilson, 1994: 2) concerned with the techniques employed to achieve and maintain the quality of a product, process or service. The intent is to find and eliminate causes of quality problems so that the requirements of the customer are continually met (Oakland, 1989). Quality Control though, unlike inspection, is concerned with providing feedback of comparative information in order to regulate the process and sustain quality to specified requirement.

2.1.4 Definitions - Quality Assurance (QA)

ISO 8402 - *All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality.*

Gryna (1988) - *The activity of providing the evidence needed to establish confidence, among all concerned, that the quality function is being effectively performed.*

Quality Assurance recognises that inspection and quality control are not enough in themselves to remedy quality problems thus QA uses the principle of *prevention* of quality problems rather than *detection* of the problems. Inspection and QC are both important tools of QA.

21

Quality Assurance focuses on compliance to procedures and conformity to specification through tracking of operations. The term Total Quality Control (TQC) (Feigenbaum, 1991) is regarded by many commentators as synonymous with Quality Assurance. Feigenbaum proposed TQC in 1956, when he promoted the need for a co-ordinated and documented approach to controlling quality across the whole organisation. Feigenbaum's model of TQC is regarded by many as the forerunner of ISO9000, the International Standard for Quality Management Systems. The Standard sets out a framework by which a management system for quality can be implemented such that the needs of the customer are fully met. Good Laboratory Practice, the "quality standard" to which laboratories performing chemical safety assessments are required to work, provides an example of an approach to a quality assurance system which is of direct relevance to this work.

2.1.5 Definitions - Total Quality Management (TQM)

One of the problems in the discussion of TQM is the apparent lack of a generally accepted description of what it actually is. There are numerous definitions, the majority proposed since the late 1980s, which add to the confusion of what different writers mean when they discuss TQM (Garvin, 1988; Wilkinson *et al*, 1992; Pike and Barnes,1994). Although some commentators see TQM as one of a number of management fads to have hit the UK in recent years, it is generally recognised as a major innovative management practice which is often viewed as a competitive weapon. Whilst it is differently described, most definitions are generally expressed in terms of a way of life for the organisation as a whole, commitment to total customer satisfaction through a continuous process of improvement, and the contribution and involvement of people. The tools of quality control and quality assurance may be embraced by TQM but the philosophy of TQM goes far further. Organisations that adopt TQM aim to develop a culture receptive to continuous habitual change and improvement aligned with the needs of its business and customers. TQM involves a fundamental organisational transformation which develops competencies across the whole organisation. It is an extension rather than a denial of its predecessors, QC and QA, in that aspects of those disciplines remain. By comparison with QC and QA, it is the complexity and scope of TQM makes it difficult to define in precise terms.

For the purposes of this research, the following definition of Total Quality Management was proposed in 1989:

> "*Total Quality Management (TQM) is a long-term strategic management process directed towards increasing an organisation's competitive advantage through commitment of all employees to meet the needs of the customer. It is a process that requires critical evaluation of all facets of the way that an organisation is managed. TQM requires breakthrough in the traditional resistance to change to facilitate continuous improvement directed towards making the organisation more responsive, flexible and adaptive to the demands of the market place*".

Many authors hold back from making a definitive statement, choosing to describe the features of TQM at some length rather than attempting to encapsulate in a few short sentences, a philosophy and way of managing and developing organisations in a manner that is comprehensively all encompassing and based upon flexibility and adaptation. The following descriptions provide examples of the many definitions in the literature:

British Quality Association (1989)

Total quality management is a corporate business management philosophy that recognises that customer goals and business needs are inseparable. It is applicable within both industry and commerce

It ensures maximum effectiveness and efficiency within a business and secures commercial leadership by putting in place processes and systems that will promote excellence, prevent errors and ensure that every aspect of the business is aligned to customer needs and advancements of business goals without duplication or waste of effort.

The commitment to TQM originates at the chief executive level in a business and is promoted in all human activities. The accomplishment of quality is thus achieved by personal involvement and accountability devoted to a continuous improvement process, with measurable levels of performance by all concerned

It involves every department, function and process in a business and the active commitment of all employees to meeting customer needs. In this regard, the "customers" of each employee are separately and individually identified

BS 8570 (1992)

A management philosophy and company practices that aim to harness the human and material resources of an organisation in the most effective way to achieve the objectives of the organisation

The objectives of an organisation may include customer satisfaction, business objectives such as growth, profit or market position or the services to the community, etc. but they should always be compatible with the requirements of society whether legislated or perceived by the organisation.

An organisation operates within the community and may directly serve it; this may require a broad conception of the term "customer".

Feigenbaum (1991: 286)

A Total Quality System may be defined as the agreed companywide and plantwide operating work structure, documented in effective, integrated technical and managerial procedures, for guiding and co-ordinating the actions of people, the machines and the information of the company and plant in the best and most practical ways to assure customer quality satisfaction and economical costs of quality.

Oakland (1989: 14)

TQM is an approach to improving the effectiveness and flexibility of the business as a whole. It is essentially a way of organising and involving the whole organisation; every department; every activity, every single person at every level to work together to eliminate errors and reduce waste.

Pike and Barnes (1994: 25)

> *A process of individual and organisational development, the purpose of which is to increase the level of satisfaction of all those concerned with the organisation; customers, suppliers, stakeholders and employees.*

Vorley (1993: 90)

> *Total Quality Management is the synthesis of the organisational technical and cultural elements of a company. It is a "hearts and mind" philosophy which recognises that the company culture affects behaviour which in turn affects quality. It is not merely the performance of the product but the performance of every activity in the company. To this end, every subsystem or function in the organisation is seen to have internal customers and suppliers as well as external customers and suppliers.*

The foregoing definitions provide a slender representation of the scope and depth of the TQM paradigm and provide the reader with minimal understanding of the activities and beliefs that lie behind the definitions. Through the definitions and encapsulated in the TQM culture run a number of common threads:

- **Leadership**: TQM requires a positive commitment "from the top". It is the "leaders" who have to create an environment which allows everyone to contribute to the organisation by developing their skills, enabling them to study scientifically and constantly to improve every process by which work is accomplished (Joiner, 1988). It is the leaders who inspire and motivate employees, and provide the policies, objectives, strategies and plans to move along the road of TQM.

- **Involvement of all the people of the organisation:** Everybody in the organisation is continually involved in improving the processes under his or her control and takes responsibility for the quality of their own output. People are the source of ideas and innovation and their expertise, knowledge and co-operation have to be harnessed to get their ideas implemented (Oakland,1989). In TQM there is a requirement for creative thinking and an ability to think beyond the needs of the immediate job or environment.

- **Companywide scope:** Every facet of the organisation is involved. TQM spreads beyond the production and direct money earning parts of an organisation into all

of the support activities. It requires consideration of every activity that an organisation carries out.

- **Long term goals:** TQM is frequently described as a long term or strategic management process of continuous improvement; cumulative gains are directed at attaining competitive advantage and achieving the organisation's business goals.

- **Customers:** Organisation goals are achieved through satisfying customer needs. TQM introduces the concept of internal and external customers and suppliers. Everybody in an organisation is a customer and has suppliers ultimately forming a chain from the original inputs to the output to the external customer. Every strategy, process or action should be directed to meeting customer needs.

- *Modus Operandi:* Emphasis is placed on effective and efficient operations, adaptability, flexibility and responsiveness in all facets of the organisation's activities. TQM stresses the need for cost effective processes and the elimination of waste through prevention of non-conformance.

- **Training and education:** Employees need to be provided with an appropriate level of training to provide an awareness and understanding of quality management concepts, skills, and organisation strategies such that they are able to contribute on the basis of ownership and personal responsibility.

- **Measurement and reporting:** TQM effectively utilises measurement and feedback processes to assess whether planned improvements are occurring. Key, quantifiable indicators of performance are identified and used as feedback on achievement to motivate those involved.

- **Recognition and reward:** Positive results must be recognised and success rewarded. Involvement must be seen as key to success and communication from management in respect of success motivates continued contribution. Staff who have a marked positive impact may be recognised as "champions" and "heroes".

2.2   Origins of the concepts of TQM

It is not the purpose of this thesis to examine the various philosophies of quality management in depth, nor to dwell upon descriptions of the technical elements of the quality management tools and techniques. Therefore the following section provides a brief overview of significant events and contributors in the development of TQM. Further information can be found in Garvin (1988), Hutchins (1990), Oakland (1989), Pike and Barnes (1994), Vorley (1994) and Walton (1986) Price (1989) who, amongst others, have provided extensive accounts of the key contributions to TQM.

2.2.1   Origins

Total Quality was not invented or launched overnight. Indeed its beginnings cannot be precisely identified because no single book or article marks the transition from its evolutionary predecessors (Garvin, 1988). Easterby Smith (1991:7) credits Walton with the "discovery of TQM" when, in 1980, she presented a television documentary featuring the work of WE Deming and his methods to improve quality and productivity, thus bringing it to the attention of the US public and resulting in an upsurge of interest (Walton, 1984). Others take the origins of TQM back in time to the earliest applications of statistical process to manufacturing. Price (1989) looks back to the German mathematician, JKF Gauss who published, in 1801, his *Theory of Number,* the knowledge which forms the basis of modern Statistical Process Control. Garvin (1988) puts the origins back to the turn of the century when WF Taylor bought about the formal acknowledgement of inspection as a separable and specific task that could be assigned to one function. Feigenbaum (1991) whose own contribution lies in the development of Total Quality Control, refers to this phase as *foreman quality control* whereby individuals performing the same task were grouped together so that they could be directed by a foreman who assumed responsibility for the quality of their work. Deming (1986), himself a major contributor to the origins of TQM, claims indebtedness to Walter Shewart, a mentor of his at the Bell Laboratories of the Western Electric Company. Shewart, in 1931, marked a watershed by his publication of *Economic control of the manufactured product* (Deming 1986); this book gave a scientific footing to QC for the first time.

These days, the origins of TQM are generally acknowledged to lie in the 1950s during the period of industrial reconstruction of post war Japan. It was at this time that the ideas on quality and productivity of WE Deming and JM Juran, originally developed at the Bell Laboratories of the Hawthorne plant of Western Electric, were moulded together into a coherent operating philosophy (Wilkinson *et al*, 1992). Earlier work of Deming and Juran occurred at a time of concern with improvement of management as a means of increasing productivity. Emphasis was placed on increasing productivity of individual workers through the technical structuring of work organisation and the provision of monetary incentives to motivate for higher levels of output. Much of the organisation of work in the USA followed the principles of the Classical Management School, a subset of which was Scientific Management, the main proponents of which was WF Taylor. The principles of Taylor's work underpin the assembly line philosophy, with each task carefully studied and defined, deskilled and restricted in scope as far as possible, and integrated into the production machinery. Criticisms of scientific management are extensive. Workers found their activities unstimulating; they were not required to understand the basis on which their work had been formulated, and they could not experiment or recommend better ways of doing a job. The theory was that there was "one best way" albeit that that way may not be appropriate for all workers. The breakdown of activity, payment by piecework, and assembly line philosophy lead to quality checking as an end-of-the-line activity; waste was high. Observation of the downside of this way of working influenced the development of Juran's and Deming's philosophy on quality.

Both Deming and Juran were employed at the Hawthorne plant at the time of the emergence of the Human Relations school, a divergence in management theory originating from Elton Mayo's motivation studies. Whereas supporters of the classical approach had sought to increase productivity by rationalisation of the work organisation, the human relations movement has lead to ideas on increasing productivity through humanising work. The Hawthorne experiments demonstrated the simple value of paying attention to workers. They generated new ideas concerning the importance of work groups, communication, motivation and job design all of which influenced the emergence of Organisation Development and Quality Management in particular. Arguing that problems of quality lay in systems deficiencies rather than

mistakes made by workers, Deming and Juran advocated that quality control should be conducted as an integral part of the management and control systems thus bringing into visibility the importance of such factors as having the right climate for improvement, the right structure and the right form of communications. Behind this thinking lay the notion that quality costs could be divided into two types, avoidable and unavoidable. Unavoidable were those associated with prevention - inspection, sampling sorting and other QC initiatives. Avoidable were those related to defects and product failure - rework, scrapped materials, repair and financial losses resulting from unhappy customers. From this observation developed the notion that management of quality should be moved away from the end of line "detection" to management by "prevention" whereby the ultimate responsibility for quality would lie with management.

From the time of the early work of Deming and Juran to the emergence of the acronym, TQM, a number of other contributors are acknowledged to have made major contributions to the concepts and tools that are now understood to form the eclectic basis of TQM. Of the most cited of these individuals are Ishikawa, Feigenbaum and Crosby.

Ishikawa's major contribution is generally considered to be the development of quality circles, the first three of which were registered with the Japanese Union of Engineers and Scientists (JUSE) in 1962. The circles, which opened up the way for workers to become involved in problem solving and the quality improvement process, were intended by Ishikawa to be one method amongst others (Sandholm, 1983). There has been a considerable amount in the academic and popular literature about the use of quality circles, their successes and failures, and comparative acceptance in the light of differing management philosophies of Japan and the West (Russel and Dale, 1989; Jones, 1983; Collard and Dale, 1985). These issues aside, perhaps the important feature of quality circles is that they not only opened up an opportunity for workers to become involved in making improvements in their workplace but they provided the evidence that demonstrated that Japanese quality improvement methods could be adapted for use in the West. Sandholm(1983: 20) comments that Western managers, in their desire to follow Japan's success in improving quality, found it all to easy to get caught up with one spectacular feature of Japanese quality improvement, Quality Circles, thinking that

they were the key to success. Unfortunately they failed to see circles in the context of other activities.

Feigenbaum recognised the importance of interrelationship of the functions of an organisation in achieving effectiveness and therefore the critical need of high levels of planning and coordination, standards setting and provision for quality measurement (Garvin, 1988). In 1956 he proposed Total Quality Control which he places at a level below TQM on the evolutionary plain (Feigenbaum, 1991). Some confusion surrounds the use of this label with authors seeing TQC as a QA function (Garvin, 1988) or sitting at a level between QA and TQM (Foster and Whittle, 1989) or synonymous with TQM. This confusion partly arises from the use of the term TQC in place of TQM in Japan but is also indicative of the confusion that prevails over the use of language in the field of quality management in general.

Another significant contributor was Crosby for his promotion of the concept of Zero Defects, an approach which developed in the 1960s out of the Pershing Missile projects in the USA. The concept of "Zero Defects" is perhaps one of the most debated and often rejected issues of quality management. Crosby intended that the performance standard of work against which failure to conform with the specification should be measured, should be the absence of nonconformity (i.e. zero defects). His belief was that to target anything other than this was to introduce the notion of Acceptable Quality Levels - a notion that he rejects on the basis that to accept say, a 98% defect free product, implies that it is satisfactory to accept a 2% error rate thus, the belief that errors are inevitable is encouraged (Crosby,1984). However, the exhortations and slogans that are frequently used to promote the concept of ZD, combined with the use of a pledge signed by employees to aim for ZD, have probably contributed to it's dismissal by those averse to such hype. Fox (1993: 223) describes Crosby as the clearest and most entertaining of the US quality gurus, with the best intuitive understanding of quality having approached it from a "hands-on" rather than an academic base.

The earlier focus of the methods of quality control and quality assurance techniques, was predominantly upon error prevention; the value and potential of quality

management as a possible basis for competition was not realised. The consequences of scientific management or overcompensation to the excesses of the human relations school had rendered many organisations inflexible, unfocused, unresponsive to change and riddled with dysfunctional approaches to improving efficiency. It was the awakening to the threat to US markets that forced a deeper look for the reasons behind the problem and urgent demand for change. In the 1970s and 1980s the strategic aspects of quality were both realised and embraced by US managers.

Garvin (1988) suggests that there was a dramatic shift in the perspective of USA top managers, who, with their markets under serious threat from the increased foreign competition, especially Japanese products, moved to respond to the challenge. They became interested in quality because it was linked to profitability. For some organisations, a new strategic vision emerged where, at the most radical end, Quality was regarded as an aggressive competitive weapon. The challenges to US managers emanated from a variety of external sources, each linking loss of market share and profitability, dramatised by the motorcar industry, to poor quality (Juran, 1989). In addition to increased foreign competition, there was a sharp rise in product liability suits and government legislation arising from, in particular, public demand for greater safety. Garvin states that the problems could not be ignored because of the large monetary sums involved. With profitability under threat and company reputations on the line, predictably, top management were sensitised to the need for greater quality. What emerged from this environment was a newer approach to quality, strongly shaped by the concerns of upper management. This was the form of strategic quality management which became widely acknowledged as TQM.

2.2.2 Emergence of TQM in the UK

"Is the quality revolution really starting here or are we witnessing yet another rising star in the British Management Firmament - shortly to join its predecessors out of sight and out of fashion? Taking the British picture as a whole, the odds are now on the latter. Not because people won't work hard for quality, but because we will end up trying to install the techniques of quality management and not understand 'it'."

Alan Hodgson (1987: 40)

The term Total Quality Management developed presence in Britain around the latter part of the 1980s although there was little evidence of it in the UK literature until the launch of TQM magazine in 1988. Most UK publications on the implementation of quality management were the products of the rapidly growing Quality Management consultancies and many lacked academic rigour. They were often prescriptive and described TQM frameworks applied in "successful" case studies - much of the data was not the product of disciplined research. Bowman and Steele (1988), while conducting a study to evaluate a quality improvement programme in a US State Agency, noted a similar situation in the US literature. They found a general paucity of theory and empirical research with most of the literature descriptive, prescriptive and promotional.

The recognition of need to improve British competitiveness in global markets, and thus quality, predated the arrival of TQM by more than a decade. The British government had made some attempts to promote the need for improved productivity and quality through a number of "quality initiatives". In 1961 the British Productivity Council organised the "Right First Time" drive; 1966 was "Quality and Reliability Year" and the DTI launched the National Strategy for Quality in 1978. These early initiatives failed to capture the attention of industry. Following publication in 1982 of the white paper *Standards, Quality and International Competitiveness* the UK government laid out a strategy to promote efficiency in industry through development of accreditation bodies and standards. In 1983 the DTI launched the National Quality Campaign with the aim of achieving

"the enhancement of the quality of British goods and services through encouraging a total approach to quality in design, production, marketing, delivery and the way a business is run."

Lascelles and Dale (1989) surveyed the impact of this campaign and concluded that if the prime objective was to increase industry's general awareness of the importance of quality management, then it was a success because the government involvement had given credibility to the message. However they note that an increase in awareness of the need for quality improvement on it's own was insufficient to provoke a revolution in the way that British industry managed product and service quality. "Industry Year", aimed at increasing awareness of the importance of a strong economy and endorsing quality as an essential instrument for improving competitiveness, was launched in 1986; in 1988 the National Quality Campaign was superseded by "Managing into the '90s", a self help business management programme designed to give British Managers a competitive edge in home and overseas markets. The latter initiative was instrumental in providing wide publicity on the value of TQM.

In the UK the National Quality Campaign had been successful in raising industry's awareness of the importance of quality management reaching over 50,000 companies (Lascelles and Dale, 1989: 207). The findings of a research programme carried out by Lascelles and Dale (1984-1988) indicated that attitudes of chief executives to the concept of quality management in manufacturing industry were generally positive with widespread belief that quality improvement could be beneficial to business performance. However, they found that even though business pressures and the National Quality Campaign may have provided proof of the need for action, executives did not understand the objectives or implications. They tended to look for instant solutions and expected TQM to give rapid returns. Dale and Lascelles noted that there was a preoccupation with Quality Management techniques rather than a real understanding of the objectives and implications.

The translocation of TQM into the UK is evidenced by publication of books by several British Authors. These include Cullen and Hollingum (1987), Oakland (1989), Dale and Plunkett (1990), Atkinson (1990), Munro Faure and Munro Faure (1992), Pike and Barnes (1994). The growth in the literature had been something like a tree, purchased as sapling from the USA but originally grown from a seed from Japan. The tree is getting larger and as more branches grow, they vary in size and shape. Yet the genetic material, the basic concepts of quality management, remains the same and the

leaves appear much the same. As the tree grows, there are more leaves, all carrying the same basic genetic material. Bits of the tree have fallen to the ground and taken root to produce a forest of clones. But at this stage the only a few trees have reached maturity and fruited so little genetic variation has occurred.

TQM gained prominence in the UK at a time of growing competition but at time when markets were expanding. The issue of business survival tended to be regarded as theoretical rather than a real threat. TQM was "sold" as a long term strategy. In its early days in Europe companies were sufficiently forward looking to accept that principle although evidence of TQM failures suggests that the reality was that many companies which adopted TQM in the late 1980's were disappointed with it's failure to have an immediate impact on financial results.

There is an increasing amount of published information on the relative success of TQM programmes. By the early 1990s there was growing criticism of TQM with a commonly quoted level of 80% failure of programmes. Cottrell (1992) provided support for this figure in a report of the AT Kearney survey, *"Total Quality - the formula for success"*. Findings of the survey suggested that 80% of TQM programmes were not yet (at the time of the survey) successful. Emphasis on tangible results was observed to be a common missing characteristic. Likewise a survey by Arthur D Little consultants (1991) of five hundred American manufacturing and service companies found that only one third felt that total quality programmes were having "significant impact" on their competitiveness.

A survey for the British Institute of Management, "Beyond Quality" (Coulson Thomas,1990) identified that many "early" quality programme appeared to be "running out of steam". James (1991: 17) has produced one of the most critical papers on the success of TQM as he links the difficulties to patchy and painfully slow development of participative management. He concludes his paper with the statement that

"Total Quality Management in 1991 is anything but "total" or "quality"

McCormack (1992: 43) suggests that despite the fact that the tenets of TQM are sound, many TQM efforts don't meet expectation because people fail to distinguish between philosophy and strategy. He sees the flaws lying in poor implementation

where organisations attempt to move forward with weak tactics and lack of a strategic framework.

Macdonald (1993: 4) makes the interesting observation that the highest ratio of organisations successful in improving quality are those from amongst the early pioneers. Many of these companies may have already been world leaders and innovators which had created environments that helped the change process; that is not, according to Macdonald, the reason for their success. These pioneer companies had no easy solutions to turn to and thus had to work out what was required for themselves. Although they were able to observe and learn from the gurus, there was no packaged advice such that they had to absorb the concepts and develop unique solutions strongly rooted in their own culture. Macdonald believes that the lower success rate now is a result of the packaging of the concepts of the gurus and the development of the consultancies. These have had the result of providing the "off the shelf" quality panacea, not tailored to company needs and often not fully understood by those within the implementing organisation. It can also be argued that the packaged approach had the effect of constraining the "shape" and development of TQM.

However, despite the many criticisms of TQM, there is ample evidence in the literature of successful companies (see Oakland 1994, Zairi 1994) and evidence of an outspreading of TQM into an increasing range of activities including non-commercial organisations.

Total Quality Management is by nature, eclectic. A feature of its development and subsequent resilience is its flexibility of form, adding to an underlying framework those methods and philosophies appropriate to the situation and context of the organisation wishing to adopt it. The developing theories and increased understanding of motivation at work have had considerable influence on the development of TQM which is often quoted as being "a hearts and minds" philosophy based upon effective contribution from motivated and trained individuals.

Successful TQM had to be geared towards transformation of an organisation. Pike and Barnes(1994) propose that TQM should be regarded as a very focused form of Organisational Development. They see it as a process of changing an organisation's culture and developing the organisation in such a way as to make it more responsive to customer needs on one hand, whilst becoming so in a more efficient and effective way on the other. Taking French and Bell's (1990) definition of OD as

> *"top management supported, long range effort to improve an organisation's problem solving and renewal processes, particularly through more effective and collaborative diagnosis and management of organisation culture - with special emphasis on formal work team, and intergroup culture - with the assistance of a consultant facilitator and the use of theory and technology of applied behavioural science, including action research"*

it can be seen that TQM has a predominance of the features described. TQM goes far beyond quality control and quality assurance - it is an intervention strategy concerned with changing the fundamental beliefs, values and culture of an organisation, harnessing the enthusiasm and participation of everyone towards an overall ideal of "right first time"(Atkinson, 1990).

As the economic downturn of the early 1990s developed, the forces demanding quick financial returns became stronger than those working for the long term strategy. At this time such methods as business process re-engineering (BPR), and delayering came into evidence. These approaches offered quantum change through a radical redesign of an organisation and its processes (Hammer and Champey, 1993; Revenaugh, 1994). For organisations looking for large scale improvement BPR and delayering appeared attractive. However, as Jackson (1994: 19) points out, Hammer's advice not to mechanise old ways of doing business, but obliterate and "start over", was not a new concept. Organisation and Methods of the 1970s and business systems analysis of the 1980s used the same approach - it was the attached "hype" that was different. TQM programmes also adopt this approach although generally in a less radical manner, tending to focus more on the total organisation and continuous, rather than discontinuous, change.

The advocates of TQM have continued to support the validity of quality management methods and the solid base of experience from where they originate. For continued acceptance, the question of whether TQM is a resilient, sound approach or a passing fad, a "flavour of the week", is an important factor of success or failure. To be perceived as one more passing fad in the context of many would undermine the seriousness with which TQM would be accepted and implemented.

Figure 2.1 overpage shows the relationship of key events in the development of TQM against the schools of management theory that have emerged this century. An interesting point is that the timing in the figure shows the approximate time of the main influence of the thinking in the USA. The UK has generally been slow at adopting US management thinking. For example, the Department of Trade and Industry Guide for Chief Executives identifies the 1950s as the years in which British industry went into decline; it was around that time that time when the human relations school of thinking was emerging in the US yet much of British industry still favoured systems based on Taylorism. A similar delayed response was evident in the appearance and acceptance of Total Quality Management in the UK.

1977 - Introduction of
Good Laboratory Practice

1989 Baldrige Prize Launched in USA

1988 - European Foundation for
Quality Management

1988 - Managing into the '90's

1924 Inspection
Engineering Dept formed
at Western Electrics -
origins of SPC

1984 - Walton
"Discovery" of Deming and TQM

1983 - DTI launch National Quality Campaign

1978 - National Strategy for Quality

1922 Radford
*The Control of Quality
in Manufacturing*

USA - Zero Defects Programmes proliferate

Taguchi develops Quality Engineering

1981 - Lorenz
Learning from the Japanese
Financial Times

1990 - Atkinson
Creating Culture Change

1951   Deming Prize Established by the Japanese Union of Scientists and
           Engineers was Instituted in Japan

1951   Juran. *Quality Control Handbook* 10 Steps

1900 Taylor adds
legitimacy to Inspection
by defining it as a
specified task

Deming and Juran active in assisting the Japanese
rebuild their industry after the World War II.
Massive training programmes in quality methods for
all levels of employees
Deming's and Juran's quality teachings adopted

1979 - BS5750
Quality Standard
issued

1989 - Oakland
Total Quality Management

1987 - Garvin
Managing Quality

1947 Japanese Union of Scientists and Engineers formed

1982 - Deming
Out of the Crisis

1946 American Society for Quality Control founded

1981 - Pascale and Athos
*The Art of Japanese
Management*
" 7-s model"

1994 - Pike and Barnes
"7-Ps Model"

1931 Walter Shewart - *Economic Control of the Manufactured Product*

Advent of Statistical Process Control. First systematic effort to achieve quality in an industrial setting

BS8580 - Total Quality
Management Standard

1930	1950	1960	1970	1980	1990

CLASSICAL	HUMAN RELATIONS	SYSTEMS	CONTINGENCY		
Taylor	Mayo	Bertalanffy	Woodward	Oakland	Reengineering (Hammer and Champey)
Fayol	Maslow		Burns and Stalker	MacDonald	
Weber	McGregor	Management by Objectives	Lawrence and Lorsch	Hutchins	"Management by bestseller"
	Hertzberg	(Drucker)		Pike and Barnes	
	Argyris		Strategic planning	Dale	One Minute Managing
			(Porter)	Lascelles	Managing through Chaos
					The Fifth Discipline

| Emphasis on purpose, formal structure, management hierarchy, technical requirements and common principles of organisation | Attention to social factors at work, groups leadership, the informal organisation, and behaviour of people | Integration of classical and human relations approaches, importance of socio-technical system. The organisation within its external environment | No one best design of organisation. Form of structure, management and success of the organisation dependent upon range of situation variables | Focus on changing attitudes and culture. Total organisation transition. Focus on systems improvement to assure customer specifications are met | Learning Organisation (Pedlar, Boydell,Burgoine Revans, Argris and Schon Senge) |

Figure 2.1   Key trends in management thinking leading up to the emergence of TQM

2.2.3   TQM in the wider context of management initiatives

It could be argued that an indicator of managerial panic is the consumption rate and shelf life of business fads as over two dozen management techniques have arrived and declined in use since the 1950s (Pascale, 1990). These techniques include Theory Z, matrix management, Managerial Grid, T Groups, Demassing, 'One Minute Managing' and Business Process Reengineering. Pascale argues that it is the ascendance of professional management that has diminished reliance upon managerial wisdom acquired from the ranks. The notion of "professional management" rests upon the premise that a set of generic concepts underpins managerial activity anywhere. This mindset created the opportunity for the development of "packaged" management techniques and their massed marketing. US managers abdicated their responsibility to a burgeoning industry of management professionals (Nohria and Berkley, 1994). The 1980s witnessed the spectacular growth of management schools, consultants, media and gurus who fed on the insecurities of managers fearful of foreign competition and economic decline. Mistrustful of their own judgement, many managers latched onto the self appointed pundits, readily adopting their latest panacea. Off-the-shelf programmes addressing quality, customer satisfaction, time to market, strategic focus, core competencies, alliances, global competitiveness, organisational culture and empowerment swept through the US corporations with alarming speed. Superficiality has been fostered and it has become accepted to use techniques without an in-depth grasp of their underlying foundation and without the commitment necessary to sustain them.

In Britain the number of "packages" to which the community has been exposed to any extent is somewhat less than in the USA and there is a degree of conservatism in the British culture that makes it suspicious of "new ideas". Nevertheless, the acceptance of TQM was coloured by experience of the various nostrums which had been tried in the not too distant past, 'job enrichment', 'management by objectives', 'participative management', 'quality circles', and so on (Hodgson, 1988: 4). There were various reasons why these initiatives did not thrive. Hodgson suggests they often came up with a 'quality agenda' which included ideas which would cost money to implement. These ran up against the cost cutting exercise, the agendas became less costly and therefore,

because of failure to implement ideas, the groups did not achieve much. They became discouraged and demotivated thus the initiatives tended to be abandoned.

At this point of time TQM continues with strength but has lost some of the hype with which it became linked in the late 80's. The acronym of TQM has widely been replaced by labels chosen by organisations to describe their particular approach or programme eg., TCS(Total Customer Service as used by Black and Decker), QIP (Quality Improvement Programme: BioFarm), QMS (Quality Management System: SciTec) and many others. TQM sits as the "grand old man" along side the faddish new ideas still geared for the fast return. It is interesting to note that of the many business fads of the last three or so decades, it is only rare instances that they have been adopted as a enduring way of doing business. An example of two such successes are Deming's notion of statistical control and quality circles (Pascale, 1990: 21).

2.3   Development of Total Quality Management - the paradigm shift

There is widespread acknowledgement that the aim of an organisation to effectively implement Total Quality Management is analogous to travelling a long and arduous journey, the end of which is never reached. Progressing from conventional management to TQM is a complicated and time consuming process involving substantial commitment of short-term resource against the prospect of long-term gains. The duration of the journey depends upon the relative starting point of an organisation in quality terms, the ability of the organisation to change, and its commitment to reach its destination. Progressing from Inspection to TQM involves changes in attitudes and focus as an organisation moves to each higher quality level. The changes required of an organisation can be considered on two levels.

1. The manner that it pursues quality - the tools and techniques that it adopts

2. Changes to the way of thinking and behaving - the culture - its values and interpretation of quality

These two levels of change are not mutually exclusive.

Earlier in this chapter, four levels of quality are briefly described (Inspection, QC, QA and TQM) - they were presented in order of progression and using the most common nomenclature of quality management. In addition to those four labels there are numerous other descriptors, sometimes erroneously or interchangeably used, that have entered the language of quality management. Much confusion exists in respect to the application of terms; the label, definition and description applied to any level is frequently dependent upon the individual commentator's view of one aspect of quality management in relation to another. The periphery of one level of quality often merges with or overlaps adjacent levels. Foster and Whittle (1989), Dale and Plunkett (1990), Cameron (1993) and Nicholls (1993) have provided definition and clarity, and considered the interrelationship of the levels for the various quality levels. The argument is presented that to successfully utilise quality management to improve the survival and development prospects of an organisation, the characteristics (tools and mindset) of the quality management paradigm must be understood. Foster and Whittle have provided a useful comparison of the approaches to quality management (Table 2.2) which they present as a developmental sequence which has historically been followed by many organisations.

Table 2.2   Comparison of QC, QA,TQC,TQM

	QC	QA	TQC	TQM
Philosophy	Inspecting quality in.	Building and organising quality in.	Organising quality in.	Managing quality in.
Goals	Defect detection	Meeting "design" specification. Defect prevention.	Cost reduction and conformity to specification through continual improvement.	Habitually and competitively meeting customer requirements.
Starting point	Product specification itemised costing.	Adoption of procedures manual.	Calculate cost of quality. Blueprinting operations. Use of problem-solving techniques.	Understanding customers. establishing QM structure. Culture change.
Responsibility for quality	QC department. Individual inspectors.	Centralised Quality Assurance unit.	Systems and operations. Through design and installation controls.	Organisation-wide responsibility through devolved strategic vision.
Principles				
Quality	Post production inspection.	Production process monitoring.	Total operational control.	Holistic.
Cost	Trade-off between cost and quality.	Specified cost at specified quality.	Cost reduction through quality improvement.	Cost reduction through quality improvement.
Improvement	Improved by increased inspection.	Improved by improved product specification and Statistical Process Control.	Project based improvement by "do it right first time" and correcting own errors.	Customer driven habitual improvement.
Driven	?	Control.	Control.	Culture.
Focus	Product.	Production.	Customer specification.	Total quality? Customer perceived quality? Enhancing quality.
Customer	Uncertain.	External.	External customer, Internal customer, Quality chain.	External/internal customer boundary no longer valid; everyone is a customer.

	QC	QA	TQC	TQM
Suppliers	Inadequate supplier inspection.	Some supplier quality agreement plus inspection.	No supplier inspection - supplier quality reliability in all production process (i.e. equipment, packaging, distribution etc.	No supplier inspection. Supplier quality reliability company wide.
Tools and techniques	Rework.	Statistical Process Control and some analysis tools.	Problem solving and quality analysis tools. SPC*. foolproof devices e.g.. Line-stop QC circles.	Organisation with a culture of quality.
Benefits	Few. Causes more problems than it solves.	Improved product quality. Evidence of procedures.	Cost reduction. Waste down, inventory down. Production to customers specification. Fewer suppliers.	Guaranteed Quality. The ability to manage change. Customer satisfaction. Habitual improvement.
For which companies?	Those who do not know any better.	Those with survival problems.	Those competing on cost and quality with long-term profitability goals.	Those with market leaders vision, competing on quality first, looking for sustained growth and increased market share.
How long to "install?"	Days (immediate).	Six months - one year.	One - three years.	Three - five years.

* SPC is Statistical Process Control . See Glossary

Source: Foster and Whittle (1989) "The Quality Maze"

43

The successful implementation of QM may be regarded as a cumulative process which starts by gaining control of the basic production and service functions and is progressively extended to a strategy which addresses the whole organisation. Foster and Whittle (1989) link the progression from control driven quality management to culturally driven quality management with market position (Figure 2.3).

Figure 2.3   The Quality Curve
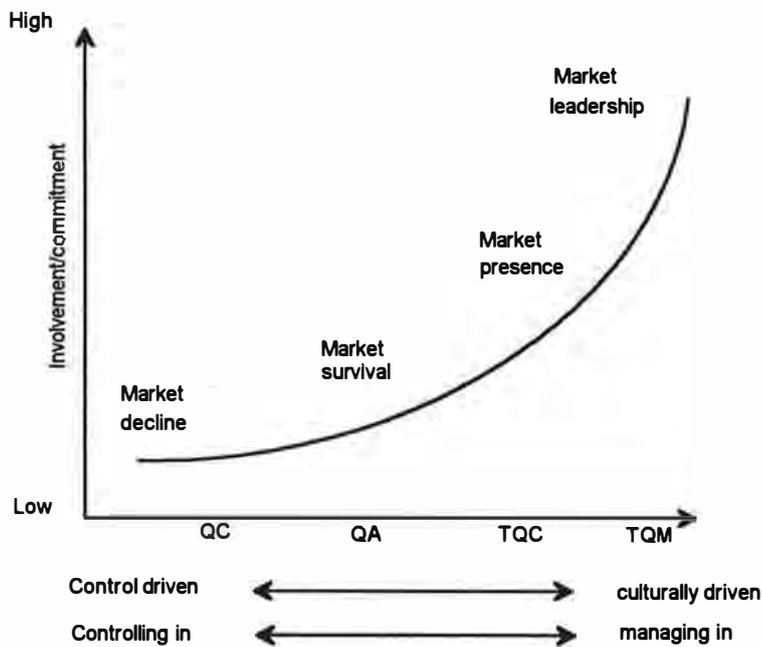
Source: Modified from Foster M, Whittle (1989) "The Quality Maze", TQM Magazine

Foster and Whittle suggest that companies that look to TQM to pull them out of a survival position are unlikely to have the "slack" and resources to allow adoption of a long term strategy. These companies, which may be at the Quality Control end of the curve are rarely driven by the needs of the customer and are therefore likely to be in market decline. At the upper end of the curve, where commitment is on habitually meeting the customers requirements through managing quality into all facets of the organisation's operations, market leadership is possible.

Dale and Plunkett consider the interrelationship between four levels of quality management. They present the various quality management tools as a subset of each

other. Figure 2.4 shows the relationship between the various "levels" using the analogy of the Russian doll.

Figure 2.4   Four levels of evolution of total quality management
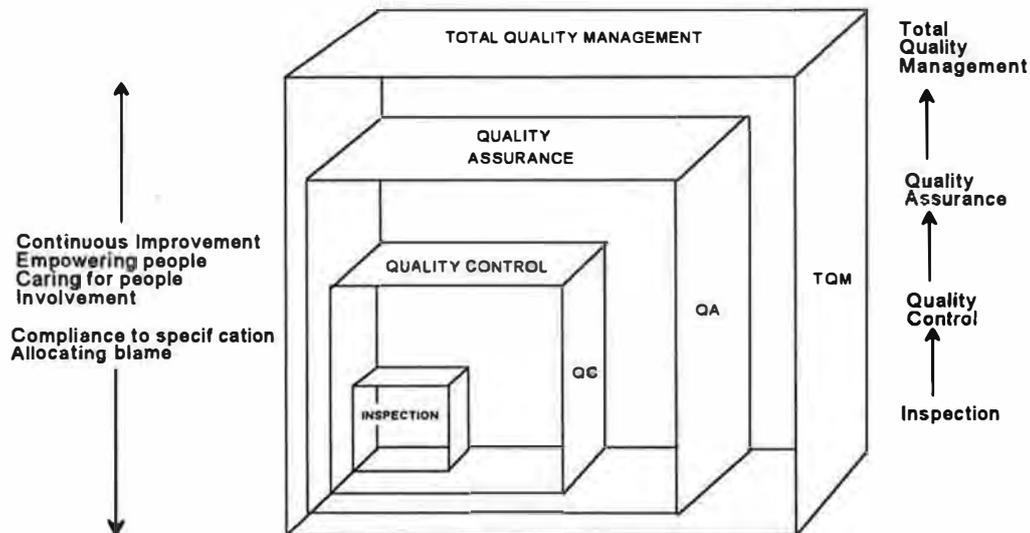
Source: based on Dale BG, Plunkett JJ (1990) *Managing Quality*

The minimal element (the doll in the centre) is "Inspection" - this level is "one below" the starting point of Foster and Whittle and barely justifies inclusion in a model of quality management. At this level, quality is not *managed;* the culture of an organisation is likely to be oriented to allocation of blame for non-conformance. The outside "doll" is TQM; at this stage the tools and techniques of the "lesser" quality levels have been assimilated and the organisation has a culture of continuous improvement.

The preceding examples both suggest that if an organisation is to move through the levels, the mindset of individuals and the culture of the organisation has to change. Cameron (1993) has developed a model of quality culture in which three different approaches to quality improvement are described. These approaches are generalised orientations towards quality, and they constitute the way that organisations think about and define quality. Cameron identifies three types of cultures shown in Table 2.5 overpage

45

Table 2.5   A model of Quality Cultures

Regarding Products	Regarding customers
Error Detection	
Inspect and detect errors	Avoid annoying customers
Reduce waste, cost of failure and rework	Respond to complaints quickly and accurately
Correct mistakes	Reduce dissatisfaction
Focus on the *output*	Focus on customer *needs* and requirements
Error prevention	
Prevent errors	Satisfy customer expectations
Expect zero defects	Help customers avoid future problems
Design it right the first time	Obtain customer preferences in advance and follow-up
Focus on the *process* and root causes	Focus on customer *preferences*
Creative Quality and Continuous Improvement	
Improve on current standards of performance	Surprise and delight customers
Create new alternatives	Engage in extra-mile restitution
Concentrate on things gone right	Anticipate customer expectations
Focus on managing *suppliers* and *customers* as well as *processes*	*Create* customer preferences

Source: Adapted from Cameron (1993)

To understand how organisations progress in their quality management efforts, it is useful to understand how quality becomes part of the organisation culture. Pike and Barnes (1994) differentiate between installation and absorption of quality. At the lower level it is a matter of *installation* of tools and techniques - and at a higher level, whilst the use of tools and techniques continues to be important, of greater importance is the cultural change that may be regarded as a necessary prerequisite or an outcome of TQM. At this cultural level the organisation *absorbs* a whole range of positive stimuli which influence the way in which people think and behave. Whilst implementation of tools and techniques can occur at any time and the action may be immediate, absorption happens over a period of time.

Nicholls (1993) identifies two deeply significant and major paradigm shifts in management thinking to which TQM has become a partial contributory vehicle. The first shift is towards the recognition of the need to achieve results through involvement, commitment, capability and attitude of people, and second towards focusing the whole

46

organisation on customer needs. To understand how TQM has contributed to the shifts, towards people and towards customers, Nicholls proposes a phased model of TQM which encapsulates the complete scope of quality management in so far as it has been recognised, as TQM I-IV. This model is shown in Table 2.6 below

Table 2.6   Four Phases in the Evolution of TQM

	TQM I	**TQM II**	**TQM III**	**TQM IV**
Overall orientation	**Systems and procedures to deliver consistent product/service**	**Involving people in the new way of working for quality**	**Integrating the whole organisation to focus on customer needs**	**Engaging everyone in competitive delivery of value to the customer**

	• QA/QC
	• SPC
	• Spread throughout company
	• ISO9000
	• Eliminating cost of poor quality
		• Commitment
		• Involving everybody
		• Get it right:
		  - first time
		  - every time
		  - on time
		• the "product" does what it is supposed to
			• QFD/QPD*
			• House of quality
			• "Internal" Customer
			• Customer defines needs
			• Integrating suppliers into process
				• Transforming leadership
				• Empowerment
				• Value-adding process stream
				• Benchmarking
				• Flatten hierarchy
				• Mission driven
				• Meeting latent needs
				• Delighting customers

Definition of quality	**Conformance to specification**	**Fitness for purpose**	**What customers want**	**Value to the customer**

* QFD = Quality Function Deployment. QPD = Quality Policy Deployment. See Glossary

Source: Adapted from Nicholls (1993) "Customer Value in four steps"

The four phases of Nicholls' model represent a sequence from the control driven, mechanistic approach where the "total quality concept is *applied*" to the output of the organisation, to the "softer" culture where quality is the way of life and the organisation is focused upon "delighting customers", i.e., providing them with something far beyond their best expectation. Nicholls contends that TQM has transcended its origins to the extent that it is now better understood by identification of the four distinct phases. Each phase can rightly be called TQM but the point to be taken on board is that TQM may exist in different forms in different organisations. TQM has become a vehicle for organisation development and for implementation of the two fundamental paradigm shifts towards people and towards customers. To the paradigm shifts identified by Nicholls, a third shift, identified by Lascelles and Dale (1991), can be added - this is towards a value framework as judged by the customer. At the stage of this shift an organisation will be continuously searching to

identify more factors or characteristics which will increase customer satisfaction still further. Its whole strategy will focus on enhancing competitive advantage by increasing the customers perception of the company and the attractiveness (the value) of the product or service. To move to this paradigm requires a breakthrough whereby the whole organisation moves to a mindset of autonomous, never ending pursuit of complete customer satisfaction. It is autonomous because it is the mindset of the individual and is no longer driven by the tools of quality management and organisation - it has become a laterally driven network of value-added chains, frequently existing across companies as customers or suppliers. At this level of TQM customer desires and business goals, growth and strategies are inseparable, and the vision of the entire organisation is aligned to the voice of the customer.

Thus it can be seen that TQM as an acronym conceals much more than it reveals. It is evident that it is not one set of unified and coherent activities or policies but rather, a complex model that may exist in many forms. Only the most generalised definition can encapsulate the wide variations of tools, techniques, and ways of being that exist under the label. Figure 2.7 summarises the paradigm shifts and significant mindset prevalent in most of the manifestations of TQM.

Figure 2.7   Paradigm shifts of TQM

Conventional	Quality
management	Management

CHANGING MINDSET

Blame culture
Emphasis on
things-gone-wrong

Reward culture
Emphasis on
things-gone-right

error detection   error prevention   continuous improvement

Inspection   Quality   Quality   A culture of quality
                    controlled in   Managed in

PARADIGM SHIFT 1 - TO RECOGNITION OF NEED TO ACHIEVE
RESULTS THROUGH DEVELOPMENT OF PEOPLE

Empowerment
People are trusted

People can aim to   People gain satisfaction
get things right first time   from constantly meeting
                               customer needs
People are involved

People are important   Flattened hierarchy with
                                        devolved decision making
Lack of trust   People need recognition
in people

People make mistakes

PARADIGM SHIFT 2 - TO RECOGNITION OF THE IMPORTANCE OF
FOCUSING ON CUSTOMERS

focus on total
customer satisfaction

                              Understanding
                              the customer
Everybody focused
Recognition of a   Meeting customer needs
"chain of customers"

Customer as the
external purchaser

Customers at   PARADIGM SHIFT 3
a distance   RECOGNITION OF THE IMPORTANCE
                          OF "ADDED VALUE"

                          Quality defined as
                          "Value to the customer"

                          Vision of entire organisation
                          aligned to voice of customer

49

2.4   The literature on TQM in professional scientific organisations

The initial survey of the literature was conducted in 1989 and focused upon the immediate subject of research into the issues of implementing total quality management. The particular focus was intended to be the literature on the experiences and difficulties of implementation in organisations of a professional scientific nature. There was a particular interest in organisations that were, by the nature of their work, bound to work to meet standards of governmental agencies and regulations.

A second area of interest was intended to be upon organisations that had implemented a form of quality improvement designed to meet the nature of work and particular culture and circumstances of the organisation. The researcher had hoped to identify literature upon the approaches of others working in the field who had taken an in-depth look at the reality of TQM implementation in practice. In particular, the objective was to look at issues related to the "soft" side of TQM, that is the influence of people, their attitudes and the cultural issues that surround the transition of organisations into a TQM culture. A third area of focus was to be upon the application of the measurement tools of TQM to the roles, tasks, systems and processes required in the area of regulatory toxicology. Finally, the review was extended to include the background and origins of the regulations that govern the work of professional scientific organisations conducting regulatory work.

As stated in Chapter 1, although the literature describing the philosophy and tools of TQM was relatively plentiful, some difficulty was experienced in identification of contributions to the literature of direct relevance to this work. It was noted that the majority of publications of the time were of USA origin; the researcher held the opinion that various commentaries on TQM in the USA seemed to be strongly influenced by the US national culture and appeared to be subject to overstatement and hype. In common with the presentations in the popular UK publications, a good deal of the US literature was noted to stem from management consultancies and focused upon the TQM strategies of manufacturing industry. Although experiences of companies implementing TQM were reported, there was a paucity of evidence of in-depth investigation and very little suggestion that difficulties might be experienced during or after implementation. It was felt that such commentaries might be subject to bias and

50

over-representation of the case for TQM and thus could not be considered a reliable source of information. However, it was acknowledged that some of the seminal works on quality management (Juran, Deming, Feigenbaum, Crosby and other respected experts in the field), emanated from the USA thus any out of hand rejection would remove these works from consideration.

Turning to the UK literature, there was found to be a noticeable lack of academic reporting on empirical research into TQM. An explanation for this was offered by a state-of-the-art survey (1989) into quality management training and research in Europe (Van der Wiele, Snoep, Bertsch, Timmers and Williams, 1989). The survey, which asked respondents about research difficulties, found that TQM research involved the use of confidential information from subject organisations, thus making publication of research findings difficult. Some respondents suggested that this factor made comparison of research data across industries particularly difficult. The observation was particularly relevant to the immediate field of this research; investigations into quality in professional scientific organisations have the potential to discover aspects of failures of quality which question individual professional competence, the very asset that such organisations are selling. In the case of the organisations studied and other similar organisations, the use of laboratory animals for scientific purposes also was an issue of public concern and controversy, thus such organisations are naturally anxious to protect their public image such that the safe option is to retain an element of anonymity outside their immediate business world. Also, the focus of the research upon quality improvement necessarily involves study of critical activities and personalities and may lead to development of findings of a controversial nature which the organisation would prefer not to reach the public domain.

The foregoing observations help to explain the scarcity of literature reporting on empirical work in professional organisations and upon the underlying reasons for the failures of TQM.

At the stage of developing the framework for this research, the most prolific of UK authors were found to be Dale and others of UMIST and the ACAS Work Research Unit (Hodgson) who had been active in research into employee participation in quality

improvement initiatives, in particular the success and failures of quality circles (Dale,1985). Both of these authors were concerned with the influence of manager attitudes to achieving quality improvement. Dale's findings on the influence of managers on the success or failure of circles is considered to be equally relevant to TQM. He suggests that many of the failures of quality circles are strongly influenced by the actions and mindset of middle and junior management in respect of whether they nurture or inhibit change. He recounts the experience of an industrial catering firm where the managers of one site were positive, helping circles to organise their meetings during the working day and responding to their proposals. On another similar site, while claiming to support quality circles, management continually found reasons why it was impractical for the circles to meet or for proposed solutions to be implemented. As a result, the former site successfully ran circles for two years up to the survey whilst the latter failed. There is nothing astounding about this observation, indeed those knowledgeable about the development of quality management would probably feel that uneven commitment to the process is so broadly observed that it is barely worth a mention. However, at the time the observation was important because it recognised what was to become one of the key issues of TQM success, that of management commitment to the process.

Since 1989 the interest in TQM and consequently the literature on the subject, has burgeoned. Unfortunately, many of the publications add little to the understanding of TQM because many authors simply reconstitute and regurgitate the ideas of Deming, Crosby and Juran that gained prominence in the 1980s. MacDonald (1994) describes this expansion as the response to the market for TQM where, amidst the rapid expansion of media to meet market demand, most books and articles played "follow-my-leader", profoundly discussing what the gurus meant by such expressions as "drive out fear" or the "absolutes of quality" rather than questioning the grounding of such concepts. McDonald asserts that at this time, critical debate and new thought was "stultified at birth".

Since the early literature review, TQM has matured and has been applied to a broader range of situations. This development is reflected in the literature whereby authors have considered comparative levels of TQM (Lascelles and Dale, 1991; Nicholls,1993;

Dale and Plunkett, 1993). Although there is continuation of publications targeted at managers on the implementation and tools of TQM, for example, Bell, McBride and Wilson (1994) and Choppin (1991), there is evidence of a wider interest in the difficulties of implementation of TQM and the maintenance of the effort to achieve the results to which the implementing organisation aspired at the outset. TQM has been looked at in the context of employee involvement in quality improvement. Wilkinson, Marchington, Goodman and Ackers (1992) identify some of the issues of increasing involvement and responsibility of employees exposed to TQM. They suggest that the language of TQM is ambiguous in that it is concerned to increase involvement, yet there is also a strong emphasis on increasing management control. Issues of control and responsibility and organisational hierarchy are of particular importance in the regulated environment of a PSO. They see TQM as shifting the focus of responsibility for quality to the people who actually do the work, suggesting a transition from authoritarian, top-down decision making to task-orientated ideals.

McCabe and Knights (1994) have looked below the surface rhetoric and the published TQM strategy common of many organisations, to consider what actually happens at the local level of TQM application. They report upon research conducted in a major financial institution and provide the interesting but debatable conclusion that TQM strategies often fell short of their goals because of weakness in strategy emanating from the upper management levels. They argued that there was a contradiction between a "quality" focus and the omnipresent profit motivations, which consequently hindered quality by emphasising short term cost saving. It is suggested that the motivation of managers was one of self protection whereby rhetoric was employed to whitewash their failures in implementation of TQM. They further suggested that managers attempted to rationalise and legitimise their behaviour so as to maintain their position of power vis-a-vis labour in relation to their fellow managers, making decisions on the basis of self interest, hierarchical constraints, the profit motive, errors of judgement, or incompetence. They noted management's desire to maximise output through increasingly fewer staff and saw this as reducing the "spaces" in which local creativity, producing innovations to improve quality, can flourish.

McCabe and Knights, looking at a specific institution, draw conclusions of a political nature, critical of management strategy. Whilst it could be argued that this situation could be generalised to other organisations, the researcher holds the view that many of the organisations that experience failures of strategy, might do so in spite of the best attempts by management to assure success. The power/self interest mindset identified by McCabe and Knights might be of lesser significance than, say, the duration of time that a strategy has been in place, the extent to which the strategy has been adapted to meet changing organisational needs or the degree of difficulty in meeting the TQM goals given an organisation's relative starting point in the TQM hierarchy.

Foster, Smith, Whittle and Tranfield (1994) have also attempted to develop a deeper insight into reasons for TQM failure. They have identified that many TQM efforts are cyclical, characterised by periods of optimism and progress followed by periods of uncertainty. They note that many TQM programmes, whether of the "off the shelf" or "do-it-yourself", run out of steam in 18-24 months. They suggest that unless the organisation is able to change implementation tack, the programme often dies. Foster *et al* go behind the map of TQM strategy specified in terms of techniques and activities, to develop a map that identifies three archetypal mindsets (planning, learning and visionary) that reflect different approaches of organisations to TQM. They argue that initially organisations tend to utilise one mindset and unless they can shift from mindset to mindset, they may lose steam. To overcome this problem, a fourth, transitional mindset, concerned with reframing the organisation's TQM paradigm and allowing transition between the other three, has been identified. According to Foster *et al* (1994;46) it is the ability to shift between mindsets that influences the eventual longevity and success of the programme.

This tends to suggest that a predominant, shared mindset arises in individuals (in the case of the work of McCabe and Knights, the dominant mindset would be the self-interested manager, and in the picture outlined by Foster *et al*, it is the mindset of the implementing managers that is assumed to be the dominant mindset of the organisation). What these accounts have failed to address is the influence of the mindset of the individual within the organisation and the power that the individual may have, depending upon the degree of autonomy, personal charisma, external professional

standing or position in the hierarchy, in perpetuating their mindset either to the advantage or disadvantage of the organisation. Ritsema *et al* (1991) recognised this problem in their article on the problems of quality management in Professional Services. They propose that in the professional organisation, quality management is to a great extent, individual orientated, aimed mainly at the knowledge and attitude of the professional. As such, there are tensions between the organisation and the professional within it that hinder the development of a systematic strategy for quality improvement. They suggest that many professionals adhere to an "achievement" orientation, valuing a high degree of freedom when doing their work. This suggests that the professional will see quality improvement as a matter of personal achievement that relates to the individual rather than the organisation.

Taylor and Pearson (1994), reporting on a case study on the feasibility of introducing TQM to a large R&D laboratory, an organisation that can be classified as professional, recognise that scientists in R&D present particular challenges in respect of TQM. They suggest that a key reason for slow adoption of TQM in R&D is that many TQM programmes have been quantitatively orientated and are not easily transferred to the R&D environment. They say that measures to quantify R&D quality are hard to identify and accept. To overcome this problem they suggest an approach of organisational analysis to identify specific quality issues upon which to focus. They suggest that this analysis *"intimately involved people in the laboratory and their personal views and as such, integrated the Human system and the TQM system"* (Taylor and Pearson,1994: 32). In fact, bearing in mind the intimate relationship and direct influence that the scientist has with quality of their "product" it is difficult to imagine that the underlying design of any successful TQM programme could fail to integrate human and operational systems.

Continuing on the theme of difficulty of quantification, Wilkinson, Allen and Snape (1990) raise the question of whether TQM is most suited for large labour groups where tasks are of a routine nature. Reporting on case studies of implementation of TQM by the Co-operative Bank plc and a producer of power tools, Black and Decker, Wilkinson *et al* observed uneven development of the programmes in both organisations. In the former, it was staff in the large centres, working in a factory like environment, who were most receptive. In the latter, the programme took hold in the

manufacturing areas, making less progress in the white collar departments. They suggest that this was, to some extent, a feature of management priorities and style but note that an influence might have been the greater ease of quantification of fairly routine work performed by a large number of people. They suggest that the large groups welcomed TQM since it gave them the opportunity to become involved and influence their immediate work situation. The relevance of this observation to this research is the identification that white collar workers, who could be considered to equate to the scientists of a PSO, were less accepting of TQM than the larger work groups conducting routine tasks. This latter group can be equated with the technical and support groups of a PSO.

2.5   Summary and areas to be addressed in this research

The literature has demonstrated extensive interest in TQM in a widening range of situations. Definitions of quality and quality management have been widely explored as has the development of the quality improvement process and the transition of companies through various quality levels. There are many dissertations on the approaches that have been taken by organisations to improve their quality but they often tend to be stronger on reporting of the process rather reporting of the impact. The "gurus", Deming, Juran, Crosby have published their methodology for improving quality based upon considerable experience of actually doing it. It is commonly argued that their writings, although not based upon academic research, have provided the greatest body of insight into the management of improvement of quality in manufacturing industry. However, their dissertations and many others based upon them, are not sufficiently broad to address the issues of implementation of TQM in PSOs. Authors of the popular management literature, through over-generalisation, have tended to write for a wide audience and have thus not added to the depth of understanding of the issues that actually arise at the local and individual level. Although there is now recognition that different approaches are required for service and for manufacturing industry, there is a notable gap in understanding of TQM in the context of professional organisations and specifically PSOs.

There is widespread evidence of organisations implementing TQM but rather less evidence of research into the impact upon the organisation. Reports tend to present the

process and a few key measures but often fail to look below the surface at what is actually changing within the work force. There are also gaps in understanding of the relevance of the transitional levels of TQM to organisations working in regulated environments who are obligated to comply with defined, long established quality standards such as GLP. No published literature has been identified in respect of the relevance of these journey stages to TQM in professional scientific organisations; this research aims to address that issue.

At the outset of this work there was no published research identified on TQM in research organisations. This gap has been only partly filled by Price and Gaskill (1990) and Taylor and Pearson (1994). However, what continues to be absent is the understanding of the impact of TQM at the scientific shop floor, where improvement of unique and variable biological systems can pose particular problems. Published research in organisations working to GLP is absent from the academic literature.

The literature is short on consideration of the impact that individuals, whether in key positions or as part of a larger group, can have upon improvement. People are often viewed as generic groups who have to be moved in a common direction. It is felt that there is little understanding of the influences that prevent this from being a realistic or even a desirable objective. This research will explore the influence of the scientific mindset on the transition towards TQM.

Although a number of surveys on the success of TQM have been published, again these have asked questions about activities that are not valid in a PSO. Success is often adjudged against such criteria as productivity measures, use of defined quality measurement tools and measurable productivity and financial outcomes. There is a gap in the knowledge of appropriate measures of success in professional environments. By looking at the influence of individuals, specifically scientists with management responsibility and science technicians, and by investigation of the problems of measurement of performance in PSOs, this research aims to fill some of these gaps.

CHAPTER 3
BACKGROUND TO
PROFESSIONAL SCIENTIFIC ORGANISATIONS
AND QUALITY REGULATIONS

Introduction to Chapter

This chapter will expand upon the brief introduction to Professional Scientific Organisations provided in Chapter 1. The nature of such organisations (specifically biological contract research companies) are discussed in the context of their role and development in the social and business environment.

The chapter also provides an insight into the background to the changing "quality environment" in respect of the influence of governmental agencies and the origins of the requirement of PSOs to perform their work to the principles of Good Laboratory Practice. An outline description of Good Laboratory Practice is provided.

Organisation of the Chapter

The sections in this Chapter are organised as follows

3.1 Introduction to Professional Scientific Organisations

Biomedical Contract Research Organisations such as BioFarm Laboratories and SciTec Europe fall into a category of organisations labelled "Professional Scientific" by the researcher. Such organisations were described in Chapter 1 as:

> *Independent commercial, public or private organisations that derive their main income as a "contractor" of scientific services (i.e., services in a scientific discipline, the conduct of which is dependent upon the qualification, skills, knowledge, social and professional standing of its employees) to industry.*

There are a wide array of different bodies and organisations which fit the above description and either directly or indirectly depend upon the development or application of science for their existence. However it is not feasible to consider the full scope of all such organisations within this thesis. The intention here is to show how the Biomedical Contract Research Organisations fall into the classification of PSOs and to demonstrate how a PSO differs from other organisations.

As the literature does not offer a specific definition of the term "Professional Scientific Organisations" it is appropriate to examine the component parts of the label to understand its origins and the scope of applicability. PSOs are discussed in respect of

1. Type and geographical distribution and growth.
2. Customers
3. Product
4. Purpose and attributes
5. Professionalism in scientific organisations

3.1.1 Type and geographical distribution and growth

The Scientific Organisations that perform biomedical work "under contract" can be considered in four major groupings. Whilst all categories share a common focus of science, they differ to various extents in respect of aspects of their profiles. The four categories considered are:

1. Independent Contract Research Organisations
2. Chemical manufacturer's in-house Research and Development:

3. Government Research Institutes and Universities:

4. Investigatory and Analysis laboratories

The subject organisations of this research are considered to fall into the first category (described in the next section) and as shown in Figure 3.1 below. Appendix 3.1 provides a comparative table of the four categories of PSOs.

Figure 3.1   Main Strands of Contract Research Activity
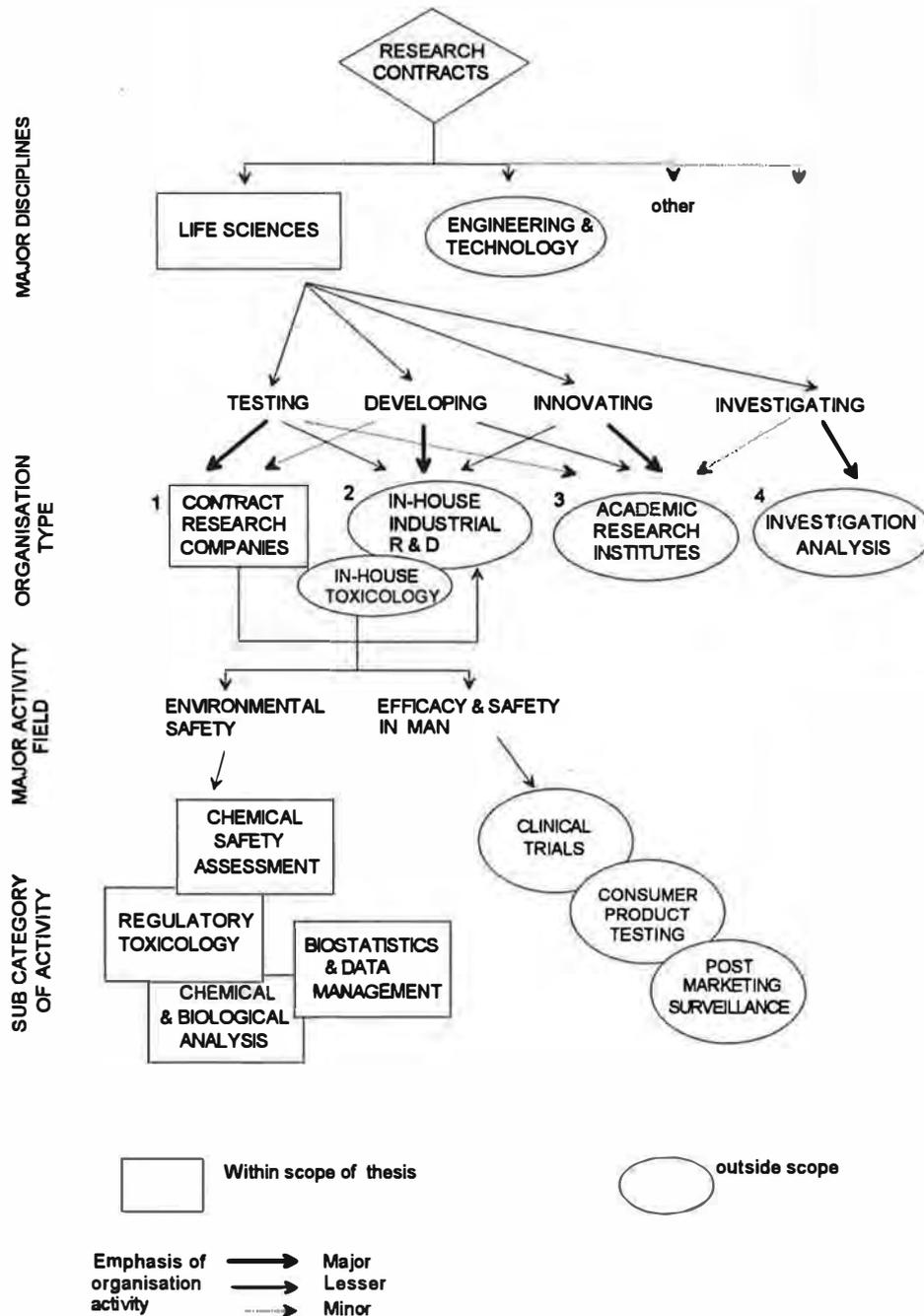
3.1.1.1 Independent Biomedical Contract Research Organisations:

Contract Research Organisations (CROs) provide a range of research, development and testing services to industry. They are most prevalent in the field of engineering and technology, and the life sciences where the biomedical CROs are active in the field of drug safety testing and clinical research (Hone, 1994). A 1991 survey of biomedical Contract Research Organisations in the Europe (Hughs, 1991) reported that 297 CROs were active in the field of scientific or medical studies. Of those, thirty-two, nine of which are in the UK, offered the service of animal toxicology conducted to Good Laboratory Practice. The distribution of CROs in Europe is shown in Figure 3.2 below:

Figure 3.2   Location of Biomedical CROs in Europe in 1991

Figures in parenthesis are CROs that conduct toxicology to GLP standards
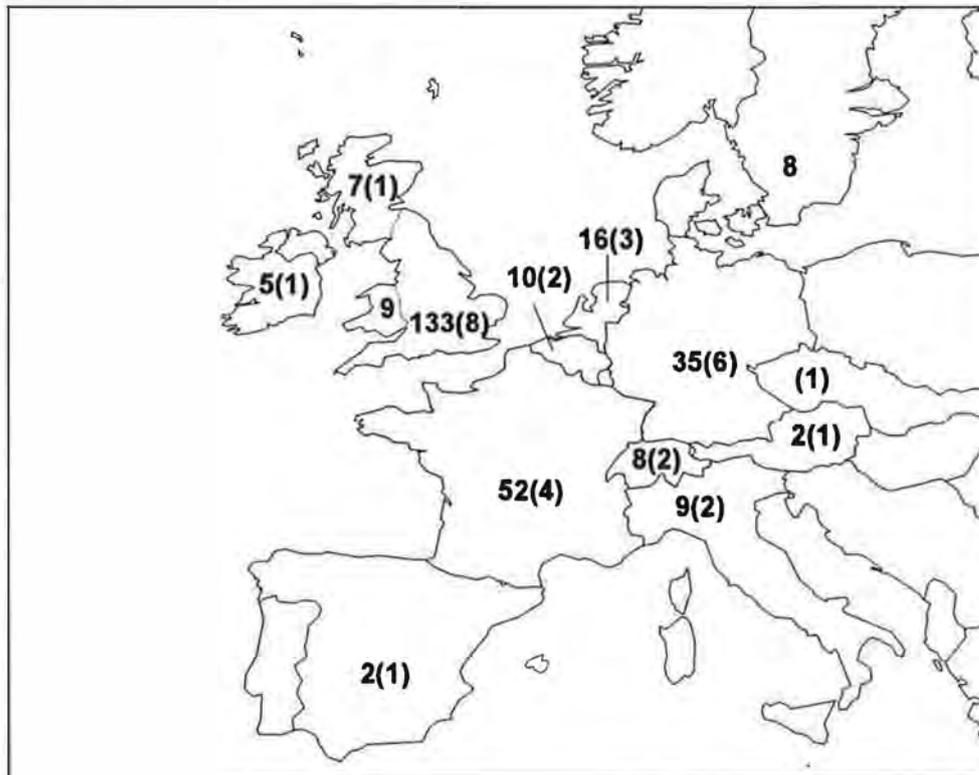
The majority of Biomedical CROs have been formed since the early 1970s (Figure 3.3) with all the major UK toxicology laboratories established before 1975. The growth in biomedical CROs was largely a response to market demand and opportunity as the demands for greater safety developed. Most CROs are relatively small in size; the majority of companies working in clinical research employ less than thirty staff. Those offering toxicology as their main service are amongst the larger organisations with several hundred employees in the major companies.

Figure 3.3 Growth of CROs in the UK (1972 - 1991)

Number
of CROs
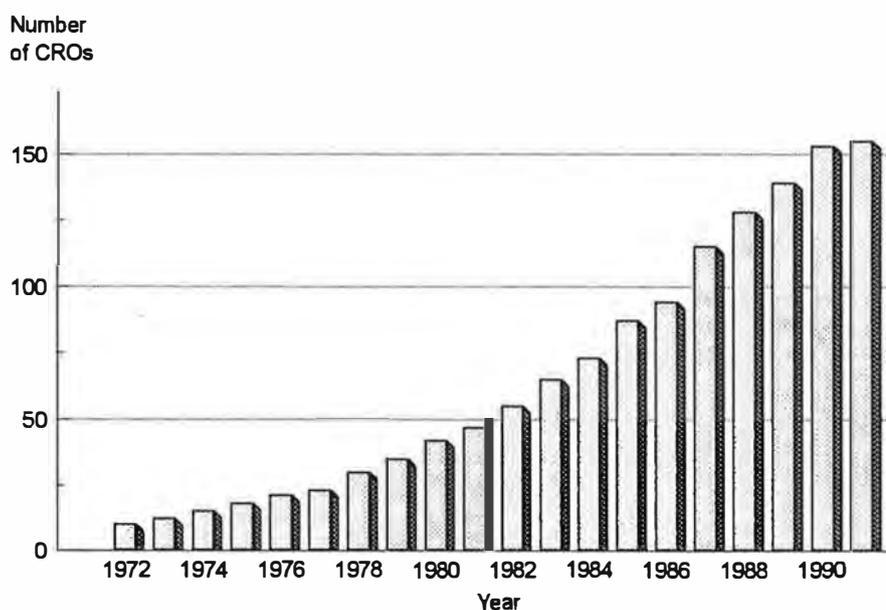
An important attribute of the CROs is freedom from direct government influence and maintenance of an unbiased and independent status. They generally do not conduct activities such as discovery and manufacture of drugs or other chemicals which might put their interests in conflict with those of their clients. CROs aim to supplement the internal activities of their client companies by providing specialised resources such as laboratory animal facilities, other specialist laboratory facilities, testing equipment, and professional expertise.

The majority of work performed by the biomedical CRO is *in vivo* (using animals) safety assessment, as required by government agencies, of pharmaceutical products and other chemicals. Animal based toxicology has to be conducted to Good Laboratory

Practice regulations (Department of Health, 1989) by individuals of appropriate qualification and training. It is the "professional profile" of the organisation and the quality of its work that enable it to compete in the market place.

Increasingly Contract Research Organisations involved in toxicity testing are linked to, or part of, larger companies. These larger groupings extend the range of services on offer into the clinical research, and analytical and environmental chemistry services.

3.1.2   Customers

Customers of PSOs are largely the discoverers, developers and/or producers of new chemical materials. They include the well known blue chip pharmaceutical and chemical companies through to the far less visible innovative organisations. Most have in common with each other, the desire to take a product to market in the shortest time feasible, or to obtain new information to support a product already on the market whereby they are required to perform safety testing to meet regulatory authority requirements. The customer organisations are generally knowledgeable buyers of a service; at the individual level, the customer with direct contact with the PSO is frequently a scientist - an expert in his discipline and often with firsthand experience of the service and standards required of the PSO.

Customers of a PSO are generally referred to as "clients". The nature of the client:contractor relationship is complex and sometimes paradoxical. It is frequently an uneven partnership between two professionals, one the contractor, the other the customer. Both may have opinions on the appropriate design of the work and interpretation of results and through direction and/or frequent dialogue with the PSO, the sponsor may have intimate involvement with the shaping of the "product". However, evidence of undue sponsor influence upon the results of the work might undermine the independence of the contractor, who is nevertheless directed to focus upon satisfaction of the sponsor's needs. The researcher considers that the nature of the sponsor:contractor relationship provides a differentiating characteristic from most other forms of customer:supplier relationships that exist in either the manufacturing or service sectors.

3.1.3 The Product of a PSO

PSOs do not manufacture any tangible product. Their output is generally an expert report, released from a "responsible scientist", conveying the results of scientific/technical work that has been conducted within, or under the control of the PSO on behalf of a third party, often referred to as the "sponsor". The total product is generally a complete service which includes provision of all resources (facilities, materials and staff) to conduct the work, in addition to consultancy, design, project management and reporting.

3.1.3.1 BFL and SciTec - Explanation of biological safety testing

The core business of the two organisations in which this research was conducted is *in vivo* (live animal based) biological safety studies designed to produce the data required to identify, quantify and evaluate the risk to human health and the environment resulting from the manufacture or use of pharmaceutical, biotechnology, agrochemical and other chemical products. Any new product is subjected to a battery of detailed and prolonged investigations, as dictated by government regulations, to determine the nature of any unwelcome biological effects it might exert. This work is performed on behalf of "sponsoring" companies and is performed to meet the requirements of governmental authorities world-wide. An explanation of the nature of this work follows:

> After a new chemical is synthesised, it is subjected to specific screening tests to determine whether or not it possesses the desired degree of biological activity. For example a pharmaceutical company wishes to know whether the substance shows activity in models relating to human disease, an agrochemical company tests the substance against insect pests, against organisms responsible for plant diseases, or against selected weeds to determine herbicidal activity. A candidate chemical that shows promising activity in the screening phase is subject to detailed and prolonged investigation, as dictated by government regulation, to determine the nature of any unwelcome biological effects that it might exert. This is the area of investigation, the testing of substances for undesired side effects, that constitutes the major part of the activity in which BFL and SciTec are engaged.

It is almost axiomatic that a biologically active substance, if given in great enough quantities, will also be found to exert some sort of toxic side effects. Generally speaking it is the gap between the dosages eliciting the desired and the undesired responses respectively, the so called "safety margin", that determines whether or not the substance is likely to have a useful commercial future. The activity of testing, commonly referred to as *Toxicology*, has within the generic, a number of specialist areas. In addition to general toxicology, other work focuses on:

- *carcinogenicity* : the potential of a substance to have cancer-inducing properties
- *reproductive studies* : evaluation of the effect of a substance on fertility, pregnancy and subsequent development of offspring
- *metabolic studies* : to track the absorption, distribution and metabolism of substances in the body
- *inhalation* : studies to evaluate the effects of dusts and vapours in the atmosphere
- *genetic toxicology* : determination of whether a substance causes genetic or chromosomal mutations
- *aquatic and environmental studies* : to test potential environmental pollutants.

The tests range from single exposure experiments to trials lasting over two years and generally use an animal model (rodents, dogs or occasionally monkeys) as the test system. Any study is run according to a written, agreed methodology, known as the *study protocol*. The protocol, which is unique for the specific substance to be tested, is supplemented by Standard Operating Procedures; these are formal, detailed descriptions of how tasks are to be conducted. A record is maintained of all activities, communications and decisions relating to the work. Any deviation from the study protocol, whether planned or accidental, must be fully explained and justified.

Although the basic building blocks of all studies are similar, there is considerable variation in complexity with frequently decisions and judgements made as studies progress. In many cases, different expertise has to be bought to bear in harmony for the studies to have a successful and timely outcome.

Figure 3.4 overpage is intended to give an insight into the nature of work design of BFL and SciTec albeit that it is a simplified representation of just one of many

variations. Overall, the companies offer over 500 "standard study types" all of which can be individually tailored. The figure describes an example of a typical study intended to evaluate the potential toxicity of a drug.

Figure 3.4   Example of typical toxicity test

Example of a typical 13 week toxicity study in the rat intended to evaluate the potential toxicity of a new drug.

The study comprises of 40 male and 40 female weanling rats, all weighing within 10g of each other at the start of the study. The rats are purpose-bred and free from disease. They are housed in a restricted access, dedicated room designed to limit environmental variables that could interfere with the study. The animals are uniquely identified to allow individual data to be gathered. They are equally divided, by random allocation, into 4 groups of males and 4 groups of females. Three groups will become the "treatment groups". One group of each sex will be the "control" group and will not receive any of the substance under test but will, in all other respects, be treated in the same way as the other animals. The other three groups will be given varying amounts of the test material, based on the such variables as the expected level of exposure in man and the level at which toxicity is expected.

The material to be given to the animals has to be prepared in a suitable vehicle, such as sterile water for injection, such that it can be given to animals by the route intended in human use and at the intended concentration. Checks are performed on each batch of formulated material to assure that the mix is stable and homogeneous.

Each day for thirteen weeks, every treatment group will be given, for example by injection, a dose of the test substance calculated according to its current bodyweight. During that time they will be observed at least daily for signs of ill effects. Their bodyweight, food intake, and maybe water intake will be constantly monitored and their clinical condition will be assessed. At intervals, typically before the start of treatment, after four weeks and at the end of the treatment period, blood and urine samples will be collected for analysis. If the test substance appears to have the potential to affect the eyes, or the blood pressure, heart-rate and so on, additional examinations will be conducted to monitor affects. At the end of the treatment period all of the animals are humanely killed and dissected. The organs and other tissues of each animal are visually examined and weighed. These tissues are chemically preserved. The tissues are later very finely sectioned and mounted on microscope slides which are then examined for evidence of unusual changes at the cellular level which might indicate toxicity.

Throughout the study, data are recorded, either manually or electronically, and monitored. Depending upon findings, there may be adjustments to the study design eg. changes in the dose level or inclusion of additional examinations. All of the data is processed, reported, analysed and discussed in a report of findings to be presented to the sponsor.

To understand the nature of the professional scientific service and how it differs from manufacturing industry and what is generically called the service sector, it is useful to look at the characteristics of the inputs and output, and "production" process that differentiate PSOs from product manufacture and other commercial activities.

a) "Input/Output" characteristics

- The output of a professional within a PSO is more than the "end product". The realisation of this must belong to the provider and the client.

- The service can only be guaranteed to a certain degree; the professional cannot guarantee the "problem" will be solved eg. the toxicologist may find that a drug that he has tested on behalf of the client may cause deleterious health effects. The relationship that the professional organisation enters into with the client can therefore almost always be characterised as an *effort* contract rather than *result* contract.

- The service is of a very heterogeneous nature and to a great extent, cannot be offered in a standardised form. With each service, the opinion of the professional is needed.

- There are few tangible elements to the service; even though it is true that the output may have some tangible characteristics (e.g. the raw data from the laboratory or the written report of the pathologist or toxicologist). The actual service is either advice, information and/or interpretation that contribute to the "problem solving" process for the client; the tangibles as such, play a minor role.

- The service cannot be corrected before delivery, but it is usually possible to adjust the part of the output which is still to be delivered because of the interactive character of the production process. Results of scientific work conducted on behalf of the client may not be the result the client would have liked but they are a matter of fact and cannot be changed. The course and design that future work takes can be adjusted.

- The service (and output) are unique to the "problem". They cannot be stored so it is not possible to supply from stock.

b) "Production" characteristics

- The complex and specific nature of the problems permit the primary processes to be standardised to a limited degree only.

- The "production" activity runs parallel to the sale of the "product"; the client is purchasing the methods and output of the production chain.

- The service (product) is not replaceable. i.e., its unique and biologically variable nature mean that it cannot be precisely replicated, nor can findings be ignored.

- The producer and client frequently have direct, interactive contact during the production process. The "inputs" to the process are variable and often unpredictable and often supplied, in part, by the client.

- The client takes part in the production process. In this respect the professional organisation has a paradoxical relationship with the client; on one hand the professional is dependent on the client as his principal, but on the other hand, the client is dependent upon the knowledge, skills and immediate experience of the professional: this knowledge and skills may give the latter a certain dominance in the production process.

- The production is very labour intensive. Although automation is favoured where feasible, much activity depends upon hands-on, individual activity.

- After delivery of the "product" evidence will remain of its production. The acceptability (quality) of the product may be judged upon the totality of actions that have contributed to the end product. A combination of professional obligation and legislation require that the "process" can be revisited by re-examination of the original inputs and outputs.

3.1.4 Purpose and attributes of a Professional Scientific Organisation

Over the past two decades, there has been an increasing trend towards development of beneficial partnerships, often of a temporary nature, between manufacturing organisations and service providers such as Professional Scientific Organisations. Handy(1989) talks about the Shamrock organisation which has at its core, professional people essential to the organisation. The Shamrock organisation contracts out all non-core activities and activities in which it does not have dedicated expertise. Porter(1990) emphasises the growth in all areas of services: growth in the underlying need for these services has been driven by increasing sophistication, internationalisation and rationalisation of in-house research activities, combined with the push for enhanced market position through growth in profitability and increased share price. Evidence of this trend can be seen in the pharmaceutical industry, a major client sector of PSOs, where the soaring costs of drug development, and "first-to-market" race precipitated by intense global competition, amongst other factors, has lead to a consolidation of the industry through mergers and acquisitions. There are a number of relatively recent examples evidenced by the emergence in the marketplace of combination names such as SmithKline Beecham, Bristol Myers Squibb, Glaxo Wellcome and Sanofi Winthrop, to name but a few. This changing environment favoured consideration of contracting-out the testing phases of development to improve business efficiency and to capitalise on the advantages offered by the CRO capability.

Although the financial drive for greater profitability provides an important incentive to companies to purchase contract services, it is not always the primary reason. There exist a number of other advantages over in-house research and development that indicate the use of PSOs. Firstly, their size, although relatively small in company terms, is frequently larger than in house provision. This has the benefit of:

- **Concentrating expertise:** Whilst the larger manufacturing companies are generally able to afford their own in-house experts, this is not the case for all companies that are required by legislation to test a product prior to marketing. For the small companies the contractor provides expertise that they may not even be aware is needed. For the larger, more sophisticated and technologically advanced, the experts of the PSO substitute, complement or supplement the in-house experts.

Because of economies of scale, a professional research organisation may also develop resource or labour intensive specialist services which would not be economically sound within an in-house research and development environment.

- **Cumulative experience:** A contract research organisation may handle hundreds of chemicals under test at any one time, whereas the developing company may only produce a few candidate drugs in a year. Many skills applied in research laboratories require constant practice to maintain competence. This "practice" is readily to hand when a scientist is repeatedly presented with the same or similar task thus the experience, competence and efficiency of the scientist or technician in the PSO may frequently outstrip his less experienced counterpart in an industrial laboratory.

- **Cost-effective resources:** Research activities such as toxicology require highly capitalised, extensive, specialised facilities. Many firms have found it increasingly hard to justify expensive in-house facilities and staff to do a job which can be done just as effectively, and frequently at less cost, by a PSO. They can use PSOs as an option to reduce a fixed cost to a variable cost. The "captive" in-house service department is a cost centre. The specialised provider can often hire and train better people, employ better methods, use better equipment and perform a service cheaper and better.

Contractors can turn to PSOs when they have resource or capacity shortfall or unexpected peaks in workload or a backlog of work.

Second, the Professional Scientific service organisation faces competition for the work and thus has the incentive to continuously raise productivity and improve quality. The constant pressure to gain and maintain clients means that the PSO have become highly focused in providing the service needed by their clients. As specialised providers they can concentrate all of their management effort on the provision of a service that may operate as a peripheral activity in the contracting firm - this benefits clients in terms of quality of work and pricing.

71

Finally, there is the issue of access to global markets. Increasingly the developers of new drugs and chemicals wish to have the ability to sell products to a global market and therefore want the certainty that the testing which has been conducted will be acceptable to the government agencies in the all of major markets of the world. Some countries - Japan provides an example - lack confidence in the PSOs of their own country to conduct work to a standard that will be accepted by governmental agencies worldwide. In this case, work may be placed with a PSO which will conduct work to an acceptable standard and has a track record of regulatory acceptance.

3.1.4.1 Professionalism in scientific organisations

There is much in the literature on the subject of professionals and professional organisations. Much of it considers what professionals are, their traits and how they are organised rather than what they actually do. The various works on the traits of professionals have been presented by Millerson (1964) and Kast and Rosenzweig (1985). Consideration has been given to the structures of organisations that employ professionals (Mintzberg,1983) (Ritsema, Broekhuis and Gruisen,1992). Pemberton and Herriot (1993) have reported on the consequences of the changing relationship between the scientific (technical) professional and the organisation in the context of the 1990s economic recession. McNulty, Whittington and Whipp (1993) have investigated the responses and changing relationship of professionals (scientists and engineers in industrial R&D laboratories and Doctors in NHS hospitals) to the market driven changes of contracting-out or the shift of focus of work to a customer:contractor principle.

For the purposes of this work, it is useful to consider professionals and professionalism in the context of the organisation purpose, structure and functions therein. Ritsema, Broekhuis and Gruisen (1992: 25) propose professional services as:

> "*the provision of services by one or more persons who are considered competent in a certain field of knowledge, acquired by prolonged training, and have the skills to apply this in practice.*"

Within this description, Ritsema *et al* recognise the essential incorporation of the individual "professional" who may adhere to certain codes of conduct, traditions and

ethics and also forms part of a group delivering services skilfully and competently. The researcher considers that the effective operation and success of a PSO depends upon more than just the "professionals" who satisfy the characteristics and widely recognised traits described by Millerson (1964)and Kast and Rosenzweig (1985) and others. It is argued that a PSO is a *professional organisation* i.e., it is the service of the *organisation* that is delivered skilfully and competently, rather than an *organisation of professionals* whereby it is the product of the number of individuals which are professionally delivered as a specified and framed output. As such, a PSO places value and demands upon all organisation members irrespective of their educational attainment, external standing and role, expecting every organisation member to make an appropriate contribution to the work, reputation and achievement of the organisation and its professional standing in the broader scientific arena. This implies that members of the organisation form a cohesive entity which behaves in an ethical manner and professionally satisfies the requirements and needs of its clients. The service that the professional organisation provides for its clients will be characterised by integrity and will be based upon the application of sound knowledge and expertise applied from top to bottom of the organisation.

If we take the tangible product of a biomedical contract research organisation to be an expert report which will be used to support an application to market a product which is likely to have a beneficial effect, but possibly an adverse effect, on man and the environment, then it would seem reasonable to expect that the author of the report should be a person of appropriate background to provide credibility and confidence in the product. Such a person may have reached the pinnacle of their scientific career. They may be, for example, a Member of the Royal College of Pathology or the Royal Veterinary College, adhering to a code of ethics. They may be a respected authority and publisher in their field and they certainly will have spent several years in higher education with at least as many years again gaining expertise in their chosen speciality. Such a person might reasonably be regarded as a *Professional* when placed against Millerson's traits (Millerson,1994) - See Appendix 3.2. But within a PSO, there are a range of disciplines and skills required to provide a total service, and a wide distribution of educational attainment, knowledge and experience required of the

people that perform those tasks. However, the credibility of the output, and a client's desire to purchase services rests heavily upon the credibility and standing of a minority - those who might be regarded as the true professionals. Yet it is evident that a large proportion of the people who make an essential contribution to the provision of a professional service would not themselves be considered as professionals when judged against the same criteria.

Mintzberg recognises the role of training and indoctrination (indoctrination being the process whereby the employee is introduced to the behavioural norms of the organisation) in the development of a professional. To some extent, he suggests that an organisation surrenders some control over the selection of their employees and the methods to which they work when it relies upon an outside body (a university or professional association institute) to provide training and certification beyond its own scope. With the loss of control follows loss of allegiance whereby professionals may tend to identify more with their profession than the organisation in which they practice it. Hutchins(1990: 135) view supports Mintzberg (1963) in that he sees the "professionalism" prevalent in British society as a disadvantage when competing with countries advanced in their quality culture such as Japan. He sees professional allegiance leading to compartmentalisation with like professions talking to like professions rather than developing a global perspective. This can represent a problem of communication and co-operation where an organisation requires a diversity of professions and specialisms to operate in tandem. But counter to this, Ritsema *et al* recognise that there are some professionals who are more altruistic in their attitude to working in organisations. They prefer to work in professional organisations in which management is emphasising loyalty to the company, group co-operation, a strong organisational culture, socialisation of new professionals, and institutional commitment.

3.1.4.2 The organisation of professionals

Few professionals work totally independently with absolutely no reliance upon others of the same or affiliated professions. When independence is claimed, the professional may well use other individuals to support his work albeit that they may not share his "professional status".

The nature of issues handled by professionals are increasingly complex, requiring interaction between them within an organisational context. An example might be the testing of a potential cancer causing drug by a Contract Research Organisation. Such work might be conducted over two or more years and require a greater range of skills and knowledge than is endowed in any one individual. In this situation, a continuum of professionals with expertise in a variety of disciplines would be needed to see the work through to satisfactory conclusion. When such a complex situation exists, especially if it is one of a large number of non-standard variants of work conducted by the same group, it is clear that professionals develop interdependencies which require management if operational chaos is to be avoided. Thus the shape of organisations in which professionals work begins to gain importance in the delivery of a quality service to a client.

Mintzberg has proposed two basic forms of professional organisation:

1. **The Professional Bureaucracy**. This form is based upon the acquisition and use of standardised methods and techniques accepted by the professional group, and is successful in a complex, stable environment. This structure fits individuals with a strongly profession-orientated professional outlook.

2. **The Operational Adhocracy**. In this form of organisation, the existence of standard methods for solving problems is denied. The basis for the service is the creative use of existing knowledge and experience by ad hoc teams made up of professionals from the relevant disciplines. This form of organisation is successful in a complex, turbulent environment and the structure fits professionals with a client-orientated professional outlook. To do that, the structure of the organisation and the interaction of its people, its functions and how it relates to its customers and the community require consideration.

PSO such as BFL and SciTec can be regarded a hybrid. Although the way in which they are structured has similarities to Mintzberg's Professional Bureaucracy, the lines of power and the roles of the professionals in the organisation take on some of the characteristics of the Operational Adhocracy. At the same time, because of the "production line" nature of some key tasks, together with the way in which tasks are standardised, certain characteristics of Mintzberg's Machine Bureaucracy are identifiable. In Figure 3.5 Mintzberg's model of a Professional Bureaucracy has the key functions of a PSO, typical of BFL and SciTec, transposed onto it:

Figure 3.5   **Diagram showing the five parts of a Professional Bureaucracy showing situation of key functions of a PSO**
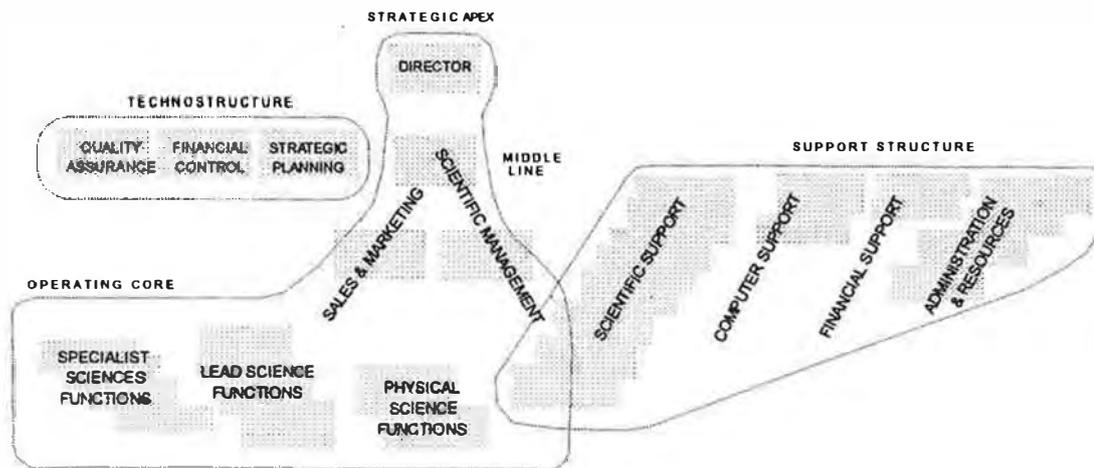
In explanation of the above Figure it can be seen that at the base of the organisation in the *operating core* are the people who directly serve the clients. This is where the majority of scientists are found. This area may be split by scientific discipline as the organisation develops and more coordination becomes necessary. At the top is the *strategic apex* from whence the control emanates. The *middle line* provides the hierarchy of authority between the operating core and the strategic apex. The *technostructure* contains staff, outside the hierarchy of line authority, who are the analysts of an organisation; they measure, standardise, plan and control activity; the quality assurance groups are found here, independent of the direct influence of the operating core. The *support structure* provides the other elaborated part of a Professional Bureaucracy; this part is focused upon providing support to the operating

core. The largest elements of PSOs can be found in the "scientific support" groups of the *support structure*. In these groups are the "hands on", practical scientists and technicians who hold day to day responsibility for laboratory work. It could be argued that this group, who are active in the "production" elements of the organisation, might be more appropriately placed within the *operating core*. As shown, there is certainly overlap between the activities of the *operating core* and scientific support staff. The placement within the two parts is therefore based upon the closeness of the professionals to the clients. It is the professionals of the *operating core* who hold the professional:client relationship and ultimately take legal responsibility for the professional conduct of the work.

The small technostructure is indicative of the relatively small size of CROs, combined with the integration of most "technocratic functions" into the core operations and support functions.

Mintzberg refers to parallel hierarchies with the operating core communicating bottom-up and the support staff, top-down. This characteristic is not a feature of PSOs. The parallel lines of authority tend to be divided into scientific disciplines and administrative activities. The requirement to have Quality Assurance staff independent of operational activities, results in a line directly to the *strategic apex*.

3.2 Background to the development and introduction of quality regulations

3.2.1 Origins of the need for toxicity testing regulations

The market for the services of PSOs such as BFL and SciTec developed out of increasing public concern over human health and the potentially adverse environmental impact of pharmaceutical, agrochemicals and consumer products (Morris, 1988: 48). Public concern was heightened in the 1960s with the publication of such books as Carson's "Silent Spring" (Carson, 1962) which alerted the public to the likely adverse impact of overuse of the pesticide DDT, and with such human tragedies as thalidomide (Persauld, 1985; Lesser 1976: 647), a drug which was prescribed for pregnant women as a preventative for nausea but produced the devastating side affect of the birth of grossly malformed infants.

At the time, the potential risks of working with chemicals of unknown properties or of introducing new chemicals was recognised well enough; some countries (eg USA, New Zealand and the UK) had legislation which required testing and government approval before marketing of pharmaceuticals, food additives, cosmetics, agricultural and industrial chemicals. However, the rigorous testing requirements of today were largely undeveloped with much safety testing conducted according to the needs perceived by the manufacturers.

The forces for change included heightened public concern, rising costs for litigation protection, particularly in the USA, and battles between insurers and producers on the matter of disclosure of scientific information (Valery, 1976). Another key factor was a shattering of the illusion of the valid testing. Until the mid seventies, agencies such as the USA Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) had made decisions on the destiny of new products based on scientific evidence which they presumed to be reliable, valid and based on high quality research. However, in the mid 1970s events occurred to destroy this presumption and cast suspicion upon all toxicity testing data submitted to regulatory authorities in the USA (Morris, 1988).

78

Chance findings, followed by further investigation, led the FDA to uncover major deficiencies in organisational and scientific data which seriously impugned on the integrity of reported data in USA laboratories (Anderson,1987). What was found was described by Brisson (1981:12) in the following way:

> "*If we define science as knowledge gained from systematic observation of controlled experiments, then what we were seeing in some laboratories was not scientific experimentation at all, but rather large pet store operations and poor ones at that.....*"

Lengthy investigation by the FDA found evidence of fraud and misrepresentation of data, untrained personnel with major study responsibilities and little or no supervision, improper animal care and laboratory procedures, and inaccurate or missing data for a vast number of studies. Such flagrant research discrepancies and breach of scientific ethics resulted in the prosecution and consequent lengthy custodial sentences for company officials of five USA Contract Research Organisations. The problem was perceived as representative of a general problem in the safety testing in industry. To address the matter "Good Laboratory Practices" (GLP), a summary of which is presented in Appendix 3.3 was proposed in 1976 and was placed on the US statute book in 1979 (US Food and Drugs Administration,1979).

Because of the global influence of the US chemical industry and the importance of the US market to the global economy, the need to demonstrate GLP compliance became a survival issue for the CROs. If they could not perform work to standards that were acceptable to the US government agencies, customers would not risk placement of work. Thus the first significant influence on the quality of the service provided to customers, had its origins in the fraud, malpractice and scientific upheaval and inadequacies of the 1970s. This enforced improvement in the way that testing laboratories carried out their business was a substantive move forward in quality management. It became the quality platform from which, for the next ten or so years, the testing laboratories in the biomedical contract research industry attracted and retained their clients.

3.2.2 Development of Good Laboratory Practice

As defined by the United Kingdom Department of Health (1989: 2)

> *"Good Laboratory Practice (GLP) is concerned with the organisational processes and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported. Adherence by laboratories to the principles of Good Laboratory Practice ensures the proper planning of studies and the provision of adequate means to carry them out. It facilitates the proper conduct of studies, promotes their full and accurate reporting, and provides a means whereby the integrity of studies can be verified."*

In the broader field of quality management, Good Laboratory Practice is one of the least conspicuous quality programmes, mostly because of its relatively narrow focus upon a defined area of activity. It does not follow any particular philosophy of quality improvement; it is a compliance programme rather than an improvement process. Whilst it shares a number of features with the international standard for quality systems, ISO9000, the focus of GLP is primarily assuring integrity of scientific data and upon the ability to demonstrate that work has been conducted in accordance with a formally agreed plan. There must be adequate authentic documentation such that, in theory at least, a reconstruction of the work can occur from the raw documentation. GLP focuses upon compliance to the specific actions and processes, facilities and people that are required to conduct safety testing to an acceptable manner. In achieving its objectives, GLP has considerable force because demonstration of compliance is essential to gain governmental approval for marketing of drugs and other chemicals thus, without a certificate of compliance, CROs would not be able to attract clients.

Although many UK laboratories started the introduction of GLP as early as 1977, in response to activities in the USA, GLP monitoring by UK government officials did not commence until 1982 (Robinson,1985; Health and Safety Commission,1982).

3.2.3   The acceptance and contribution of GLP

After its conception and communication of intent, there was extensive criticism of GLP on an international basis. Smith (1977: 1227) reports that industry officials estimated that the new regulations would increase the cost of testing by at least twenty per cent and Parker (1981: 67) suggests that the lack of knowledge and the anticipation on how the GLP regulations would be implemented, negatively coloured management attitudes. Vagueness and ambiguity of the early drafts of GLP bred apprehension because it was envisaged that the scope of the proposed rules was too extensive. They were taken as an invasion of what was perceived as company rights; not only were they regarded as a dictate to the scientists but also as an encroachment into the domain of management judgement. As Wadell (1988:121) noted, this was the first time that laws were being bought to bear on sacrosanct areas of the professional skill and judgement of the scientist. The requirement to comply with GLP hit at the professional pride of those scientists who claimed that such practices had always been a normal way of life for the scientist with integrity (Waddell, 1988).

Whilst GLP may have had the effect of sharpening the focus in areas where attention was required, its main impact was to require independent and credible compliance (with the regulations). Waddell (1988:122) noted that the perception of Quality Assurance staff, the inspectors and auditors required by GLP, as no better than "snoopers and nit-pickers" trampling over the professional judgement and pride of experts. He observed that

> *"The whole area of accountability, documentation and internal/external review was clearly going to get a rough reception from certain sections of the scientific community, not because they had anything to hide but because the whole area smacked of Big Brother"*

The volume and vehemence of the opposition could be taken as tangible indications that the GLPs constituted a major change to the way in which testing laboratories would have to conduct their business.

Over the past two decades GLP has contributed much to improve the quality of work performed by organisations working in the field of chemical safety assessment through improved compliance, increasing adherence to, and more exacting interpretation of the rules of compliance. However, acceptance was far from spontaneous. It is argued by

Siconolfi (199: 371) and Waddell (1988:124) that whilst there are improvements in the documentation of science, GLP has not done much to improve science itself. They claim that it provides a classical case of the introduction of legislation for one reason and its benefits lying elsewhere. The real impact of GLP lies in the achievement of higher levels of competence, and science which is better controlled, duplicable and more ordered. However, it is difficult to judge how far GLP has progressed with its original objective of fraud prevention. There is little doubt that tightening up documentary requirements, use of Standard Operating Procedures and the requirements for written study plans would mean that fraud would be more difficult to commit but conversely, carefully committed fraud would probably be more difficult to detect.

There are recognised limitations in the application of GLP. For example, the Environmental Protection Agency recognises that inspections of laboratories to assure that they are in compliance may simply demonstrate the standards observed at a specified point in time. These standards, Goldman(1985:3) of the US EPA suggests, only indicate that a laboratory is in compliance for the conduct of a specified study conducted at a known point of time. This does not necessarily mean that the same laboratory will be in compliance next month or next year, nor even for other studies conducted at the same time. Goldman's assertion denotes an underlying lack of trust by the US government agencies whereby testing laboratories are regarded as suspect and guilty until proved innocent.

Since its introduction, GLP has increasing been accepted as *the* quality system for laboratories. This has been observed to lead to derision or dismissal of other quality processes. However, GLP can only be viewed as a milestone which addresses a defined range of scientific activities. The regulations have changed remarkably little yet the depth of interpretation and scope of influence has strengthened, calling for questioning and revision of laboratory procedures. Constant inspection, audit and review of scientific operations and management, have led to recognition of more areas to which standards and expectations can be applied. Thus a laboratory which met the compliance requirements in 1976 would be unlikely to be regarded as compliant today unless it has progressed its quality practices considerably.

CHAPTER 4
SELECTION of ORGANISATIONS
and COMPARATIVE PROFILES

Introduction to Chapter

Chapter 3 introduced Professional Scientific Organisations in general terms and discussed the nature of biological safety testing in the context of the product of a PSO. In this Chapter the basis for selection of the client and corroborating organisation is discussed and comparative profiles are provided.

Organisation of the Chapter

The sections in this Chapter are organised as follows:

4.1   Selection of subject organisations

The "selection" of the primary client organisation in this research was opportunistic and could be considered as "subject selection by default". The context was as follows: the researcher was present in the organisation as an employee, the organisation had a specific management problem to be resolved (improving quality), and the combination of the context of a biomedical contract research organisation and Total Quality Management, represented a unique phenomena on worthy of study.

In the late 1980s when this work originated, the understanding and application of Total Quality Management was widening but in the population as a whole, TQM was far from widespread. There was no published research identified on the subject of TQM in organisations with the same or similar profile to BFL. This observation has been supported by a recent case study of TQM implementation at the Esso Research Centre (Oakland and Porter, 1994). They report that during the mid 1980s when a team wished to explore TQM approaches for use at the Esso Research centre, they could not identify published methodology on TQM in research organisations. Thus with the absence of published methodology of TQM implementation in a professional scientific organisation, and with consideration of a combination of the needs of the organisation and the aims of the researcher, a methodology was needed that would satisfy both. Simply put, the organisation wanted to change; it wanted somebody to develop the programme for TQM implementation and it wanted somebody who understood the organisation and its culture to facilitate that change. As an employee, the researcher was keen to have considerable involvement in that process because of her perception of the value that TQM would bring to the organisation. The situation appeared to offer a rich environment for in-depth study.

In the UK in the late 1980's there were six independent biomedical contract laboratories conducting full-profile toxicology testing for industry (Hughs, 1991). Of those six, all held Department of Health GLP compliance certificates and competed in the same market sector for business. Five of the six organisations were initially considered as suitable for the research (the sixth was eliminated from consideration because its reputation suggested an inability to compete with the other companies because of

underdeveloped expertise and facilities). An outline profile of these organisations is given in Table 4.1 below:

Table 4.1   **Comparative profile of PSOs conducting toxicology**

	Organisation				
	A	**B**	**C**	**D**	**E**
Established	1972	1975	1968	1964	1976
Location	East Anglia	Northern England	Scotland	East Anglia	Welsh Borders
Number of employees	650	500	450	1000	250
Division of larger company?	yes	yes	yes	yes	from 1992
Parent company nationality	USA	USA	Europe	UK	USA
Annual Turnover (£M)	20	19	18	40	10
Core business	Toxicology	Toxicology	Toxicology	Toxicology Chemistry	Toxicology
Quality Assurance Unit established	1977	1977	1977	1977	1977
GLP compliant	yes	yes	yes	yes	yes
TQM strategy in existence	yes	yes	yes	no	no
Collaboration established	yes	yes	no	no	no

Of the five organisations shown in Table 4.1, three were known, through common knowledge within the industry and personal contact of the researcher, to have active total quality management strategies in place. BioFarm Laboratories (A), the principal subject of this research was one of the three. With the intention of obtaining multiple sources of data on the same phenomenon through conduct of a comparative case study, it was decided to approach only the PSOs that had a strategy of TQM implementation,

thus eliminating from selection, Organisations D and E. Both of the remaining companies (B and C) were closely matched in respect of the selection criteria having a similar profile to BFL by way of business mix, staff profile, age of company, size of company and annual earnings. One of the two organisations, Organisation B, (SciTec Europe) agreed to cooperate.

4.2   The subject organisations - summary description and comparison

Having discussed the general attributes of PSOs in the previous chapter, this section provides a comparative overview of the two organisations in which this research took place. The two companies were BioFarm Laboratories (the "client" organisation) and SciTec Europe, (used for corroboration and comparison).

Table 4.2 below provides a summary comparison of the profiles of the two organisations

Figure 4.2   Organisation comparison of BioFarm Labs and SciTec Europe

	Client organisation *BioFarm Laboratories*	*Corroborating organisation* *SciTec Europe*
Established	1972. Independent, privately owned British company. Breakaway group from existing research company	1974. USA parent Company. Purchase of an existing research company
Location	South of England (Essex) Second location from 1975 in East Anglia (Suffolk)	North of England (Yorkshire)
Major relocations	1984 to Suffolk	None
Change of Managing Director	During 1989 and November 1992	During 1987
Corporate linkage	Purchased by US based company in 1976 Launched as independent company on American Market in 1987	Purchased by Corning in 1979 Became part of Corning Laboratory Services Inc. in 1990
Core business	Regulatory Toxicology	Regulatory Toxicology

	Client organisation ***BioFarm Laboratories***	**Corroborating organisation** ***SciTec Europe***
Client base	Pharmaceutical and Chemical companies based in all civilised countries of the world. Strong Japanese market.	Pharmaceutical and Chemical companies based in all civilised countries of the world Strong European market
Employees at start	Less than 20 (start-up company)	Approximately 270 (Purchase of existing research company)
Employees in 1992	643 full time equivalents	509 full time equivalents
Staff profile	Mainly scientist and technicians	Mainly scientists and technicians
Revenue 1992	£20.3 million	£19.7 million
Queens Award for Industry - export	Winner 1983 and 1989	Winner 1989
Investors in People	Awarded 1994	Awarded 1994
Quality Assurance	Good Laboratory Practice implemented from 1977 in response to requirements of the American Food and Drug Administration	Good Laboratory Practice implemented from 1977 in response to requirements of the American Food and Drug Administration
Total Quality Management introduction	Decision to implement by MD	Corporate parent requirement.
Parent company TQM expertise	None	Corning Programme. Recognised as a world leader in TQM
Use of Consultant	1987 Early programme development and feasibility by consultant. Consultant approach rejected by senior managers in favour of internally developed and run programme.	1987 -1990 TQM programme designed and introduced by consultant. Internal Consultants (US parent company based) available for guidance, advice and materials

4.2.1 Employees and structure

The employees two organisations were similar in distribution and mix of education and skills. Both are white collar organisations employing around 60 percent graduate to post doctoral scientists and science technicians. The scientific and technical staff are supported by what can loosely be termed scientific/clerical support. This group include data processors/collators, word-processing staff and other individuals who generate the tangible output (scientific reports). Indirect staff (i.e. those who do not immediately contribute to the revenue earning activities of the company) are typical of many organisations and include finance, sales and marketing, IT development and support, facility maintenance. Essential to both organisations are the Quality Assurance staff required for GLP compliance.

Both Organisations were structured by scientific and/or technical speciality. Although there are some differences in of the smaller scale activities, essentially the same disciplines exist in both organisations; the extent of commonality can be see in Figures 4.3 and 4.4 overpage.   Some of the smaller activities in both organisations operated on an autonomous basis but the core operations of toxicology are organised in a form of matrix management whereby the projects are managed by "Study Directors" (the project managers required under GLP). In both organisations, these scientists are grouped according to the discipline they cover. Other departments and disciplines, with their own line management, reported to the study director groups in respect of the scientific aspects of work. In both BFL and SciTec, the reporting line for the support sciences which is predominantly staffed by technicians (animal facilities, necropsy, histology, pharmacy/formulation) is separate from the reporting line for project managers (Study Directors).

One notable difference between the two organisations was the number of layers in the hierarchy. In part this relates to size of operation and the presence of "deputies" in the BFL hierarchy. It was also influenced by a recent restructuring of SciTec into a more "customer focused" operation, shortly before the research took place. Similarities and differences in the two structures, can be seen in Figures 4.3 and 4.4 presenting simplified organisation charts.

Figure 4.3   Organisation Structure - BioFarm Laboratories
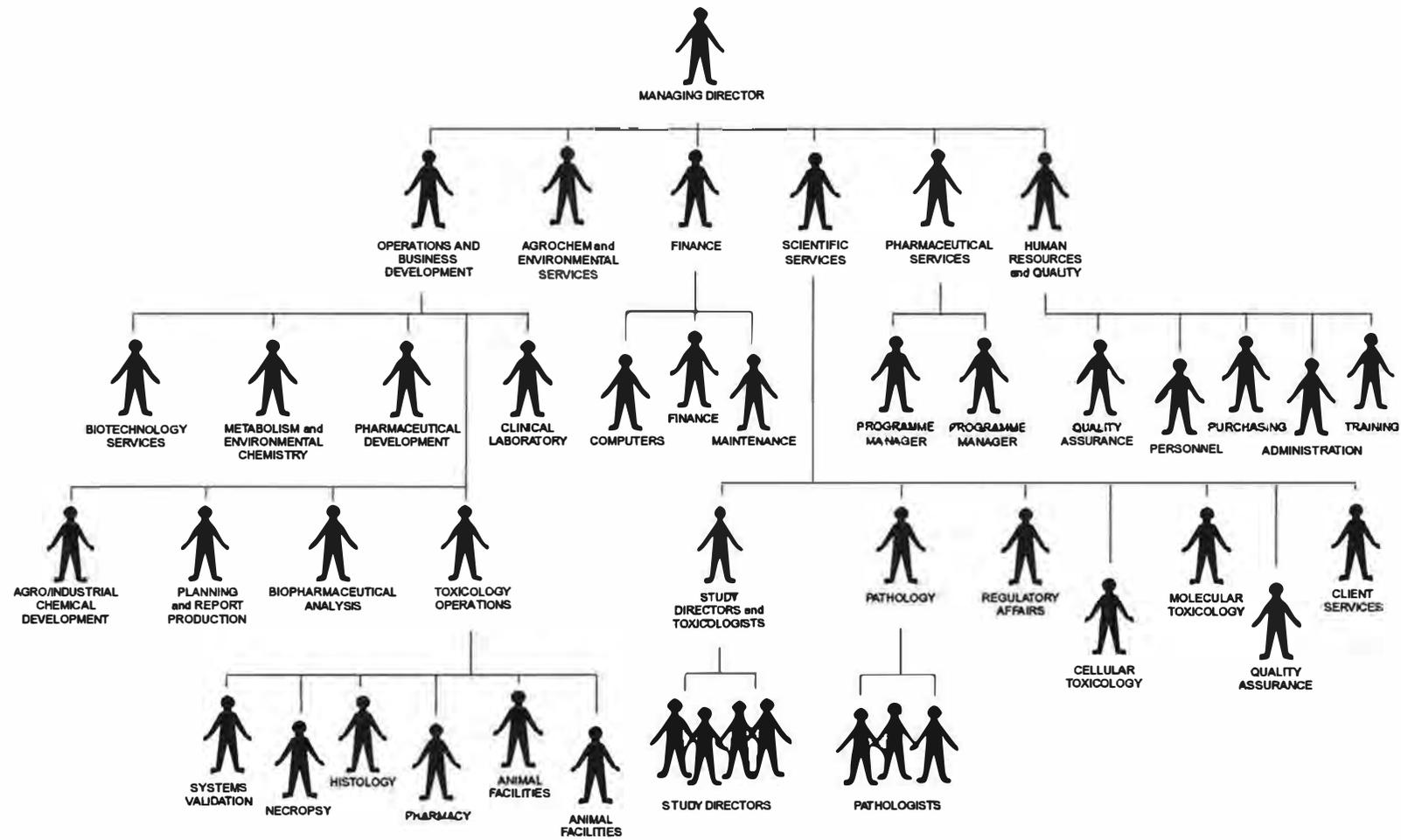
Figure 4.4   Organisation Structure - SciTec Europe

In respect of size of the two organisations, Figure 4.5 shows the relative number of full-time-equivalent staff employed between 1989 and 1992. The most interesting point of comparison is the constant growth of SciTec vs. the down turn of numbers by BFL. This difference was largely accounted for by the downturn in the toxicology market experienced over the early 1990s. BFL responded by staffing to need whereas SciTec expanded in other disciplines such as molecular biology and chemistry. A similar picture is seen in the financial comparison.

Figure 4.5 Comparison of the number of full-time equivalent employees

number of staff		1987	1988	1989	1990	1991	1992
SciTec		290	329	405	445	456	509
BFL		479	605	690	691	660	643
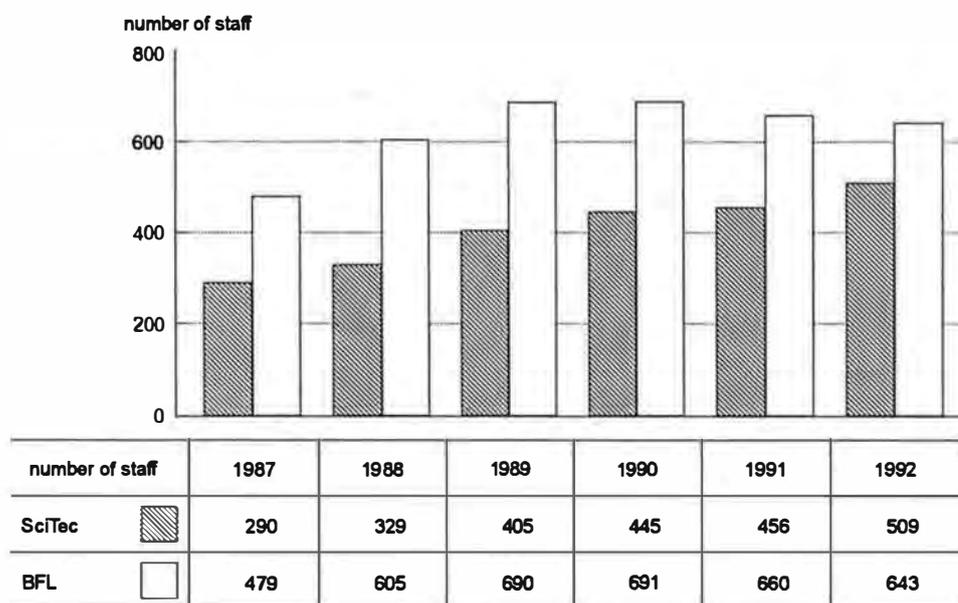
4.2.2 Financial comparison of BFL and SciTec

Figure 4.6 shows the revenues of SciTec and BFL for years 1987-1992. Figure 4.7 shows operating profit (revenue minus costs) for the same years. The purpose of presenting these figures is to show that whilst the operating performance of the two companies can be differentiated, they were operating in the same financial league at the time of their moves to implement TQM.

Figure 4.6   Comparison of company revenue from 1987 to 1992

Revenue	1987	1988	1989	1990	1991	1992
SciTec	6.4	9.0	11.8	13.7	16.9	19.7
BFL	12.3	16.0	20.7	22.7	21.7	20.3
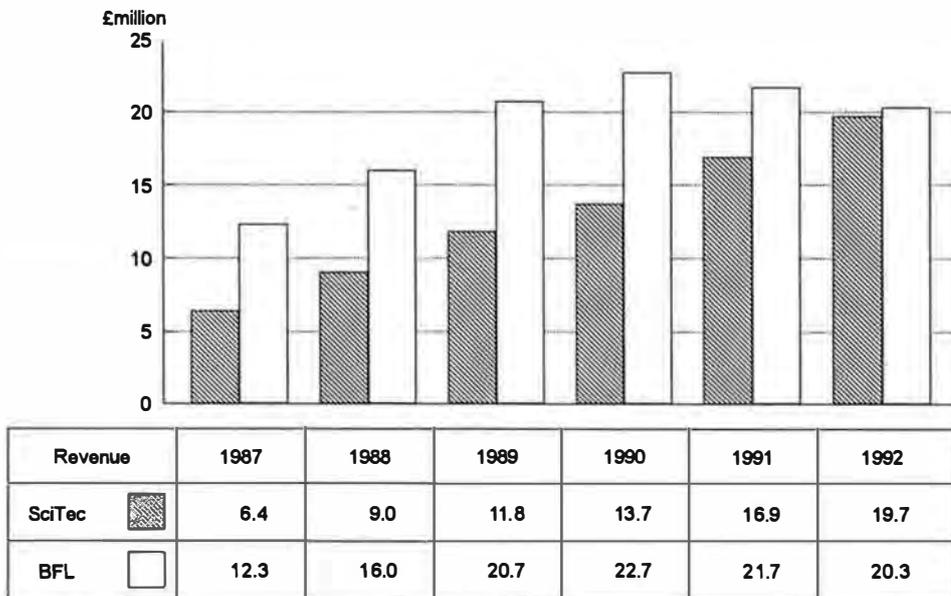
Figure 4.7   Comparison of company operating profits for 1987 to 1992

Operating profit %	1987	1988	1989	1990	1991	1992
SciTec	9.1	14.6	15.7	12.3	10.6	12.6
BFL	13.5	21.6	23.4	21.7	20.0	12.3
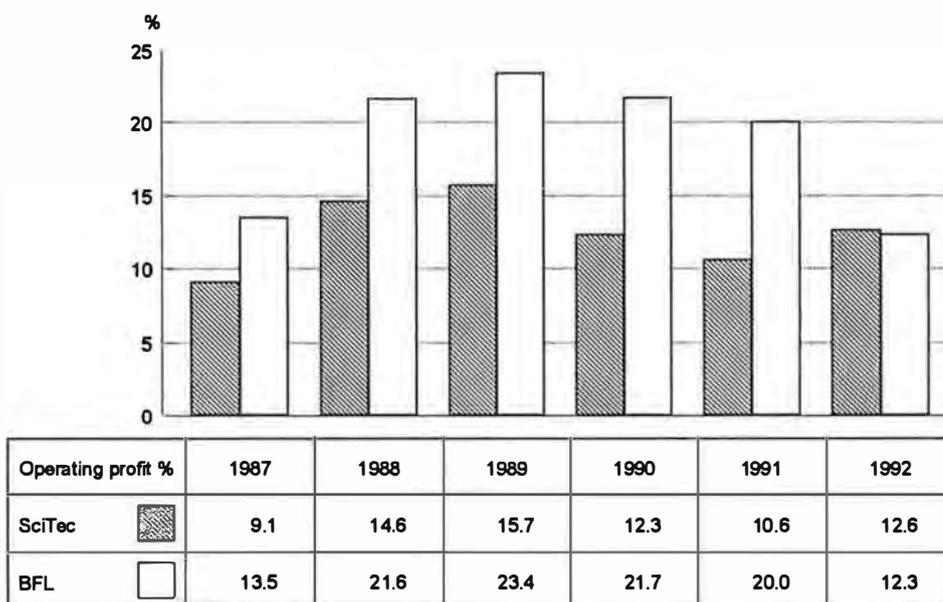
The most noticeable difference in the financial performance of the organisations is the continued growth, year on year, of SciTec's revenues versus the steady growth to 1990 followed by a year on year reduction for BFL. The operating profit of BFL was around fifty percent greater than SciTec up until 1989. Both organisations show year on year growth of the percentage profit up until 1989 followed by three years of reduction back to 1987 levels for BFL. SciTec shows a slight recovery of profit margin to a level in line with that of 1988. Detailed financial information was not available at SciTec to allowed an in-depth comparison but it seems that the explanation for the different performance of the two companies rests in their market positioning and development of new areas of business.

BFL had continued to focus upon its core business of toxicology which had been badly affected by the economic downturn of the early 1990s. By comparison, SciTec had taken the decision to expand upon its chemistry operations, compensating for the flat to negative growth in toxicology. By 1992, the level of revenue generated by chemistry was around fifty percent and growing. Not only did they benefit from this move in terms of acquiring new business but it was also business with a good margin, relieving some of the pressures that BFL was subject to in an increasingly price competitive market.

4.2.3   Quality Management

As quality management is the core issue in this thesis, it would be remiss not to mention it in a comparison of the client and corroborating organisations.

Both organisations have a Quality Assurance Unit as required to meet the requirement of Good Laboratory Practice. These units, which monitor the quality of the scientific work of the organisations, were established in 1977, thus the history of working to the principles of GLP was equally established in BFL and SciTec. Both Organisations made their early moves to introduce TQM in 1987 using, unknown to both organisations at the time, the same TQM consultant.

CHAPTER 5
BIOFARM LABORATORIES
ORGANISATION and QUALITY SYSTEMS

Introduction to Chapter

This Chapter builds upon the information provided in the earlier chapters to consider the nature of BioFarm Laboratories, the client organisation, in greater depth. It reports on the data gathered in the diagnostic phase of the research (Indicated in box 1 of Figure 5.1) and discusses the characteristics of the change activity (box 2) to be implemented.

Figure 5.1   Conceptual model of Action Research case study at BioFarm
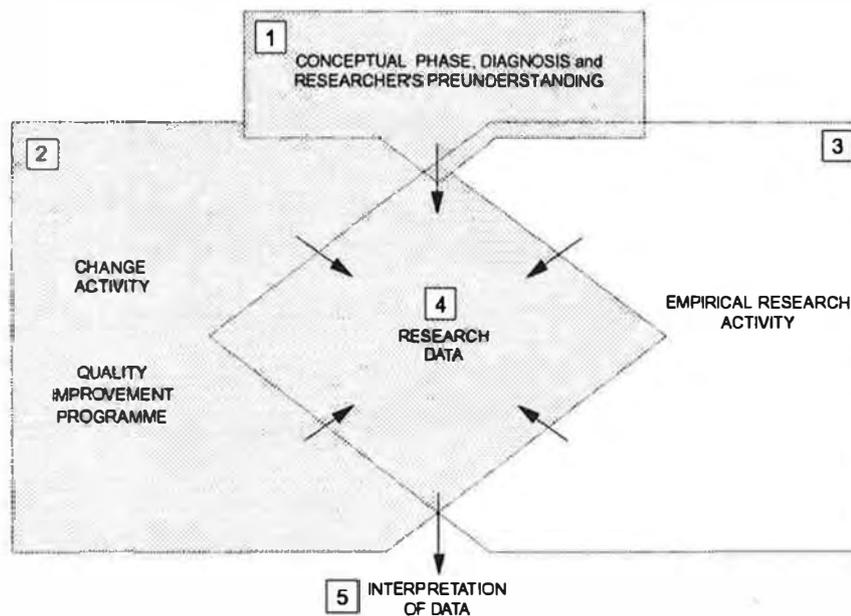
Before progressing with change activity it was the intention of the researcher to develop an in-depth understanding of the organisational context (history, development, organisation and operating structure and in particular, quality systems) in which that change would take place. It was necessary to have a clear understanding of the context in which change was expected to occur and how the variables of the context might affect the success change. Thus this chapter builds upon the researcher's prior knowledge of the organisation, considering its nature in some depth. In particular, the

95

reporting structure, the product and processes and the management of quality are considered. The discipline of Good Laboratory Practice is visited again as it represents the hub around which quality in the organisation has been understood and evolved.

Much of the background material formed part of the knowledge base of the researcher because of employment as a manager within BFL for over fifteen years. To provide rigour and objectivity and to avoid inadvertent bias resulting from over reliance upon the researcher's memory and historical perception, the researcher's view was consolidated by a diagnostic review of archive information from a variety of paper documentation including memoranda, management reports, company reports, scientific protocols, organisation charts and personnel records, combined with exploratory interviews.

The focus of the chapter is upon the systems in place to manage quality, the climate for change and introduction of TQM in the form of the Quality Improvement Programme (QIP).

Organisation of the Chapter

The sections in this Chapter are organised as follows:

5.1   Historical perspective of BFL

BFL was founded as a privately owned independent company in 1972 and had been purchased by a US company in 1976. In 1987 BFL and a USA sister company were launched as a single organisation on the US Stock Market. Services included biological safety testing of pharmaceuticals, biologicals and chemicals (including agrochemicals and food additives); clinical research and development of pharmaceuticals; management of agrochemical research and development; chemical risk assessment and risk management; and analytical laboratory services. Such services were provided under contract to clients in the pharmaceutical, agrochemical, biotechnology and general chemical industry throughout the world.

5.2   Organisation Structure

As discussed in Chapter 3, the organisation has many of the characteristics of a professional bureaucracy (see Mintzberg, 1983). The organisation's structure is a relatively simple functional hierarchy with up to ten levels of reporting depending upon detail of activity, range of staff skills, and size of the group. Essentially, employees are grouped by their specialism, their requirement to share resources and the extent of the desire to achieve a standardised output. However, the high degree of interdependencies of processes and knowledge between functional groups, particularly in the operational core of the company, resulted in an overlay of matrix reporting. Figure 5.1 a and b (overpage) show the organisation structure by function.

Over the timespan of this research, the organisation structure remained relatively stable with just one significant change. That was the creation, in 1991, of the Office of Research Liaison with, "*as its primary mission, the further improvement and marketing..... of the more fundamental aspect of (the company's) scientific expertise*". This office was headed by the ex-head of pathology. Pathology was split and became two distinct groups, (1) Pathology and (2) Histotechnology (Figure 5.1b).

Figure 5.1a   Organisation Structure - pre 1991

QUALITY ASSURANCE
SCIENTIFIC OPERATIONS
STRATEGIC PLANNING
FINANCE AND PURCHASING
RESOURCES AND ADMINISTRATION

QAU (21)   ARCHIVES (5)
BUSINESS DEVELOPMENT (9)
FINANCE (25)   PURCHASING (4)
PERSONNEL (17)   FACILITIES (28)   SECURITY (10)   ADMINISTRATION (18)

LEADING SCIENCE GROUPS

SUPPORT SCIENCE GROUPS

SHORT-TERM STUDIES
REPRODUCTIVE STUDIES
TOXICOLOGY AND ONCOLOGY
COMPUTING
PATHOLOGY
CHEMISTRY
ANIMAL MANAGEMENT

IMMUNOTOX (3)   AQUATIC TOX (8)   CELL BIOLOGY (13)   ACUTE TOX (6)

DEVELOPMENT (15)   DATA PROCESSING and STATISTICS (10)
PATHOLOGY (15)   HISTOLOGY
CHEMISTRY (32)   FORMULATION (46)
TECHNICAL DEVELOPMENT

PROJECT MNGT (48)
VETS (4)   CLINICAL PATHOLOGY (11)

HISTOLOGY (60)   NECROPSY (22)   ELECTRON MICROSCOPY (5)

ANIMAL TECHNICIANS
(21)   (36)   (38)   (35)   (18)

BEHAVIOURAL STUDY (4)   PROJECT MNGT (18)   NECROPSY & FOETAL EVALUATION (12)

( )   Figures in parenthesis indicate the number reporting through that line

Figure 5.1b Organisation structure - post 1991

RESEARCH LIAISON (3)

QUALITY ASSURANCE
- QAU (21)
- ARCHIVES (5)

SCIENTIFIC OPERATIONS

STRATEGIC PLANNING
- BUSINESS DEVELOPMENT (9)

FINANCE AND PURCHASING
- FINANCE (25)
- PURCHASING (4)

RESOURCES AND ADMINISTRATION
- PERSONNEL (17)
- FACILITIES (28)
- SECURITY (10)
- ADMINISTRATION (18)

LEADING SCIENCE GROUPS

SHORT-TERM STUDIES
- IMMUNOTOX (3)
- AQUATIC TOX (8)
- CELL BIOLOGY (13)
- ACUTE TOX (6)

REPRODUCTIVE STUDIES
- BEHAVIOURAL STUDY (4)
- PROJECT MNGT (18)
- NECROPSY & FOETAL EVALUATION (12)

TOXICOLOGY AND ONCOLOGY
- VETS (4)
- PROJECT MNGT (48)
- CLINICAL PATHOLOGY (11)

SUPPORT SCIENCE GROUPS

COMPUTING
- DEVELOPMENT (15)
- DATA PROCESSING and STATISTICS (10)

PATHOLOGY (15)

HISTOTECHNOLOGY
- HISTOLOGY (80)
- NECROPSY (22)
- ELECTRON MICROSCOPY (5)

CHEMISTRY
- CHEMISTRY (32)
- FORMULATION (48)

ANIMAL MANAGEMENT
- TECHNICAL DEVELOPMENT
- ANIMAL TECHNICIANS (21) (36) (38) (35) (18)

Changed positions

( ) Figures in parenthesis indicate the number reporting through that line

In explanation of Figure 5.1a and 5.1b, the "top manager" was the Managing Director. Reporting to the Managing Director were five senior managers responsible for Scientific Operations, Quality Assurance, Resources (personnel, security, facilities and administration), Finance, and Strategic Planning. This number was extended to six with the addition of the Office of Research Liaison.

The Director of Scientific Operations had two formal upward report lines; (1) the major grouping of Scientific Operations, which constitutes the major "production" entities of the organisation and (2) Business Development.

(1) *Scientific Operations:* There were three major categories of department that constituted this group:

a.) "Lead Science" : responsibility for project management providing the scientific expertise to design and direct projects and to provide the principal interface between clients (the *Sponsor*) and the company. At the time this research was conducted there were three such departments

1. Toxicology and Oncology
2. Reproductive Studies
3. Short term Studies

b.) "Support Scientific" : responsible for the provision of scientific and technical expertise and resource to conduct the laboratory aspects of projects. In general, the groups provide a service to the total company, from a central resource. The departments of Support Science are distinct in their range of activities. In this category are:

Chemistry

Formulation

Animal Management

Necropsy

Histology

Pathology

Electron Microscopy

Computer Science

The division between Leading Science and Supporting Science is neither

precise nor absolute. For historical reasons, pragmatism or operational convenience, a number of support activities are included in the reporting structure of the Lead Science Groups, and the chemistry department may function in a Lead or a Support capacity.

    c.) *Business Development*: The Sales and Marketing group. As a professional organisation, the operational groups, in particular those of the Lead Science departments, have a great deal to do with generating new business and obtaining repeat business. They work closely with the business development group in this respect.

(2) Quality Assurance: The Quality Assurance Group has a functional relationship with the scientific groups of the company. The existence of the department stems from the requirement for the company to conduct its work in compliance with Good Laboratory Practice. The importance placed on Quality Assurance as an independent activity is indicated by the reporting line of the Quality Assurance Manager directly to the Managing Director.

(3) Finance: Activities carried out by this group are those traditionally present in financial management and accounting and purchasing.

(4) Resources and Administration: This grouping, made up of personnel, security, facilities management and administration, provide centralised services and are responsible for maintenance of the site infrastructure. The group has some "production" duties, predominately in printing, binding and despatching of scientific reports.

(5) Strategic Planning: At the time of commencing this work, the position of Director of Strategic planning had just been established with the aim of conducting investigative assignments into matters that would effect the future development of the company.

(6) Research Liaison: The creation of this office, along with strategic planning, was indicative of upper management's desire to look to the strategies for the future, to take the company forward by increasing scientific status and expertise, and to further the company's interests in potential new ventures.

5.3 The company "product"

In Chapter 3 the nature of the product of a PSO was discussed in the context of the nature of toxicology and in respect of input and output characteristics. That description is expanded here by looking at the way the product is perceived by those who produce it, and discussing the dependencies between groups that are necessary to generate an output.

5.3.1 Managers perception of the "product"

At BFL, there was not full agreement on exactly what constituted the nature of the "product" of the company but neither was there conflict, rather a difference in scope. Interviews with managers provided definitions ranging from output of the specific activity conducted in a manager's area of responsibility to a holistic view of a total service. Most managers described the "product" in terms of the tangible output - an expert report, or a total service. The characteristics of the service were widely used to qualify the initial description. The following provide examples of responses :

"... we test new agrochemicals, pharmaceuticals, industrial chemicals in a variety of ways to be sure they are adequately safe to be sold. Our service, by and large, is to either design a testing program or follow one that's already been set up by our clients. We do the test, write the reports and produce them in a professional way such that they'll satisfy the regulatory authorities ..... Along the way, we provide the best possible advice." [L4]

"A high quality scientific service that satisfies the clients' requirements and those of the broader environment, in which I would include the regulators and the legislators.' [L17]

"We are selling an expertise. The communication of that expertise is the reports that we write for clients that require that service. In short we are selling a service to our clients...... You can't see the "product" only as the report because there are personal communications that happen all of the way through, right from the minute that the (marketing director) talks to the client and up to (the financial director) asking for payment after the final report. It's not just that narrow band of time whereby somebody despatches a report and it is responded to by the client." [L3]

5.3.2   Production responsibilities

In manufacturing industry it is relatively easy to describe the product as the tangible output of the manufacturing process - it is the product or range of products that are made to be sold to a customer. The majority of manufactured products are mass-produced to a consistent form - indeed, achieving consistency has been a primary objective of quality processes since the early days of mass production. Frequently a product is manufactured to a standard specification, and an example of that product can be examined by a potential customer before commitment to purchase is made.

The product of a Professional Scientific Organisation varies somewhat from the former model. First and foremost, the customer cannot examine an exact replication of the "product" that he will be getting. He certainly cannot be totally confident that the result for which he is looking (usually a clean bill of health for a new chemical) will be assured - thus the end product may well be what the customer needs, but not necessarily what was wanted. Secondly the organisation is selling its expertise. Although a tangible product can be identified, it is part of a wider provision of a total consultancy service. The tangible product is unique - a scientific report of findings related to a trial on a specified chemical produced by an expert for an individual customer. The report is a collection of data from work conducted by various disciplines within the organisation, with summary and discussion. The laboratory-based processes and techniques that generate data are generally conducted in real-time with little opportunity for rework of an activity should it fail. The tangible product of the report, a paper document, is supplemented by an intangible - an implicit quality standard that the report has to be acceptable to the regulatory authorities. The regulatory authorities, who will assess a product's suitability for release into the broader environment by review of the report to assure that testing requirements have been met and the data indicates that the product is "safe", may be regarded as the ultimate customer of the organisation.

A simplistic representation of the activity from demand to delivery of a report is provided in Figure 5.2 overpage

Figure 5.2 Simplified flow of events from demand to delivery

```
                            New product
                          developed by client
                             (Sponsor)
                                 |
                                 v
                           Request to CRO
                            to perform
          Feedback to agree  necessary testing
          work specification
                           CRO provides expert advice,
                           produces testing protocol
                                 |
                                 v
                         CRO appoints responsible scientist
                              (Study Director)
          Instruction
                   data                    Report produced
                                                |
          Laboratory work                       v
          conducted                     Report provided to Sponsor
                                                |
                                                v
                                       Sponsor submits report
                                       to regulatory authority
                                         for approval
```

Third, unlike manufacturing industry where the final product is generally finished in the production area, in a professional scientific organisation the final crafting of the tangible product occurs at high level. This is a consequence of peer review, whereby a senior scientist ultimately releases the "product" to the customer. The scientist with legal responsibility for the work (the Study Director) has the role of directing the project and co-ordinating activities of the contributing disciplines (see Appendix 3 - Summary of Principles and Requirements of Good Laboratory Practice)

The overall process at its least complex may take just a few months. Major projects frequently take two or more years to complete and final judgement on the product may not occur until several years later when it is reviewed by the regulatory authorities such as the US Food and Drug Agency (FDA).

The complexity of the processes, the fact that much of the work is (and can only be) conducted in real-time at a specified time point if it is to be valid, and the irreplaceable nature of materials or lost data combined with the potential impact of the end result on

society at large, call for stringent quality controls. The amount of data generated by the various disciplines and the number of handovers between disciplines provide plenty of opportunity for error and conversely, opportunities for performance improvement.

The final significant feature of the product of the company is the extent and degree of interaction between the customer and supplier. Many purchasers of the services of the company are themselves experts in the conduct of safety testing. They frequently wish to retain close contact with the progress of the work and may wish to input instructions and review findings as the programme of work progresses. The customer has opportunity to comment upon a draft of the final report and may request changes in, say, presentation style or format. Discussion and debate may occur over interpretation of findings. It is this interaction which provides some of the intangible elements of the company's product.

Figure 5.3 shows a simplified process drawing showing inputs and outputs of the "production" process. To avoid an over-complex representation, the figure presents only the major disciplines and the major information flows.

Figure 5.3 Schematic of production process
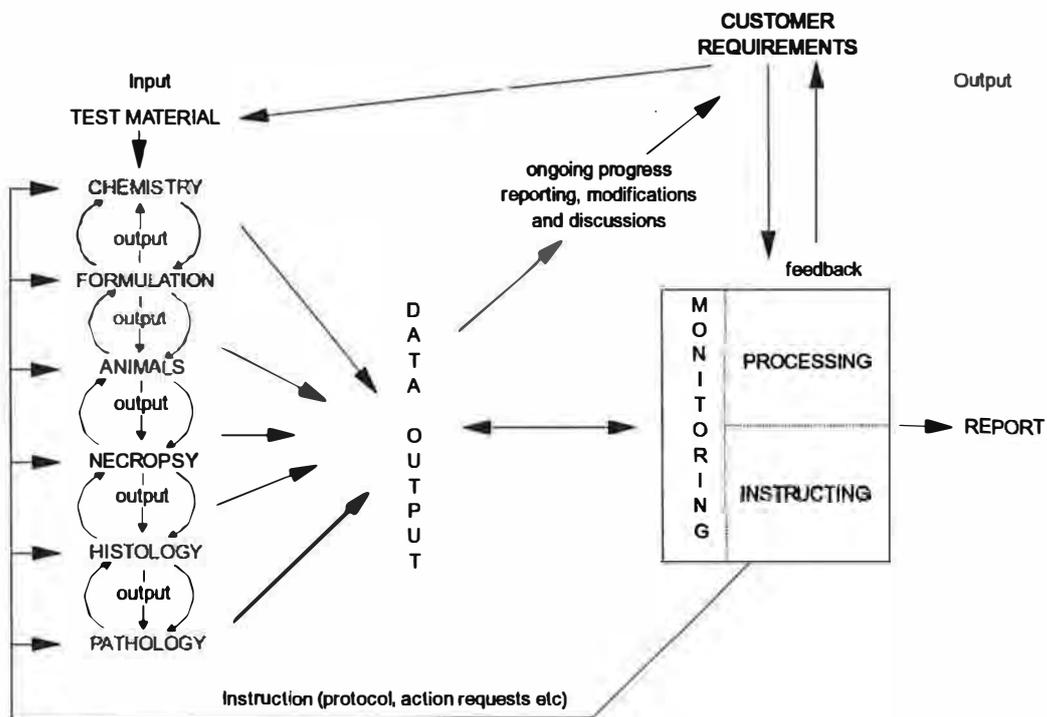
From the figure, it can be seen that the major input is the test material (the customer's product in need of testing) and the major output is the report. Groups on the left of the schematic are the scientific and technical departments (Support Science) that carry out the laboratory processes. The groups form a chain, with each link passing an output for use in the next activity in a predefined sequence. All links generate data for interpretation and inclusion in the final report. The direction, co-ordination, monitoring and interpretative elements of the process sit within the large box to the right. This box represents the "Lead Scientific" group where the responsible scientists (Study Directors), toxicologist and their support staff are located.

5.3.3 Responsibilities for quality in the production process

The overall process is subjected to scrutiny by a Quality Assurance Unit which audits outputs and individual processes. The systems and processes which must be in place to run a study in compliance with the principals of Good Laboratory Practice, and the responsibility for each aspect is shown in Table 5.4.

Table 5.4   Responsibility for Quality

Activity	Quality Assurance	Line Management	Individual worker	Study Director	Top Management
Assuring that a functioning Quality Assurance Unit is in place and operating	●				●
Agreeing specification with the customer (sponsor)				●	
Production of study plan (protocol)	○			●	
Assuring that studies are run in compliance with GLP	●		○	●	
Production of Standard Operating Procedures (SOPs)	●	●			
Management of SOPs	●	○			
Keeping management appraised of issues requiring attention	○	○			
Performing Inspections of procedures	●				
Assuring study design is appropriate	○			●	
Maintaining activities of QA activities and findings	●				
"Signing off" work as GLP compliant	●			●	
Checking completed work and work in progress		●	●	○	
Implementing corrective action	○	●	●	●	○
Improvement of procedures	input	●	●		

Activity	Quality Assurance	Line Management	Individual worker	Study Director	Top Management
Quality Control of procedures and data		○	●		
Planning and scheduling work		●	●	●	
Assuring that work is completed to time schedule		○	●	○	
Technical Quality of work		●	●	○	
Retention and storage of data	○	○	○	●	
Audit of complete study	●				
Inspection of suppliers of key products	●	○			
Quality checking of incoming product			●		
Maintaining communication with the sponsor	○	○		●	
Responding to sponsor complaints	○	○	input	●	○
Investigating technical/scientific problems		●	input	○	
Maintaining laboratory at appropriate standards		●	●		
Assuring adequate resources (staff and equipment)		●			●

Key: ● primary responsibility   ○ input/secondary responsibility

5.4 Management of Quality before implementation of the Quality Improvement Programme

5.4.1 Before Good Laboratory Practice

Between the founding of the company in 1972 and 1976 no formal mechanism for management of quality existed. At the time there was no demand for formal quality assurance systems. It was a time when the science of toxicology was still an emergent discipline in the UK and the accountability required of today's science was not established and Quality, as it is understood today, was not part of the language as noted in the following quotations:

> *"Quality, in respect of data quality was not part of our language at the time. Clients tended to judge laboratories according to their people rather than the product"[L1]*

> *"People's ideas of what constituted quality were very different then to what we consider it to be today. Quality, although the term was not really used, was to do with excellence of scientific interpretation and slick reports"[L21]*

Quality was achieved through the professional competence of the scientists and technicians - it was driven by their personal pride in their job, motivation to keep abreast of developments in the field, the need to operate at a level consistent with the state-of-the-art; these features were combined with a desire to feel that BFL was the "best in the business". The standard of work was dependent upon common sense, personal capabilities and motivation, peer pressure and supervisor requirements. Standard procedures were sometimes non-existent or informal, passed on by memorandum or word of mouth; organised training and assessment of competence were largely absent.

5.4.2 Good Laboratory Practice - the QA era

In 1977, Good Laboratory Practice was introduced (see Chapter 3), and formalised systems for quality assurance were implemented. The Quality Assurance function has since then, played the key role in assuring that work has been conducted in compliance with the principles of GLP. However, the focus of Quality Assurance is on compliance with the regulations and its role is to inspect, review and monitor work which will be submitted to the regulatory authorities for permission to market a product. The scope

of GLP, and thus the influence of the Quality Assurance Unit, had been confined to scientific operations. The QAU did not, for example, consider efficiency of practices or design of processes, nor did it cover the wider range of activities, outside of the scientific operations, required to operate an effective company.

With GLP came the need for more documentation, more standardisation of procedures, and increased checking of work. The Quality Assurance Unit was established as an independent department reporting directly to the Managing Director. QA staff had no line authority over the staff carrying out programmes of work. The role was essentially reporting and advisory; they carried out inspections of procedures and formally commented on whether or not a procedure had been conducted according to pertinent Standard Operating Procedures and in compliance with GLP. Where deficiencies were noted, the obligation to take corrective action lay with the line manager and/or the Study Director. The early days of GLP were characterised by imprecision - the concept of GLP was new to business and there was some uncertainty of exactly what was required.

> *"there were a lot of grey areas: the interpretation of GLP had not occurred consistently and there were a lot of questions. You had previously very much worked on common-sense and now rules were being put into place".* (L21)

Since the inception of GLP, the function of the Quality Assurance Unit has changed very little - indeed GLP *per se* has changed very little. Developments have predominantly occurred in the area of interpretation and clarification of the requirements. The Unit grew and systems were developed and refined but the focus, with the assurance of quality of the science and documentation thereof, remained much as it started in the late 1970s.

5.4.2.1 The impact of GLP on BFL

For contract research laboratories such as BFL, the increasing demand of government agencies to work to perform toxicological testing to GLP principles meant that they had to adopt GLP if they were to continue to exist in their established market sector. Many of their client companies from the pharmaceutical, agrochemical and industrial chemical companies intended to market their products globally and without proof of

GLP compliance, submissions to government agencies in the economically advanced countries would fail.

At the time, BFL was a young and rapidly growing company. The Principals of the company welcomed the introduction of GLP:

> *"The company's interests were favoured by GLP - we felt they would challenge the company and that was good. GLP was an unmitigated "good thing" because it gave us assurance that there was a chain of responsibility through from Local managers to the shareholders. We considered that when it was in place, everything that could be done to certify the veracity of the data, would be done. We saw no deficiencies in GLP that would mean that we would not wish to establish it throughout the company."* [L1]

It was not felt that having GLP in place would in itself provide any competitive advantage because the company already considered itself, and felt its clients recognised it, as market leader in the UK. According to the Deputy Director of the time

> *"We did not feel it (GLP) would give us an advantage over the competition because we were cocky enough to feel that we would exceed the competition whether or not GLP was in place"* [L1]

In 1976, whilst staff understood the reasons for the existence of GLP, initially enthusiasm for it was limited because few staff saw the need for it within the organisation. Staff projected a feeling of "it (fraud and malpractice) is not happening here" and "there is nothing wrong with the way we do things". However, as the understanding of the market implications became known, most staff readily embraced the principles.

At senior management level, there was a worry that staff would leave the company in search of a more stimulating environment:

> *"We worried that work would become humdrum because of the removal of individuality, random actions, intuitive or spontaneous action and experimentation and the use of checking and standardised paperwork"* [L1]

This worry proved to be largely unfounded because there was still ample space in the new systems to allow for scientists to apply their individual style of work. Thus most scientists and technicians introduced the changes perceiving them as:

> *"no change - we will continue to perform good science as we always have."*
> [L21]

Clients started to increase their interest in the way in which studies were conducted, often appointing "monitors" from their own staff to visit BFL to ensure that work was being conducted in an acceptable manner. In part, this increased involvement by the sponsor occurred in response to criticisms of the FDA that sponsors (clients) had not adequately monitored work or verified data performed by contract laboratories; sponsors wished to assure themselves of the veracity of data that would ultimately be included in their submission dossiers to regulatory agencies. The increased interaction between client and company provided an opportunity for the client to become increasingly aware of the value for money provided by BFL. Thus the client became able to differentiate levels of service provided by different laboratories through measures other than report.

> *"The frequency and number of visits didn't really change but the scope of the visits expanded - what visitors were interested in changed.... Prior to GLP when a client visited he tended to follow his speciality; if he had a background in clinical pathology, he'd look at the Clin Path. operation; if he was a clinician, he'd look at the animals; and if he was galemetrically aware, he might look at Pharmacy. (Visitors) went where they felt they had expertise. It was rare to get people who felt that they wanted to audit or even inspect - it was far more on the basis of discussions of the project progress in general terms. After GLP they had to be a lot more even-handed."* [L1]

Over the next ten years GLP compliance came to be considered as the cornerstone of quality and reliability. It was considered as the "passport" needed to gain entry to the market. The more level competitive platform had positive and negative implications for BFL. The base level at which laboratories were expected to operate was raised, thus reducing the differential between those previously at the lowest level and those who considered they had the highest standards such as BFL. In reality, the increasing visibility of BFL's work to its sponsors, combined with market pressures, meant that the laboratory worked harder at improving quality to build on and maintain a reputation for excellence in science.

BFL felt that market leadership resulted from the expertise of key staff, excellence of scientific interpretation and impeccable presentation of reports. It placed considerable emphasis on the professional conduct and expert knowledge of its scientists and aimed to provide a "Rolls Royce product" for which it felt that clients would pay a premium.

But whilst the company considered that it did much more than its competitors to satisfy its clients needs - this view was largely based upon anecdotal comment from sponsors and other external contacts and the fact that sponsors continued to place work with the company - it rarely looked in depth at how well, or by what means it achieved that point.

5.5 Management of Quality Systems before TQM

Table 5.5 (overpage) presents the management tools used to monitor effectiveness of the company and improve performance before the initiation of the Quality Improvement Programme; a full description of activities can be found in Appendix 5. Review of these activities and their output suggested that BFL was rich with activities targeted at improvement of many facets of activity. Most activity originated out of the need to improve performance and a desire to manage the company and its resources effectively. The guiding force and influences in the company lay in its management and committee structure. The hub of quality was the Quality Assurance Unit's activities focused on the scientific operations. Even before the development of a quality improvement programme, there is ample evidence (minutes of meetings, memoranda, reports of working parties) to suggest both local and central initiatives, outside the QA arena, intended to improve aspects of performance.

The emphasis on staff training and development was indicative of the organisation's desire to promote its professional image and the recognition that if staff were not capable, no amount of controls would deliver quality. The picture was of a company striving to progress by using the appropriate instrument available at the time. However, there had been problems; for example, the management of the company were conscious that high turnover of staff (19% pa in 1987) was damaging to stability, profitability and growth (operations and administration meeting minutes 1987-1989). Operational managers were conscious that technical errors often occurred because of inexperienced or undertrained staff. This situation had been exacerbated by the high turnover. Thus the response was to take on this challenge, understand the reasons for high turnover and act accordingly. Whilst centralised activity dominated, individual departments also developed their own initiatives to find solutions to problems within their areas.

Table 5.5   Management of Quality before QIP

Identity	
Committees and work groups	Management committees
	Ad hoc working parties
	Standardisation and simplification
	Quality Circles
Quality Assurance	Standard Operating Procedures
	QA audits
	Computer systems validation
	Peer Review
	Editing Panels
	Subcontractors and Suppliers
Quality Control	"product" checking
	Calibration
Records	Study documentation
	Central files
	Archives
Measures and metrics	Error Rate Analysis
	Error Reports - Quality Enhancement Notes
	Late reporting Performance Analysis
	Reports of staff turnover
	Appraisal
Information	Company Briefings
	QAU reports to management
	Sales Reports
	Management Information Systems
	Management accounts
Departmental development	Project based initiatives
Training, Education and development	Company and Department Induction Modules
	Scientific seminar groups
	Further Education

	Identity
	Scientific and technical training
	Training records
	Training Standards
	Management training
Project management	Study management
	Project coordination
Company ethos	Company Philosophy
	Suggestion Scheme

5.6   The Climate for Change

Throughout the company, many had a feeling of "if something needs to be done, we can get on and do it". Departments had considerable autonomy to manage as they felt appropriate for their function and staff profile, thus issues were often tackled locally with considerable enthusiasm and sometimes, self congratulation. However, this autonomy of action resulted in groups with their own agenda (which may or may not have been part of the total company strategy) working to locally defined goals.

The committee structure presented in Table 5.5 provided a forum for senior managers to present problems that they had identified in their areas but which might be of general interest, or might benefit from the input from other members. However, managers often preferred to report upon a *problem solved* unless the cause of the problem was perceived to be another group. In the latter case, tabling the issue frequently occurred at an early stage. The ACAS survey conducted in 1987 likened this phenomenon to warring "Clans and Chieftains" (ACAS, 1987).

The company had pulled itself out of the economic recession of the early 1980s. Staff reductions had occurred and in 1984, the company consolidated its operations to one location, disposing of the previous "headquarters". This brought into close working contact the staff of two sites, some of whom had conducted duplicate activities and some departments that had only existed at the closed location. The "merger" bought friction between groups that had previously "enjoyed" an unofficial competitive base.

116

The site merger caused a melting of the previous structure and hierarchy which gradually settled to its new form. As the business picture strengthened, the culture of the company shifted from one which had been dominated by a "task culture" to an increased "people" orientation. This change occurred partly in response to the need to recruit and retain effective staff; it was evidenced by the increasing focus of training and personal/career development, and the increased consideration of staff welfare issues. According to the Director this change was in line with his vision

> *"...... to become a respected part of the scientific community, with status deserved by those striving, through application of science, to make a contribution to society. I want us to be a place where people come, not just to earn, but because they can feel appreciated for what they give; so they can forward themselves at the same time as progressing the interests of the company"* [L1]

The change described above was not part of a planned company development strategy, rather, it was more of an evolutionary response to changing circumstances:

> *"In the early days when (the founder) asked me to join him in this new venture, it was literally a matter of living from hand to mouth. We just didn't know where the next penny was coming from - or if there'd be any money coming in. We did everything ourselves - I would even go down to the dog building and clean them out, take blood samples and just do whatever was necessary to get by. We didn't have time to think about the more exemplary practices of managers - we certainly couldn't afford for any of our few employees to take time out to further their education or to contemplate their navel. All that came far later as we became more prosperous. It wasn't that we didn't believe in treating people well, we just could not afford to do more than we did. We reasoned that staff would rather work their butts off and have a job than have all the luxuries of our client's companies and the high probability that we would fail to survive"*. [L1]

By the second half of 1980s, the company had moved to a position where it felt that it was trying to do the right things in respect of its staff but there was a growing concern of a minority of influential managers about the increasing amount of introspection perceived to be moving the focus from the core business. One senior manager(L4), recorded his observations thus:

> *".... there has been a significant shift in the company's attitudes and business style... these changes include but are not limited to:*
>
> - *a number of departments have recently introduced training officers or training programmes, and a further companywide induction/familiarisation programme is planned together with externally run leadership courses etc.*

117

- *career development and/or part time study have been given increased importance in several departments*
- *We have, over the past year, intentionally raised the company's profile in the local community*
- *because of the current "glut" of business and our frenetic level of operation, the wide involvement and zeal which previously characterised our marketing efforts has decreased*
- *the total time spent in internal meetings has increased greatly............*
- *contacts have been developed with (the local university), considerable effort has been put into organising the Diploma in Toxicology course, and we are developing other involvement outside the sphere of (our core business)*
- *when certain employee groups have been identified as "problem areas"(high staff turnover), special schemes have been introduced........*
- *The priority accorded to office space and furnishings have increased from a very low level to the far higher level exemplified by (the new building)*

.... many of these changes have been introduced to help our operations or have been forced upon us by operational constraints. I think it behoves us to step back from the pressing matters of everyday business to ask

- *do all of these changes characterise an* <u>*appropriate transition*</u> *from a small company to a big one?*
- *is there any danger that we are changing "the message" too fast or too radically so that staff see (education) as the only means to a valid career path, thus giving lower importance to practical experience and technical skills - the major contributors to work quality and efficiency?*
- *are we staying in shape for the next (inevitable) downturn in business?"*

The culture of the company, its position on the evolutionary growth projection from small to large company, the success factors and demands that prevailed at the time, were all influential factors in the decision to implement TQM in the form of a quality improvement programme (QIP), and the style of that programme.

5.6.1 The State of the Organisation - Summary

Table 5.6 summarises the state of BFL based upon observations and information gathering during the diagnostic phase of this case study.

Table 5.6   Summary of state of BFL

Category	State	Evidence source
Structure	Change of top management as outcome of Market flotation . New Managing Director - strong leadership. Traditional hierarchical organisation, published organisation charts, memorandum announcing staff changes and redefining structures. Stable senior management. Weakness: Inflexibility	Organisation charts, memorandum, observation, company reports
Strategy	Company sees itself as top of the market. No formal strategy to assure continuance in that position. No strategy planning for the future. Planning based around annual budget construction and pursuit of financial targets. Weakness: Shortfall in strategic planning.	Opscom minutes, anecdote, sales plan, memorandum
Staff	Dominant type is the cautious, conservative, dedicated scientist. Divisions in staff groupings - "graduates", "technicians" and "administration". Diversity of management styles and types. Weakness: poor cross functional co-operation High level of inexperience	Observation, Opscom minutes, ACAS report, staff turnover records
Skills	Highly qualified individuals with specialist capability for their discipline. Skills development important Weakness - minimal business and management	Personnel records, training records, memorandum, meeting minutes
Systems and processes	Strong on systems and paperwork. Plenty of mobility of hardcopy but moving towards electronic management information systems. Strong on meetings - short on useful output of meetings. Weakness: a) over-complex systems prone to error. b) late reports c) handovers between functions	Internal reports, Standard Operating procedures, Staff handbook, committee minutes, QA audits, QA inspection reports, working group minutes
Customers	External - no recognition of concept of internal customers	Observation
Quality	Strong QA and QC. Added on rather than managed in. Tendency to "after the fact" checking. Good documentation. Response to error is to add more checks. Quality principally associated with core scientific activities	QA systems documentation, error reports, SOPs, sponsor audits, DoH audits

Category	State	Evidence source
Culture (style and shared values)	Professional and confident - sometimes high handed. Reactive firefighters. Fairly open society - equality of opportunity. "Company Philosophy" declares desired values. Loyalty to department stronger than loyalty to company. Moving from "task" culture to "people" culture	Observation, written correspondence, committee minutes, Staff handbook, briefing notes
Resources	Activity at frenetic level. Expansion of staff number hindered by recruitment lag time. Resources (space, equipment and people) are limiting factors to the ability to start projects.	Planning charts, occupancy charts, management accounts, MIS output, memorandum, minutes of meetings, Staff Liaison Committee minutes
Competition	No organised market intelligence. Intelligence gathering through chance, competitions published material. Competition felt to be increasing. Exchange rates (Japanese Yen) and increasing competence to conduct toxicology in Japan is leading to shrinkage of major market.	Anecdote, sales reports, competitor files, committee minutes, observation, sales brochures, advertisements, staff recruitment advertisements, newsletter, conference papers and customer anecdote etc.
Business performance	Strong performance. Selling to capacity at premium price	Management accounts, company reports, sales reports

5.7   Background to the decision to introduce Total Quality Management

Good Laboratory Practice had provided a vehicle for the company to cover a considerable distance in terms of the quality of scientific service; it had been the primary motivator in the development of a strong quality ethic in a scientific environment. Yet there were problems with scientific and technical error and in particular, whilst the final standard of BFL reports may have been excellent, they were frequently presented to the sponsor considerably later than scheduled. There was minimal formal quantification of error such that each occurrence was addressed as a one-off. The cost of failure tended to be viewed as the cost of the materials required to repeat work free of charge. However, the somewhat subjective feeling was that systems were critically near to breaking and appeared inadequate to prevent repeated adverse events.

A memorandum to senior managers (Managing Director [L1] 1986), commenting on *"adverse occurrences"* over the preceding 10 months, surmised that contributing factors to these could include

> *"inadequate training, inadequate supervision, inadequate briefing or instruction (internally), inadequate communication externally, over-elaborate systems, records or instruction, boredom, or inadequate time allowed".*

However, in spite of these observations, the attitude persisted that the science conducted by BFL was excellent; there *were* errors but this was no different from any other laboratory and even if a customer was lost, it would be a temporary situation as they would eventually return. The frenetic level of work at the time and projected into the future provided a potentially false level of confidence in respect of continued customer loyalty.

In 1987 a corporate decision was made that the company needed to take positive action to improve its products and services. This decision was taken in an environment that was becoming increasingly competitive and at a time of vigorous growth, and against a background of deepening regulatory audit control. At the same time intelligence was gathering on the increasing Japanese investment into their own toxicological resource. This was particularly significant because around forty percent of the company's revenue accrued from the Japanese market and increasing expertise in Japan, which had so far

relied upon the expertise of western laboratories for toxicology services, threatened BFL's principal sources of income.

The Managing Director and Head of Quality Assurance introduced the notion to the company that Total Quality Management represented an "initiative" that could support future development and enhance the competitiveness of the company. At this time TQM was a relatively recent arrival in the UK; managers viewed it as a novel concept of which the majority had no knowledge and thus no prejudice or preconceived view of its potential. Working with an external consultant, a short presentation on the philosophy and methods of TQM was delivered to senior managers in June 1987. Enthusiasm of managers was limited but sufficient to continue the initiative.

To take the project onto the next stage a weekend workshop was attended by the Managing Director and eleven senior managers. The objective was to build upon the earlier presentation and provide an understanding of the framework of the TQM programme that might be implemented by the company. The "style" of TQM presented to the group was biased to manufacturing industry and used slogan and exhortation. It was highly structured, characterised by heavy reliance upon commitment through companywide orchestrated training programmes. Prominence was placed upon the creation of a superstructure of committees to manage the quality systems, motivate people towards the objective, identify problems and monitor progress.

The approach was regarded by those who would have to implement it as demanding of excessive resources, far too inflexible and without consideration of the existing management structures. Resistance of a high proportion of the group to take on board the concepts, combined with significant reservations about the proposed framework for implementation and the relevance of TQM to a contract research organisation, led the workshop to stall ahead of time.

The group accepted that there was a need to improve the quality of BFL's service, but expressed doubts about the justification to expend the resource required, and the failure

to build upon the existing structures and initiatives (see Table 5.5). The managers felt that the consultant had failed to grasp the subtle differences between the approach to delivery of a product taken by a professional service company to that of a mass production industry. According to notes made at the time, reservations about moving forward with the consultant rested on the following arguments:

1. *BFL would not be well served by "off-the-peg" quality improvement methods which had been developed around the circumstances of a manufacturing industry*

2. *No outside expert knows the business as well as those working within the organisation*

3. *The nature of the business (toxicology) is sufficiently different from that of other businesses which had adopted Total Quality Management to leave major doubt as to whether any outside approach could properly suit the needs of the company*

4. *Scientists are trained to the knowledge that error is always present and that it can only be minimised (never banished)*

5. *Scientists are trained to regard rhetoric, propaganda and slogans as suspect; that is not to say that they are too high minded to use such techniques on others, but merely that they recognise them when they are exercised on them.*

6. *The BFL resource was inadequate. The shortfall in staff numbers and the heavy demand on time would have constituted an intolerable burden.*

The concluding notes (Notes on Total Quality Seminar, 1988) recorded after the weekend workshop stated:

"The overall conclusion was that the company was not in a position to proceed with a "Total Quality" programme, partly through lack of staff resource at present, partly because of the feeling that its applicability and value to BFL and the type of work that we do had not been adequately demonstrated.

It was agreed that there was value in attempting to achieve greater quality and that we would investigate ways and means of achieving this within available resources and more in keeping with our culture. If and when a TQP were initiated, it should be more tailored to our requirements than the scheme offered by (the consultant)".

123

Overall, the forces for moving forward proved to be stronger than those restraining movement in that direction (Figure 5.7 below).

Figure 5.7   Force field analysis. Driving and restraining forces affecting decision to implement TQM
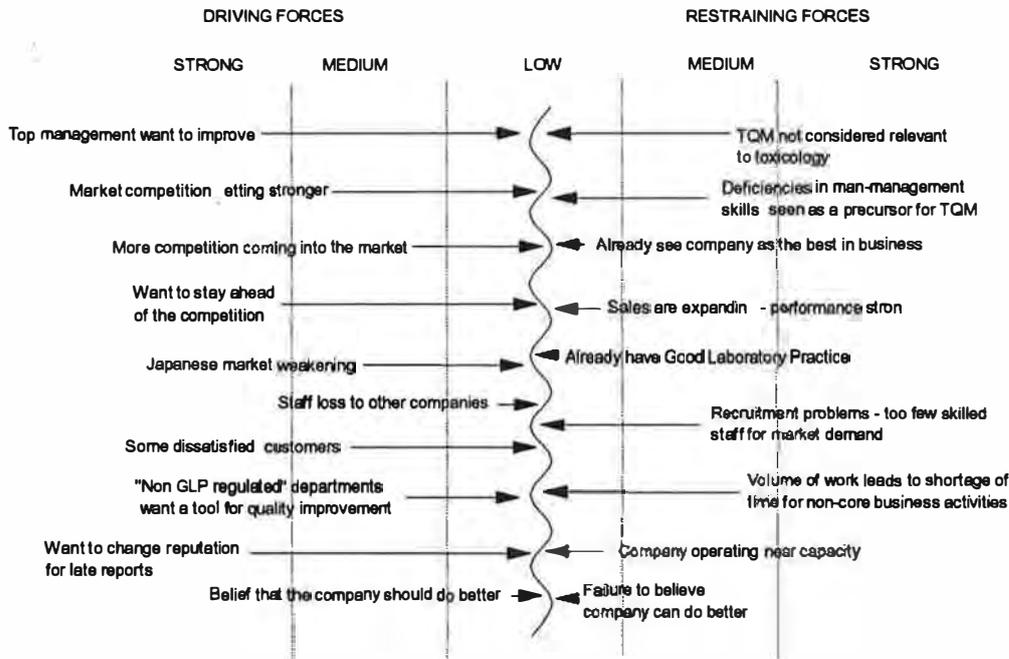
Note on figure 5.7 The data presented above was derived from multiple sources, predominantly from discussion at committee meetings, meeting minutes, participant observation and internal reports. The position on the scale from low to strong occurs for each force, is a matter of the researcher estimation of the relative strength of each view and/ or frequency of comment upon the issue.

Observation suggested that the strongest forces were internally generated with particular weighting placed on the desire of top management to see some form of quality improvement programme implemented. This was consistent with past behaviour of the company whereby the desire and actions to improve performance frequently originated internally, either from the departments themselves or at the behest of top management. The Head of Quality Assurance made the following observation

> *"Between 1983 and 1987 we were amongst the best in terms of all things. We had the best facilities, staff, systems and product (with the exception of late reports, which, at the time we didn't see in the same negative light as we see it today). Improvement was borne out of internal rather than external pressures. The "error report" was an example of an internal pressure. (The*

124

Managing Director) wanted it to provide information about our performance - a measure, a quality improvement tool and not a big stick as it was perceived." [L21]

The most significant of the restraining forces was the issue of resources, principally shortage of experienced staff to manage the work volume. The classical dilemma existed - managers spent much time fire-fighting and problem solving thus had little time for proactive planning and organisation such as focus upon staff development and problem prevention. Thus the turnover of staff remained too high, recruitment lagged behind and more problems than desirable occurred. Managers were conscious that systems were near to a crisis point and the quality of work was in jeopardy. At the same time, staffing inadequacies, mainly numbers shortfall and inexperience, served as a vector to highlight inadequacies in cross-departmental co-operation, planning and organisation. It appeared to many, that without remedial action, the quality of work which was already affected, would suffer further. Over page (Table 5.8) are extracts from the meeting notes of the Operations Committee which show a rising level of frenetic activity the time leading up to and just after the weekend workshop

Table 5.8   Extracts from Operations Committee Highlights

Month	*Extract of note made after meeting.*
August	Most departments flat out, at capacity. Numerous vacancies. Graduate-plus level hard to fill.
September	Most departments flat out. Technicians hard to find. Having to lower standards for recruits. Rooms full to capacity.
October	Frantic all round. Necropsies late and prolonged (staff shortage), ANMAN full (recruitment continues). HISTO are 15,000 tissues behind. QAU not receiving report on schedule. Archives bulging - data for archiving often not sorted.
November	All frantic. Short term study starts delayed. Some 30 late reports in Toxicology (awaiting edit). QAU report review backlog improving (because of delays in Tox?) REPRO studies can't start until mid 1988. Massive workloads predicted in Pharmacy and chemistry. Recruitment continues. Overtime excessive.
December	All busy. TOX report delays reflected in trickle to QAU who then may not cope with the flood to follow. Protocol production delays. Necropsy very busy. HISTO 2,000 animals behind - need 3 months overtime to catch up. Lots of recruitment activity but losing as well as gaining staff.
January	STSG - report backlog growing. REPRO full to crisis point. METAB deluged with work (potential clashes over space). ANMAN workload intolerable: double booking of space, overbooking of resource. "Planning" is reactive; quality in danger. Lots of overtime to avoid delays. Availability of CHEM resource affecting timing of work. Excruciating pressure on study starts. Inadequate communication, no protocols, no warning, maxi workloads (ANMAN, PHARM); Increasing workloads vs. unformed management skills in unit leaders (PATH)

Department Abbreviations: ANMAN - Animal Management; CHEM - Chemistry; TOX - Toxicology and Oncology; PATH - Pathology; HISTO - Histology; REPRO - Reproductive studies; METAB - metabolism studies; STSG - Short term studies group; QAU - Quality Assurance

5.8 Taking the decision to implement Total Quality

The company arrived at the point where the decision was taken to implement a programme of quality improvement. That programme would be internally devised and led and would be designed to take into consideration the nature of the work environment, the resources, and culture of the company. This situation provided an interesting and unique opportunity for the co-development of a research project based upon an understanding of factors that affect implementation of TQM in a contract research environment. (see Figure 5.1).

The broad framework of phases of the quality improvement programme (QIP) was developed at the outset of the project (Table 5.9). At this early stage of the project there was not a consistent view of the scope of the programme. The company had decided that it did not want to implement a "TQM" programme. It was not the concepts or underpinning philosophy of TQM that had been rejected, rather the particular approach of the *one* consultant to TQM. QIP was one of a continuum of TQM forms - it shared many of the tools and characteristics of the "traditional approach". It was a programme based on home-grown methodology under the belief that this would create ownership and be more acceptable than an alternative "off the shelf" offering: The programme was:

> devised and presented using the language of the company.
>
> developed with the resources of the company in mind
>
> facilitated by one *of* the company who understood the company.

Thus the point of departure from the "traditional form" was that the managers believed it to be appropriate. The same approach was reported by Oakland (1994) in respect of implementation of TQM at the Esso Research Centre in a research and development environment.

QIP was devised to have the following features and characteristics:

1   **Subtlety**: Spreading ripples rather than a "Big Bang" - "the way we think around here".

2   **Sophistication**: Professional productions rather than American style razzmatazz. This was a rejection of the flag waving practices common to TQM programmes at the time and such events as "family days" and "celebrations of success" - "the way we do things around here".

3   **Gradual Development**: Oak trees from acorns rather than fast growth Leylandii. The belief was that gradual incremental progression was more achievable than breakthrough (Juran) style change.

4   **Realistic**: Project by project rather than attempting to solve all problems at once. This goal respected the shortage of resources and conflicting demands upon time.

5   **Training**: Focus on management and supervisory skills as well as scientific and technical skills.

6   **Feedback**: Measurements to demonstrate achievement and improvement trends

7   **Flexibility**: There would not be a rigid structure prescribed by events placed and a time line. If the programme needed modification because for example, changes in priorities or lessons learnt, then modification would be possible.

8   **Use of existing forums**: The Operations and Administration committees would be the principal monitoring and steering groups. No separate "umbrella superstructure" would be set up thus there would be no duplication of effort, fewer resources required and the two committees would simply include monitoring of QIP within their agendas and schedule of meetings.

9   **Freedom**: for departments to develop their own initiatives, identify priorities and respond in a way that suits their function. This allowed those departments

who already had quality enhancing initiatives in place to build upon those rather than starting afresh.

10 **Dispersal**: Minimal centralised co-ordination and added paperwork - reflecting the often stated desire to avoid bureaucracy and put back the onus for action upon departmental managers.

11 **Involvement**: Supported from top down. Involvement of all functions of the company. Managers were expected to ensure participation of their staff.

12 **Quality Assurance**: The function continues to assure GLP compliance.

Figure 5.9 shows the formally stated activities that formed the framework for the implementation of the programme:

Table 5.9   Phases of the Quality Improvement Programme

	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
PHASE I : MANAGEMENT DETERMINATION																
Diagnosing the current situation; demonstrating the need for Quality Improvement	●	●	●	●												
Evaluating the Quality Management options		○	●	●												
Agreeing on the style and culture of the Quality Improvement Programme				●												
Defining the goals and objectives					●											
Estimating the costs of the programme		○				○				○				○		
Gaining Management commitment		○	○	●	●	○										
PHASE II : EDUCATION AND AWARENESS																
Communicate objectives Companywide					●	●	●	●								
Bring QIP into visibility. Develop Quality awareness		○	○	○	●	●	●	●	●	●	●	●	●	●	●	●
Commence Quality-orientated training	○	○	○	○	○	●	●	●	●	○	○	○	○	○	○	○
Focus the whole company on 'customer needs'					○	○	●	●	●	●	●	●	●	●	●	●
PHASE III : PREPARING FOR ACTION																
Identify and agree 'quality indicators' in all sections of the company				○	●											
Define and agree targets and standards					●	●	●	●								
Prepare and introduce the 'tools' for reporting and feedback				○	●	●										
Communicate the details of activities companywide					●	●			●				●			
PHASE IV : ACTION AND REVIEW																
Tackle real quality problems	○	○	○	○	○	○	○	○	●	●	●	●	●	●	●	●
Measure progress against targets and standards. Review and renew targets	○	○	○	○	○	●	●	●	●	●	●	●	●	●	●	●
Review and improve systems. Simplification and standardisation	○	○	○	○	○	○	●	●	●	●	●	●	●	●	●	●
Form 'quality action' groups. Encourage self-direction					○	○	○	○	○	○	○	○	○	○	○	○
Train and educate: Improve scientific and technical skills	○	○	○	○	○	●	●	●	●	○	○	○	○	○	○	○
Improve 'human' skills					○	○	○	○	○	●	●	●	●	●	●	●
Improve training skills					●	●	●	●					○			
Reduce quality control: encourage individual responsibility for 'getting it right first time'													●	●	●	●
Provide feedback: communicate success companywide					○	●	●	●	●	●	●	●	●	●	●	●
Communicate successes externally									○	○	●	●	●	●	●	●
Review achievement of total programme and modify as necessary					●		○		●		○		●		○	

Activity level   ● High Profile   ○ Low key

5.9   Launch and implementation of QIP

A memorandum to all staff from the Managing Director, announcing QIP, served as demonstration of his support for the programme, described it in the context of other activities, and put around it defined boundaries.

> *" The first phase of the programme involves making us all aware of the benefits of quality culture. In the second phase we shall define the mechanisms for fostering quality and identifying appropriate targets. Existing initiatives in the field of quality enhancement will not be set back or abolished by the programme : rather we shall seek to improve, intensify and disseminate our currently somewhat localised efforts. A later phase will introduce simple monitoring methods and refinement of earlier concepts. These phases will inevitably overlap, proceeding at different rates in different departments. Indeed this note is not intended to announce a point of departure, but to define our position after three years of progress along a seven year pathway."*

Implementation broadly followed the phases indicated in Table 5.9. Earliest activity was focused upon heightening awareness of senior managers to impact of quality failure within the company and quality enhancement concepts and tools. This activity was supplemented by departmental seminars and by inclusion, within the modular induction training scheme (see Table 5.5) of a standard presentation on quality. The objective was to bring the issue of quality enhancement into everyday language of the company without the use of high profile publicity which, it was thought, might make staff sceptical of the programme and its intentions. It was intended to develop frequent low level exposure to the ideas. Throughout, a strong emphasis was placed on the notion of the internal customer and the need to move away from the dominating fire-fighting mindset.

The only centrally originated outward visible sign of QIP was the adoption of a quality logo based on the existing logo of the company. This logo was to be used on internal communications relating to any aspect of quality enhancement.

A "Central Core", the researcher and the Associate Director of Scientific Operations, provided a pool of expertise by way of facilitation, training, organisation, advice and support.

131

Outside QIP but working towards the objective of improving "human skills" a series of supervisory and management workshops were developed for all staff holding or aspiring to supervisory positions. Amongst other supervisory/management skills, these workshops were intended to provide the skills required to enhance the quality of supervision, motivation, instruction and feedback - the skills considered imperative to have a positive influence upon staff development and attitude, thus quality.

CHAPTER 6
METHODOLOGY OVERVIEW

Introduction to chapter

This Chapter provides an overview of the methodology selected for this research. Action Research, the framework for this research is described and justified. The relationship between the researcher and the subject organisations of this research are discussed in the context of the chosen methodology. The methods used for facilitating organisational change and the techniques used to measure it are described. Finally, the methodological implications for researchers-as-employees conducting inquiry in a directly competing organisation are considered.

Organisation of Chapter

The sections in the chapter are organised as follows

134

6.1   Basis of method selection and broad research strategy

Companywide quality improvement (TQM), the subject of this research, required that change took place within a client organisation (the client-system) BioFarm Laboratories. This change was intended to effect the broad outcome of an improvement in the quality of the "product" of the organisation. The change strategy was the development and implementation of a programme of quality improvement (QIP) suited to the culture and business environment of a contract research organisation.

The Action Research approach, the philosophical basis of which is discussed later in this chapter, was selected because it was considered that it would meet the dual aims of both facilitating that change and thereby solving an organisation problem of less than optimal quality, and provide deep insight and understanding into factors that influenced the nature and extent of that change, thus making a contribution to learning. A methodology was required that provided sufficient scope to investigate effects of the change on an organisation wide basis. It was considered that action research was well suited because it could provide

breadth : the "problem" was companywide and required a solution with equal scope

depth : the nature of the research was holistic yet it was felt that learning would come from in-depth study of some aspects of change within the broader organisational context.

time : the observable or affects of change were not expected to be immediate thus the research was envisaged as a long-term commitment with longitudinal monitoring of the effects of change

involvement : the research activities were to be primarily guided by the needs of the organisation and close collaboration was required to avoid goal conflict. The researcher needed to be immersed within the organisation and to facilitate and experience some of the situations to be studied.

In addition, because of the single organisation nature of the primary research, the methodology had to address the need for generalisation of findings. When the research was originally formulated, it was intended to conduct an in-depth inquiry in the client

organisation and to use two other similar organisations to corroborate findings. However, there was a failure to gain access to one of the two organisations. Consequently the broad framework of this research consists of an action research programme, pluralist in method selection, in the principal client organisation and an investigation in a second "matched" organisation. This would obtain new data, compare data and build upon the understanding of initial findings. Figure 6.1 presents the broad research framework diagramatically.

Figure 6.1 Research Framework
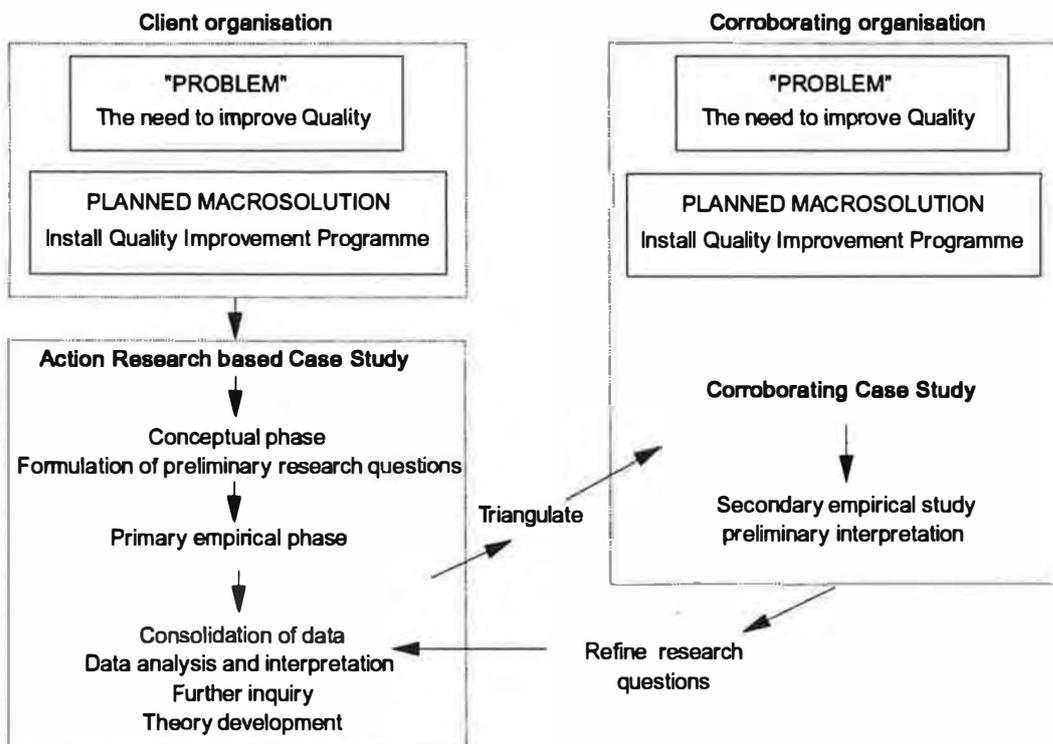
During development of the research strategy, use was made of the special understanding, insights and experience that the researcher had of the organisation, its culture and the broad nature of the change required. This "preunderstanding" as it is termed by Gummerson (1991), allowed the researcher to move directly into "action" rather than first spending considerable time gaining familiarity with the organisation and gathering basic information, as an external researcher would have needed to do. Gummerson sees preunderstanding as wider than just knowledge. It implies a certain attitude and commitment on the part of the researcher and involves their personal

experience as an essential element in the process of collecting and analysing information.

As an "insider", certain opportunities of access that would not be accessible to an "outsider" were available. Conversely, it was recognised that there were also areas and activities to which access might be barred because of the position that the researcher held within the organisation, politics or prejudice. Access by an independent researcher to the inner workings of a biomedical contract research organisation is unusual because the confidential and controversial nature of the work conducted tends to discourage such organisations from "opening their doors", thus the unique characteristics of such organisations have not been the subject of research.

6.2   The Action Research Framework

Before progressing to the various methods and techniques employed under the broader framework, the general nature of action research is considered.

The practice of action research is a good deal older than the term itself. It is considered that Mayo's research at the Hawthorne plant of Western Electric in the late 1920s and early 1930s and the work of Taylor at the Bethlehem steel works had most of the traits that are said to be the characteristics of action research (Warmington, 1980). These experiments occurred in organisations which were concerned with finding practical solutions to practical problems. They were long-term with the researchers devising new methods as they went along. The complexities of organisations, and the holistic nature of many of the changes desired within them, makes action research an appropriate strategy to study such changes.

Definitions of action research differ somewhat between authors. Kurt Lewin (1947) is generally given credit for being the first self conscious action researcher; he did not attempt any full definition of the term but did use phrases such as *"problem centred research"* and *"a research programme within an organisation whose progress is guided by the needs of the organisation."* As defined by Brown and McIntyre (1981) action research is *"where the emphasis is on the researcher's role as an actor in a*

structure which he is endeavouring to improve" (Brown and McIntyre,1981: 244) The best known and most widely used definition of action research is that published by Rapoport (1970: 499). He presents it as *"research which aims to contribute both to practical concerns of people (including people in organisations) and to the goals of social science, via joint collaboration within a mutually acceptable ethical framework. It is characterised by*

1. *The immediacy of the researcher's involvement in the action*

2. *The intention of both parties to be involved in the change*

Warmington (1980: 25) sees Rapoport's definition as incomplete. He places emphasis on the need for a clear conceptual framework and asserts the critical need for collaboration between researcher and the client throughout the process. He proposes that Rapoport's definition would benefit from the addition of *"Action research must have a clear conceptual framework which is acceptable to the researcher and which may have to be imposed on the research on the initiative of the researcher himself"*. He contends that without such a framework, the whole of the research is necessarily at risk and could be reduced to processes of manoeuvring, experimentation or confrontation unrelated to any clearly defined endpoint. He proposes the model presented in Figure 6.2 below:

Figure 6.2   The Action Research Process (Warmington)
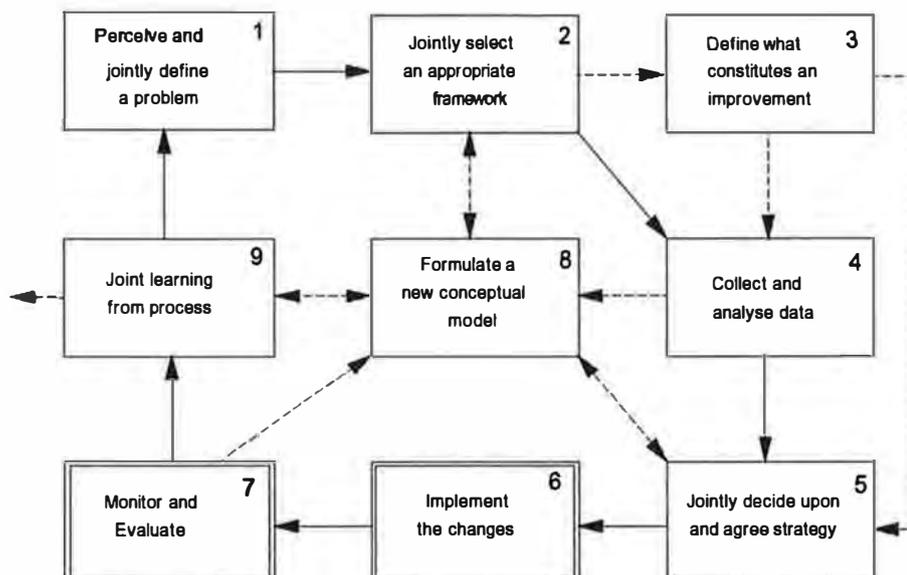
In his support and explanation of the model, Warmington emphasises certain traits, characteristics and dilemmas of action research. The key elements are the need for a holistic framework (box 2), the complexity of gathering appropriate types and depth of data in organisations unused to this demand (box 4), and the critical nature of collaboration throughout of the whole of the process, in particular agreeing the framework and strategies of intervention (box 5).

Action research has received its share of criticism, especially from those of the positivist persuasion who see its application to the conduct of "good" science as deficient in many respects. Seashore (1976; 103) believes there is "*a degree of inherent incompatibility between action and research*" in the sense that maximising one tends to minimise the other; Foster (1972; 529) noted that those involved in action research are "*either doing research with little action or action with little research*" and Argyris et al (1985) suggest the term *action science* is preferable to action research for the following reasons. Firstly, projects that have been labelled action research have sometimes not fulfilled the requirements for scientific research, often coming closer to journalism. Secondly, action researchers often limit themselves to the use of traditional methodology that stems from the positivist paradigm. The basis of Foster's criticism relates to two issues, 1) the dilemma of role-conflict between the researcher and the client organisation, and 2) the selection of observation techniques regarded as lacking in rigour when judged against the criteria of positivist science. However, as pointed out by Susman and Evered (1978), action research is bound to be found wanting if measured against the criteria of positivist science, whereas it is perfectly justifiable from the viewpoint of other philosophies such as phenomenology.

Action research has its advocates, in particular those who see positivist science as an incomplete methodology for organisational research, measuring the impact of intervention, and particularly for organisational problem solving (Clarke, 1976; Susman and Evered, 1978; Cherns *et al*, 1976; Warmington, 1980; and others).

The philosophical basis of action research is that it uses "grounded theory" as opposed to "grand theory" thus placing value on subjective data such as anecdotes and admitting

for interpretation, data from a wide range of techniques. It is strongly influenced by phenomenology and the hermeneutic paradigm (Gummerson, 1991) thus placing value on the researcher as a participant in the process of trying to understand reality. It is the immediacy of the researcher's involvement in the process that provides the major divergence from the positivist paradigm (Rapoport,1970). Inevitably, the interactive nature means that there will be some effect on the client organisation (Gummerson, 1991) - indeed it is that combined with the intent to make a contribution to science, that is the raison d'être of the strategy.

Figure 6.3 outlines the major differences between action research and scientific research based upon the descriptions of Gummerson (1991), Pedlar(1987) and Susman and Evered (1978).

Figure 6.3   Major differences between scientific research and action research

Scientific Research (positivist)	**Action research** (hermeneutic)
Positivist science, "Grand" theory	Generates theory "grounded in action"
Well defined, narrow studies	Narrow as well as total studies (holistic)
Broad, universal and free of context. Aims to be a basis for generalisation	Narrow, situational and bound by context. Can be difficult to generalise
Starts from theory.	Starts from experience of the data.
Requires logic and reason. Researchers seek to maintain a clear distinction between facts and value judgements: they search for objectivity.	Gives credit to feelings and emotions. Distinction between facts and value judgement is less clear; recognition of subjectivity.
Has clearly stated hypotheses and objectives. sampling frames and research methods etc. Thought is governed by explicitly stated theories and hypotheses	Often has vaguely stated areas of research. Hypothesis may develop from it. Researcher's attention is less focused and allowed to float more widely
Assumes that the natural science model of research is appropriate for the social sciences	Sees "scientific " frame of reference as necessary but not sufficient

Scientific Research (positivist)	**Action research** (hermeneutic)
Exists independently of human beings Researchers are detached they maintain a distance between themselves and the object of their research. They take on the role of the external observer	Exists integrally with human systems Both distance and commitment; researchers are actors who also want to experience what they are studying from the inside
Observation of the present	Observation of present plus interpretation of present from knowledge of the past. Preunderstanding that often cannot be articulated in words or is not entirely conscious (tacit knowledge) takes on an important role
Characterised by certainty, tidiness and fixed time periods	Characterised by uncertainty, untidiness and ongoing nature
Prime importance is assigned to methodology. tends to be one "right way" of doing research. Statistics and mathematical techniques for processing of quantitative data are central	Data are primarily non quantitative. Uses methodology where it seems relevant and develops alternative methods where suitable methods are not available
Regards methods as value neutral. Researchers try to be emotionally neutral and make a clear distinction between reason and feeling	Methods are used to develop social systems and release human potential.
Uses narrow range of research techniques. Research concentrates on description and explanation	Uses wide range of techniques. Research concentrates on understanding and interpretation
Requires logical consistency and controls for results confirmation. The emphasis is on following the original proposal to fruition	Evaluates whether actions produce desired consequences and emphasis on research as exploration allowing that direction may change unpredictably during the research process
Conservative: stems from static views of that which now exists	Radical: builds new views to explain and predict
Researchers discover an object of research external to themselves rather than creating the actual object of the study	Researchers partially create what they study, for eg, the meaning of a process or document

Gummerson (1991) has provided a useful synthesis of the literature on action research biased towards the organisational and management research. This has provided a useful reference for this work.

Insofar as the framework for this work was developed, the extent and nature of intervention had to be agreed between the researcher and the organisation at the conceptual stage of the strategy. Consideration had to be given to such constraints as the *actual* permitted depth of access to information and local improvement goals. The relationship between the organisation members and the researcher-as-an-employee carrying out both research and operational duties was a sensitive issue that had to be considered. The researcher's own philosophical preference leans towards the hermeneutic persuasion with considerable value placed upon the contribution of observation and an understanding of situations in context to interpret events and individual actions. However, in this project, the data gathering processes and techniques are a mixture of qualitative and quantitative methods. As will be explained later in this chapter, the techniques were selected based on the reciprocal role that each held in respect of its purpose as a "tool" of intervention and change with data gathering.

6.3 Collaboration between researcher and client-system

The issue of the extent and nature of collaboration between a researcher and client system has received plentiful consideration (Chein, Cook and Harding, 1948; Bennis, 1966; Rapoport, 1970; Foster, 1972; Susman and Evered, 1978; Warmington, 1980; Gill and Johnson, 1991; Gummerson, 1991). For action research to be successful there appears to be general agreement that good collaboration with the client organisation is essential. Foster (1972; 537) points out that many programmes never get beyond the diagnostic phase and flounder on the rocks of establishing and maintaining the participative, co-operative research relationship with the client organisation. He quotes Bennis's (1966) perception of the collaboration relationship which must be characterised by

"a joint effort that involves mutual determination of goals

142

"a spirit of enquiry - a relationship that is governed by data, publicly shared"

"a relationship growing out of mutual interaction of the client and the change agent"

"a voluntary relationship between the change agent and the client, with either free to terminate the relationship after joint consultation"

"a relationship where each party has equal opportunity to influence each other"

Warmington (1980: 32) states that the action researcher should clearly emphasise to himself the fact that *"Action Research should be primarily guided by the needs of the organisation, and that it must be collaborative and client centered,* (where this is the case) *then the goals of the two parties need contain relatively few conflicts"*. This "balancing of the goals" is the "goal dilemma" identified by Rapoport (1970) where the resolution in one direction leads away from the science and the resolution in the other direction leads away from the action. The challenge is one of assuring that the goals, explicit and implicit, of both parties are adequately communicated to, and understood by the other. As goals may change during the project, they must continue to be agreed, understood and communicated. It is relatively easy to make the simple statement about agreeing and communicating goals but the action required to ensure that this activity is effective and communicated in such a way as to help rather than hinder the project, requires deeper consideration.

The practice of achieving a clear understanding of the goals on the part of both parties can present difficulties as individual perceptions about goals are as important as the goals themselves (Warmington,1980). He cites an example of outside researchers being regarded with suspicion by organisation managers, each viewing the other's perspectives as inappropriate, the managers viewing the researcher's approach as too academic and long-term rather than addressing immediate problems. In respect of this project, where the researcher as the change agent is an "insider", there are certain inherent advantages resulting from the researcher's knowledge of the organisation and its overall objectives. Nohria and Berkeley (1994: 131) recognise the advantages of the change agent being an "insider" because of their *"sensitivity to context"*. They see as valuable, the ability to adapt new ideas in context, with the change agent able to judge

143

the parameters of a particular situation and deciding what ideas will be acceptable and work in that context. Context includes macro and micro management - from the cultural milieu of a host country to personalities of employees on a management team. Managers who are sensitive to context have a keen sense of company history, including successes and failures of the past. They know the client-system's physical resources intimately, and they understand the organisation and employees strengths and weakness' so that they can discern what actions are possible and how much an organisation can be stretched. But this situation brings with it the expectation of organisational managers that this knowledge and insight will be applied to assure bias towards meeting the organisation needs first and foremost.

Both Gummerson (1991) and Gill and Johnson (1991) recognise this problem of role ambiguity where the researcher is essentially taking on the role of an internal consultant and as such, the slant of this relationship can have implications for the research. Gill and Johnson purport that the researcher, even if working as a full time manager will be stereotyped as an academic. Gummerson (1991: 186) considers the issue of conflicting loyalties thus

> *"A researcher who concentrates on satisfying the requirements of the researcher role will be, first and foremost, an academic researcher and considerations relating to the consultancy role will be of secondary importance. From the client's point of view, there is a risk of the researcher becoming an inferior consultant.*
>
> *A researcher who concentrates on satisfying the requirements of a consultancy role may well come into conflict with the demands of good research.*
>
> *Once the research role comes into conflict with the role of consultant, the latter must be given priority. If this does not take place, the change process will itself be affected by the academic research. This creates an unsatisfactory situation both for the client and for science."*

In the case of this research project, where the broad objective of the organisation was to bring about a change in the whole company, there was clearly the need to involve far more members of the organisation in the communication loop than just those who initially endorsed and sponsored the project. The project was announced to all staff by

memorandum from the Managing Director. Ostensibly the memorandum was intended to give authority to the researcher and provided the background and context for the launch of the Quality Improvement Programme (QIP). The broad framework of QIP, already agreed, was presented along with a statement about the researcher's role: *"this role should be seen as lying outside, and distinct from, her function as department head"*. For QIP *per se*, the memorandum also provided tangible evidence of top management commitment to the project.

A second dilemma of action research, ethics, is identified by Rapoport (1970) and discussed further by Warmington (1980). For the internal researcher the ethical and goal dilemmas are inextricably linked. Throughout this research, whatever the method or technique adopted, the researcher frequently requested or was provided with confidential information that was given on the understanding that it would never be attributed to the provider. Information upon which action would be taken if acting in the manager role had to be ignored as anything other than research data. Recognition needed to be given to the risk that informality in some of the data collection methods may lead to superficiality. The informality of methods such as observation and anecdotal information gathering may not be obvious to all individuals in the client organisation, indeed some transactions which inevitably affect the researcher's view of some aspect of the client-system, may be unconsciously provided by a member of the organisation. When this happens, the researcher may have an ethical dilemma in respect of whether or not to divulge that they may well use that information in for example, aiding interpretation of other data.

Top management endorsement of the project might suggest privileged access for the researcher thus the researcher had to keep in mind that some members of the organisation might provide information in the hope that it would be passed on, or might fail to provide information because of that fear. Also, co-operation might be given because of the top management endorsement but kept to the minimum required to avoid adverse comment. The methodological issue here was the need to be aware of the increased potential for bias because of the role dilemma. The practical and applied

consideration was that of maintaining credibility through being seen to retain impartiality over a prolonged period of time.

6.4 Generalisability of Action Research

Gummerson claims that by definition, action research projects are pursued through the medium of a case study and frequently within a single organisation context (Gummerson, 1991: 180). In the case of this work, in the interests of testing generalisability to an extent, the research domain has been extended to include a second organisation. However, the matter still requires further consideration. Warmington (1980: 25) contends that it is unlikely that action research will result in universally applicable generalisations, recognising that it is probable that results will be contingent on the situation studied and thus must be interpreted as some kind of contingency theory. Gummerson (1991: 191) obliquely supports Warmington when he concludes that validity in action research case studies is high and generalisation quite possible but he questions the desirability of generalising knowledge in a social context. He states that it seems increasingly important to generate theories that act as a guide to action, but which can be continually modified and revised - such is the case with TQM where *continuous improvement* is seen as a key strategy.

Yin(1989: 21) suggests that the reasons behind the criticism of a case study's inability to provide a basis for scientific generalisation are not always unjustified as some case study research lacks rigour in the methods thus permitting sloppy recording, bias and equivocal evidence to influence the findings and conclusions. Yin states that case studies, like experiments, are generalisable to theoretical propositions and not to populations or universes. In other words, it is the investigator's goal to expand and generalise theories and not to enumerate statistics. In designing this research, it was felt that the rigour of the experimental techniques and the development of theory *could* come from a single location, but if the relative uniqueness of the phenomenon were replicated elsewhere, theory building and learning would benefit from some triangulation.

Although much of the literature on action research refers to its use in the social sciences, there are a number of examples of action research projects which were undertaken to solve specific managerial problems and at the same time to generalise from the specific to contribute to theory; the changing of factory culture at Glacier Metal Company (Jaques, 1951), effecting organisational culture change (Seashore and Bowers, 1963), the growth of small businesses in Yorkshire and Humberside (Gill 1985), and improvements to industrial relationships at BP's Stanlow refinery (Lumley, 1978) provide some examples.

The issue of generalisability of the theory arising from this research project was considered during the initial development of the research strategy. It was felt that an extension of inquiry into other suitable matched organisations would provide a point of comparison and corroboration. The meaning of "matched" in this case is an organisation in the same business field, of similar age and size, sharing and addressing a common problem in a similar time frame. Out of five potential organisations, two were considered particularly well matched and were approached to request for collaboration. Ultimately access was gained to SciTec.

6.5   Overview of methodology at BFL

With an action research strategy providing the broad framework, and with the objective of implementing a quality improvement programme targeted to achieve companywide improvement, it was decided to select techniques that would provide information from multiple sources to obtain as broad a picture as possible and to provide a degree of triangulation (Denzin, 1970).

The wide scope of the project and the time and resources available, meant that it was impossible to gather information on all aspects of change resulting from QIP. Therefore, to obtain a picture that was wide enough and of sufficient depth to draw general conclusions, it was decided to adopt a flexible participant-observer approach, supplemented by a mixture of single time-point and longitudinal data collection techniques. The intention was to gather a mix of "total client-system" insights and conduct other in-depth inquiries distributed across the organisation as problems or issues of particular interest were identified.

6.5.1   Research Questions

Although the diagnostic phase of the project was initiated in advance of QIP and before the empirical field work had commenced, a combination of observation of what was happening in the company during the information gathering and discussion phases, combined with contributions from the literature on TQM, gave rise to certain research questions presented below:

1.   Does the mindset of the dedicated professional scientist act as an impediment to adoption of the TQM philosophy?

2.   Are individuals who have previously been exposed to motivation theory more receptive to TQM than those who have not?

3.   How great an influence does the individual leadership style of managers have (positive or negative) on the uptake of TQM?

4. How does an organisation's previous exposure to quality systems influence its receptivity to TQM. Is the stage of its development on this front likely to influence the ease with which TQM can be implemented?

5. How influential is the past exposure to management fads in influencing receptivity to TQM?

6. Meeting the business pressures and priorities of an organisation appears to take a higher priority than TQM. Is this a accurate observation?

7. Where the nature of the organisation is flexible, and there are few "mass production" tasks, can the use of measures to demonstrate improvement in quality become a demotivator?

8. Are the tangible measures of success of TQM likely to be masked by the variety of internal and external influences on the organisation?

9. Reward and recognition for achievement are generally regarded as a "good thing" in TQM programmes. Is it possible that they could also have a negative influence on the credibility of TQM?

10. It is assumed that TQM is about getting organisations to work together and breaking down barriers. Is it possible that in reaching this end point, conflict and competition can arise and that has the potential to impart a destructive influence on the implementation of TQM?

6.5.2 Research Framework at BFL

To address the research questions a conceptual framework was developed; research findings would ultimately arise from a combination of empirical research activities and from data that was generated as the output of the prescribed QIP activities. Figure 6.4 provides a conceptual diagram of the research process at BFL showing the pooling of the data from three different elements of the research

Figure 6.4   Conceptual model of the research process at BFL
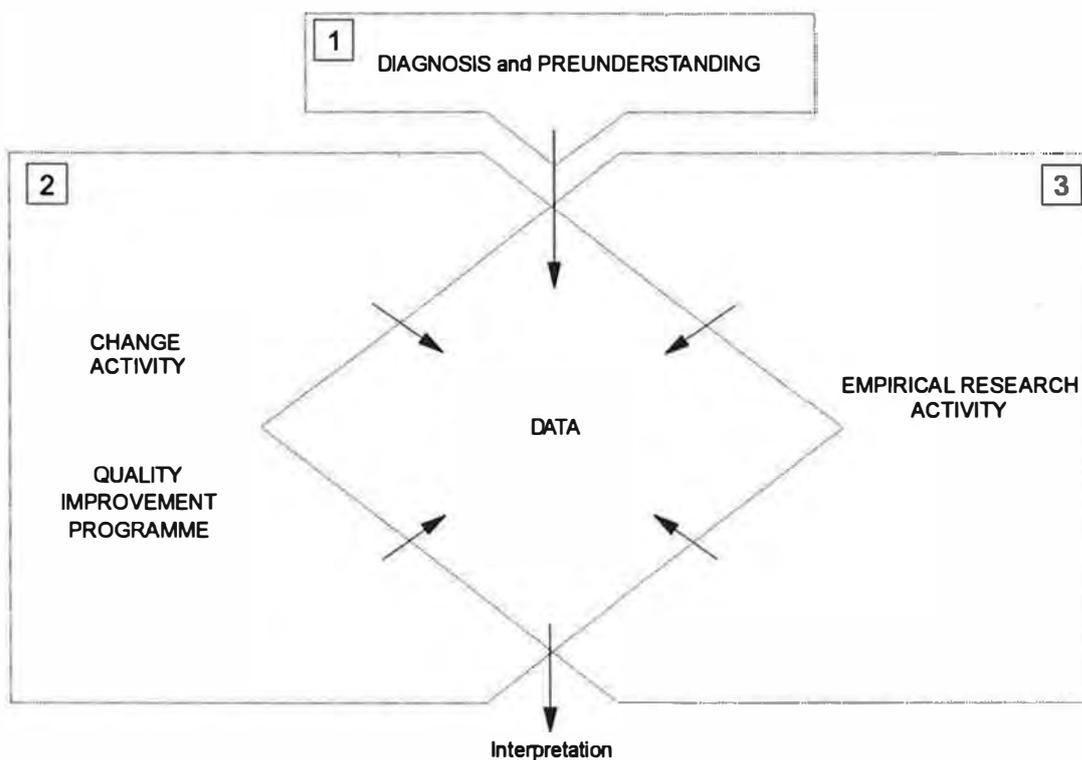
In explanation of the above figure, the conceptual design of the research was based on the notion that there would be three originating data sources. These were:

1.   the knowledge of the organisation that the researcher bought to the project. This was to be supplemented by archival and documentary evidence

2.   data that derived as a result of actions taken as part of QIP and

3.   data that derived from investigatory activities devised to understand the former.

150

There was intended to be reciprocity between the change process (2) and the empirical activity (3). To explain this further, it was considered that an important factor in the improvement of quality was the development of people's awareness of the need for quality improvement combined with increasing evidence that there was activity occurring in the company in which they had a part to play. Any stimulation of thought about the need for quality improvement or QIP *per se*, was thought likely to have a positive impact. Thus, actions taken as part of the empirical research would be taken in the overall context of QIP, and whilst having no direct value in terms of improvement, they would have the value of keeping staff alert to the issue of quality improvement.

The basic road map of phases of QIP was developed at the outset of the project (Chapter 5). This programme prescribed activities intended to achieve the desired change in the organisation. It was the intention to map the measurement rods to this phased plan and to develop tools that served to stimulate the change process yet also provided a data source. In parallel and linked to the change activity of QIP, a pluralist mix of empirical activities were to be utilised. These activities were intended to provide the measuring rods for the effect of the change process.

Returning to the conceptual model (Figure 6.5 overpage) some meat can be put on the bones and show the individual components of the three elements.

Figure 6.5   Conceptual framework of the BFL case study
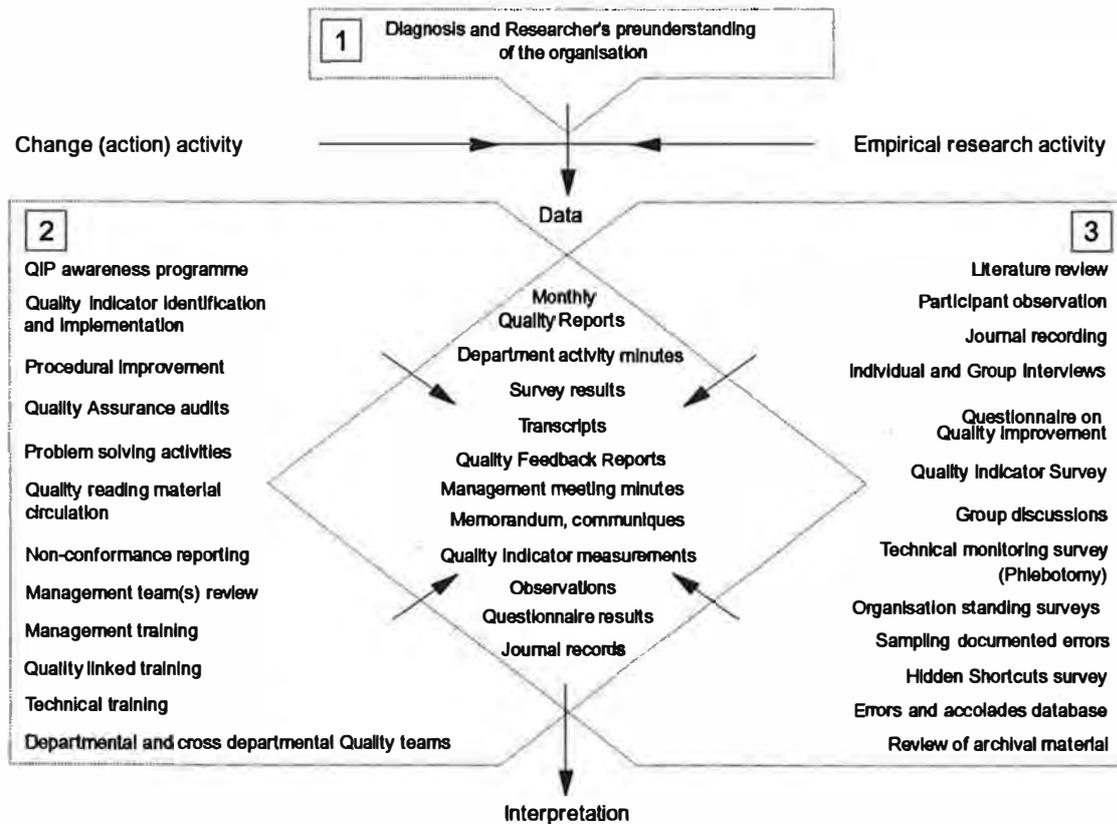
Figure 6.5 shows the component activities of the three elements of the research activities at BFL. Listed under (2) Change activity, are the principle actions that are prescribed as components of QIP. These activities are intended to inform, enhance skill or performance levels, change attitudes and behaviour and/or measure performance. On the right hand side (3) are the parallel research activities which provide the deeper insights into the effect of the change activity. These are explained in greater detail in the next section of this chapter. Both (2) and (3) combined with the preceding diagnosis of the organisation (1) provide sources of data listed in the centre diamond of the diagram. Pooling of these data provides for context sensitive interpretation.

A summary of the purpose, scope and timing of activities is provided in Table 6.6 overpage and expanded upon in the next section of this chapter.

Table 6.6   Summary of activity

Evidence Collection Method/Change activity	*Where applied/period*	*Abbreviated description of purpose*
BioFarm Laboratories		
Quality Assurance reports	Scientific departments Continuous	Pre-existing Quality Assurance activity providing a measuring rod for compliance with GLP and science-linked failures of quality.
Technical training	Scientific departments	Error eradication, problem reduction and greater efficiency through increasing core skills of technicians and scientists.
Non-conformance reporting	Whole company Continuous	Change from blame culture to problem solving through recognition and reporting of potential error causing issues. Quality awareness and involvement in QIP.
QIP training and seminars	Whole company (650)	QIP orientation. TQM awareness. Departmental goals setting. Opening up of cross departmental channels.
Management training	Whole company Potential supervisors to senior managers	Change towards development of better man management skills leading to improvements in communication, co-operation, motivation etc. and reduction in staff turnover.
Departmental and cross departmental Teams	Cross company	QIP activity targeted at removal of cross departmental barriers and general improvement at interfaces. Focused activity on identification and resolution of quality issues.
Circulation of reading material	Cascade to whole company via 70 (est.) supervisor and above staff	TQM awareness. Stimulation and ideas sharing.
Historical diagnosis	Holistic contextual Quality systems Archival material	To understand historical build-up and current context to the need for a programme to improvement
Participant Observation	Whole company Situational	Observation of effect of QIP implementation, participation, attitudes and visibility.
Journal keeping	Holistic	Historical record of change. Day by day recording of interesting events directly and indirectly related to improvement.
Empirical evidence gathering	Holistic	Information gathering on improvement initiatives, activities, changes in processes/systems.

153

Evidence Collection Method/Change activity	Where applied/period	Abbreviated description of purpose
Survey of Quality Indicators	12 respondents covering whole company Survey and measurement reports	Point of time collation of longitudinal measurements of quality improvement. Measured participation strength and area selected for improvement and attitude to measurement.
Monthly Quality Reports	Whole company by department over 2 years	Stimulation of system. Information gathering on improvement activity in progress.
Interviews		
Semi-structured	Twenty two senior managers	Exploratory and explanatory information on attitudes, communication, style and observations of senior managers.
Loosely structured	Small groups.	Discussion group to give window onto attitudes, barriers, participation to QIP.
Unstructured	Small groups, individuals	Exploratory and explanatory interviews to understand specific events. Point of time window onto attitudes, barriers, participation in QIP.
Technique improvement survey	Those involved in specialist activity. Around 30 technicians 1987 to 1992	Action learning cycle. Measured the extent of improvement achieved through planned, continuous change. Holistic measurement of attitudes and value of feedback. Technical survey data x 2.
Document review: Survey of errors and complaints	Whole company All correspondence 1989-1993. Estimate of 500,000 communications.	Longitudinal measurement of the numbers and type of errors as an indicator of QIP effectiveness and changing levels of customer satisfaction.
Sampling of documented errors	Two major technical departments. Animal Management and Pharmacy. 2 x surveys - covering 500,000 (estimated) data-points	Demonstration of inadequacy of error measurement as a indicator of company performance.
Hidden shortcuts survey	Covered major department - Seven respondents covering approx. 150 staff.	Confirmation of evidence. Point of time window onto hidden, unacceptable activity at "shop floor level".
Organisation standing survey	Managing Director and 17 Senior Managers from all functions	Stimulant of the system. Managers view of quality improvement progression.

6.5.3   Empirical Research Activity

6.5.3.1   Participant Observation

Participant observation has been used as the dominant linking element of other methods throughout this research. This method has been used to gather subjective data, generate hypotheses and ideas for testing by other methods, and to gain insights and impressions about the individuals and groups within the organisation. This was done by spending time within the organisation, communicating, emphasising and soliciting views of organisation members. Participant observation provides greater understanding of flows of events, personal prejudices, and political allegiances which cannot reliably be obtained by interview, questionnaire or other data collection methods outlined in this chapter.

Consideration was given to the fact that this work, which concerns the introduction of change throughout an organisation, was intended to affect the work based operations of the researcher and those aspects of the organisation for which operational responsibility was held. Lawler *et al*(1983: 43) identify two problems that can occur when the action researcher is both actor and researcher. Firstly there may be a credibility problem when the person responsible for the change reports on effectiveness of their own efforts and secondly, when a person is involved in both change and measurement, there may be a conflict of interest between what is good for the change and what is good for the research. This can take the form of competing demands for time and energy on whether or not particular measures should be collected. However, it can be argued that action researchers in a participative role are more sensitive to timely and relevant data and are more motivated to collect the data than an independent observer might be especially when the participant observer has a long-term interest in the result of the work, even after the period of intervention has ceased.

Much research using participant observation has been performed by external researchers who move into an organisation specifically to perform the research and then at its conclusion, withdraw. In the former situation the participant observer has to be accepted and must spend time gaining a detailed awareness of how the system functions, the geography and hierarchy of the organisation before he can begin to carry

out any role within the organisation. In the case of this study, obtaining acceptance and knowledge of the organisation was not an issue because of the considerable time that the researcher had spent with the organisation before embarking on the research. However, the question as to whether the research was overt or covert was considered.

In the early stages of the setting up of the research, it was easiest to remain covert. However, for the research to be effective it was important that the role of the researcher was defined and understood as role-neutral specifically by senior managers, thus dispelling uncertainty about authority or suspicion of objectives. This was done through a written announcement from the senior executive. The researcher further identified the role to be played in meetings and during formal interviews.

As mentioned earlier in this chapter, the participant observer must be aware of the need for high ethical standing in respect of their interaction with members of the organisation. Prime consideration was given to maintaining trust and confidence with the recognition that should this fail, the willingness of the subjects to participate might be reduced to the minimum level of cooperation required for their formal role. In addition, consideration was given to constraints applied to the amount of time that individuals would be prepared to give to research activities which did not immediately or directly benefit their own operations. Whenever the participation of a subject was required, an explanation for the reason of that data collection was provided.

6.5.4   Data Collection methods

6.5.4.1   Observation

In addition to the role as participant observer, the role undertaken was frequently just as observer - when the researcher is an insider, the role of observer provides a particularly rich contribution to understanding and information gathering. The observation role can be adopted as a positive action, for instance, the role was at its most dominant during meetings where the proverbial activity of "fly on the wall" was adopted, or it can be unplanned and passive, with the observer noticing and taking note of those aspects of the environment that appear to have relevance to the research. An insider, who has a face which is familiar around the organisation, has a marked advantage over the outsider in respect of access. People do not question why they are where they are or what they are doing as might occur with a less familiar person. However, the fact that behaviour might be modified when the researcher is perceived in their manager role, has to be considered. Thus what is seen, might not be a true reflection of reality.

Where the "active" observer role was used it could be by invitation or by a request to observe. In some cases, an invitation to attend a meeting was given. At other times, permission to attend was sought of the convenor. The majority of meetings observed were to departmental quality team reviews or group briefings. In these situations, it was important to take a back seat and let the conduct of the meeting, whatever it might be, to take it's own course. Occasionally questions were asked and the researcher felt it was appropriate to respond - however, the intention was to observe the interaction and listen to discussion without any participation. Notes were taken by hand and, if written notes of the proceedings or outcome of such meetings were produced, a copy would be requested.

157

6.5.4.2 Journal keeping

Throughout the research, a one-page-a-day diary was maintained. This document became a depository of information, data and observations and impressions providing a source of insight through reflection of the data. The dairies were used as a scrap book, recording events as they occurred or soon afterwards. The events recorded were not solely or always directly linked to QIP *per se* but included other matters that impacted upon the company environment as a whole or were thought to have potential to influence or throw light on any aspect of research. Frequently they were unstructured anecdotal data on interesting or critical incidents. The journals were used to record ideas generated in response to observations. They had particular use for recording impressions of events such as meetings where only the formal proceedings would otherwise be recorded.

Using reduced photocopying (17% of original size), it was relatively easy to copy and paste into the document a variety of memorandum, reports, letters, fax copies and so on. This could then be supplemented by the researchers commentary and observation. The journal was also used for keeping track of relevant documentation which otherwise might easily become untraceable in the milieu of company documentation. Information was frequently cross referenced to make it easier to follow a trend.

The one-page-a-day format allowed for retrospective entries where supplementary information developed, and it was also used as a conventional diary to record planned research activities. In reviewing findings and understanding events, the journals acted as an invaluable memory jogger - when conducting research with such a broad scope as this project, over a prolonged period of time, it is virtually impossible for the researcher to recall all that has gone before and some sort of mind-jogger is useful.

6.5.4.3 Empirical evidence gathering

A major source of information from which insight into progress of each group within the company could be assessed, was the documentation that it produced on its quality improvement activities and other related changes. Departments were asked to copy documentation (memorandum, meeting notes, announcements, newsletters, measurements and so on) to the Central Core (the researcher and Associate Director of Scientific Operations[L21]). This would be done in the majority of cases but there were omissions, principally inadvertent and sometimes deliberate, of matters that were not considered relevant to QIP or which individuals did not wish to divulge. By remaining alert to developments around the company, the researcher was able to follow up on leads upon which no information had been received. Also, the habit was adopted of wandering around the company, reviewing noticeboards - those in offices and staff rooms often provided supplementary information - and taking copies or writing down notes on displays. People would be asked about their QIP activities and should any new of interesting initiatives be mentioned, they would be asked if they had any supporting documentation.

6.5.4.4 Circulation of reading material

At intervals (roughly once a month) reading material on the subject of quality management was circulated around the company. Articles were carefully selected for their readability and current relevance. Occasionally, to encourage reading after receipt, a précis of the article, interesting observations or "what do you think?" questions were attached. The purpose of this circulation was to enhance the readers knowledge of quality management and to stimulate ideas of what could be done, and comparisons of what could happen or had happened in the company.

Under the belief that "unsolicited mail" frequently finds an immediate route to the wastepaper bin, steps were taken to differentiate the articles from other internally circulated material. A purpose designed circulation slip was attached. This slip displayed the QIP logo and the circulation list so that recipients were aware of who else held a copy. Either the article or the covering circulation slip was copied on coloured paper - variation of form between each circulation was deliberate. To encourage

sharing, recipients were asked to circulate the article the article to their staff after reading. The circulation list varied according to the material. Most often, a central company communication list of key people (around 80), combined with other targeted individuals was used.

There was no way of knowing exactly who read the articles or indeed whether the recipients read them or passed them on. It was notable that a minority of recipients would suggest other names for future circulations or ask for additional copies. Only when a response was called for, for example, when an article "Levelling Out The Future" (Lascelles and Dale, 1991) was circulated to a limited group and recipients were asked for their opinion of where the company fitted in the model presented in the article, did the researcher get a firm idea of who read the article.

Evidence of apathy for reading material came to light when a collection of papers on TQM in toxicology was published by the American College of Toxicology (Science and Compliance : Study Management through Toxicology, 1991). To save upon a massive circulation of paper, the abstracts only were circulated stating that full copies were available for those who wished them. Recipients were also told that a complete copy had been placed in the library. Only eight copies were requested and judging by the mint condition of the library copy after one month, it had not been accessed.

6.5.4.5 Training and seminars

To introduce staff to the philosophy of TQM and the expectations of their participation in QIP, seminars and training modules were used. The seminars, normally about half a day duration, were organised for individual departments and varied in format depending upon the departmental function, the level (seniority, job function and/or skill level) of staff that would be attending and the preferences of the departmental head. The objective was to address individuals who would have a key role in the implementation of QIP within their department; it was the departmental manager who decided upon the attendees. Wherever possible one of the Central Core would meet with the department head in advance of the seminar - they would agree objectives and discuss any special requirements or focus that the department required.

The second form of training was a session contained within the companywide Modular Induction Training Scheme(MITS), a series of twenty introductory seminars intended to give new and existing staff an insight into all activities of the company. By including a module on total quality within this scheme, the objective of getting a consistent message to all staff was met. The scheme predated QIP in its conception, thus it underpinned the desire to utilise existing initiatives to implement quality management and assured that QIP was viewed as an integral part of the whole company business. Thus the concept of "quality managed in rather than added on" could be endorsed.

Induction modules, lasting around 2- 3 hours, were attended by around 20 staff on each occasion and were run once every three weeks. The attendees were either recently employed and may or may not have previous work experience, or they were established employees who had been working in the company before the genesis of the Modular Induction Training Scheme but had not undergone formalised general familiarity training. This mixed grouping had some particular advantages for QIP; 1) individuals were able to discuss quality issues that impacted upon other groups, 2) individuals were presented QIP as a companywide activity and 3) as with other of the induction modules, the mixed group encouraged the development of interdepartmental co-operation and introduced staff to others with whom they might otherwise not come into contact. This feature was regarded as valuable because it was thought that a major contributor to many of the failures of quality within the company, happened because of problems at departmental interfaces.

Elements included in the modules were:

1. Introduction to the aims and objectives of the Quality Improvement Programme

2. Definitions of Quality - what it means to the individual; what it means to the company.

3. Customers - the notion of and identification of internal and external customers.

4. Costs - Relative cost of prevention, appraisal and failure.

5. Meeting the requirements - targeting error-free work.

6. Measurement - introduction to Quality Indicators as measures of improvement.

6.5.4.6 Quality Indicator Identification

All departments were asked to identify aspects of their work that had the potential of improvement and to decide upon a metric which would measure the impact of the current performance and then the improved performance following change or focus upon the task. The intention was that early measures would be of simple tasks, probably tasks or activities that were conducted by one person or a small group working together such that the people making the measurement were the group that had control over that task. The early identification of simple tasks was hoped to get staff into the habit of looking at the quality of their output and to understand that it was possible to achieve tangible improvement with relatively little effort.

Over time, it was intended that the targets for improvement would be more complex, looking at the performance of systems or processes rather than single tasks. How the measurements were made and used was left to the selection of department heads and/or the groups collecting the measurements. Guidance on suitability of the selected measure or upon ideas of what would be suitable, was available from the Central Core. Several problems were identified in setting up the Quality Indicators. The first was getting people to understand that, in general, a measurement alone will not bring about an improvement in performance - although observation suggests that this argument is flawed as improvements were noticed to occur without any change in the way a task was carried out. The second, was the identification of suitable targets to measure. A third problem was the tendency of some groups to wish to measure an output that affected them, of a procedure performed by another group. Being potentially divisive, this practice was discouraged. At the outset it appeared that groups that performed large numbers of repetitive tasks on a routine basis found identification of indicators far easier than groups engaged in such tasks as project management.

No "rules" were placed upon the form or frequency of measurement or the format of the output. It was thought that staff would be keener to participate if the strictures were few and far between.

162

6.5.4.7 Survey of Quality Indicators

Observation suggested that there was an uneven distribution and use of Quality Indicators across the company and that records of Quality Indicators that had not been successful were sparse. It was decided to develop a survey to capture data on actual activity and the attitude that people had to indicators. Representatives from all areas were asked to complete a survey form for each Indicator that they could identify. The survey form is presented in Appendix 6.3.

Underlying the questions asked in the survey were certain trains of thought and predictions of the expected outcome. Table 6.7 provide explanation of the information elicited and thoughts lying behind each question.   A full schedule of questions asked, the reasons why they were asked and predicted responses can be found in appendix 6.1

Table 6.7   Purpose of Survey on Quality Indicators

	Purpose of survey as stated for the purpose of recipients	Unstated question
1	To identify all of the Quality Indicators that have been introduced since QIP started	1. When did indicators commence relative to the introduction of QIP? 2. What was the rate of adoption? 3. Who/which groups adopted indicators?
2	To develop an understanding of whether or not Quality Indicators have been instrumental in improving any aspect of individual, departmental or company performance	1. Have some types of indicators been more or less useful than others? 2. Have indicators actually made a contribution to improving performance? 3. If quality indicators have made a contribution to improved performance, is this more likely to be at individual or group level?
3	To identify the aspects of performance where measurement actually demonstrates proved performance	1. Does measurement *per se* bring about improvement? 2. Can improvement occur and be identified where no measurement is performed?

6.5.4.8 Monthly Quality Reports

Within the objectives of QIP was a desire to keep any additional work burden related to the programme to a minimum compatible with achieving objectives, and to keep bureaucracy down to a minimum. The only formal reporting requirement with which departments were obligated to comply, was the production of a monthly progress report (Figure 6.9). This report was not part of the original plan for QIP; it was introduced for an eighteen month period as a tracking tool to remedy a failure in communication about quality improvement activities from some departments and to improve exchange of information and ideas. At the time of introduction, it had become difficult to track completion of initiatives or those that had failed or been dropped for various reasons. Also flagging efforts in some departments had been observed. The reports were submitted monthly to the Central Core and reviewed by the Operations Committee.

The format of the report was intended to be helpful to the user. The guidance notes on completion were built into the report. They were suggestions of appropriate matters to consider in respect of starting and progressing quality improvement initiatives. The report was divided into four sections :

Section 1: *Quality improvement initiatives started during the past month*. Required a brief description of the origins, objectives, people involved, targets and/or criteria for measuring success. It was acceptable to include any activities in the department designed to improve any aspect of performance. This flexibility was to intended to collect information from Departments that might have ignored QIP and were reluctant to admit that initiatives were linked to the programme. It was not of any real consequence whether initiatives were launched under QIP or not - provided that they happened. From the research perspective, it was an interesting observation that threw light onto attitudes about QIP.

Section 2: *Quality Improvement initiatives terminated during the past month.* This section asked for brief details of activities which had terminated by design or otherwise. It was recognised that all initiatives would not reach satisfactory conclusion, thus there

would be a certain degree of drop out. Also, within the history of the company there was a record of starting initiatives and failing to bring them to satisfactory conclusion for a variety of reasons such as lost enthusiasm, lost direction, time, hitting the proverbial brick wall and so on.

Section 3 : *Progress of existing activities.* An update on the status of current activities was requested in this section. The intention was to gain insight into the difficulties encountered, revisions of the objectives or criteria for success, achievement or otherwise to date. Within the section was an implicit suggestion that for an initiative to progress, actions such as meetings to review progress would be needed.

Section 4 : *Identification of quality issues*: A request for identification of issues that the submitting department felt to be in need of review. These could be issues that were companywide or area-specific.

Figure 6.8 provides an example of the format of the report. For ease of completion, it was available on paper or in electronic form.

Figure 6.8   Example of Monthly Quality Improvement Report

QUALITY IMPROVEMENT MONTHLY PROGRESS REPORT

For month of :   Department:

SECTION 1: Quality improvement initiatives started during the past month
Give a brief description of the origins, objectives, people involved, targets and/or criteria for measuring success. Include all activities initiated to improve some aspect of the department irrespective of whether or not they were initiated under QIP.

SECTION 2: Quality Improvement initiatives which have terminated during the past month
Provide brief details of activities which have terminated by design or otherwise. Please indicate whether the activities reached a satisfactory conclusion. Where initiatives have failed, try to give the reason why eg lack of enthusiasm, no longer relevant, too tedious to measure etc.

SECTION 3 : Progress of existing activities
Provide update on the status of current activities, e.g. difficulties encountered, revisions of the objectives or criteria for success, achievement or otherwise to date.   Give outline details of meeting held and purpose, with indication of staff involvement from your group or others.

SECTION 4 : Identification of quality issues
Please record issues identified which are need of review but have yet to be addressed. These may be company or area specific related.

166

6.5.4.9   Interviews

Over the duration of the project, interviews were used extensively and in a variety of forms and for different purposes. The purpose of the interview strongly influenced the methodology applied. A summary of interview types and purposes is presented in Table 6.9 below:

Table 6.9   Interview types and purpose

Type	who	Purpose and protocol
1 semi structured individual interviews	senior and top managers	1. Fact finding and exploring views; one to one; fixed schedule of open questions; taped
		2. Follow-up after critical event; one to one; face to face; manual recording
		3. Historical fact finding and clarification; face to face or telephone; open questions; defined subject areas/questions; manual recording
2 loosely structured group interviews	pharmacy technicians animal technicians histology technicians study directors	1. Exploratory; prompt schedule of subjects to cover; facilitated discussion format; face to face; up to seven to one; manual recording;
3 unstructured individual interviews	individuals. technicians and middle managers	1. Explanatory - interviews clarifying events and feelings after significant occurrences; face to face; one to one; manual recording
		2. Exploration and explanation of views on QIP quality teams. One to one; face to face; manual recording
		3. Informal question and answer. Clarification and explanatory; Very brief (up to 5 minutes) face to face or telephone, manual recording.

Description of interview methodology

The researcher conducting interviews from the insider participant observer standpoint has unusual circumstances which require due consideration:

1.   Interviewees are generally known, often socially, to the researcher - in some cases, the researcher may have been influential in the career

development of a subject, or they may have frequently been in dispute with a subject. Politics and history have to be left behind.

2. The subject may sometimes be bemused as to why certain questions are asked. They may think, for example, that "the researcher must be perfectly aware of my view on that matter as we have discussed the issue on and off for years". The researcher wants to legitimise and confirm the view for research purposes and thus feels the need to include the matter.

3. The issue of establishing rapport between interviewer and researcher is somewhat easier when the interviewer is an insider. However, the researcher has to spend time disengaging from the employee/manager position such that it is clear to both parties that interaction is confidential to the research.

4. Particularly at senior level, the insider researcher has to be aware of the political nuances. Managers in senior positions have generally developed the skills to manipulate information, introduce ambiguity, and be sparing with information they do not wish to divulge. Conversely, they are unlikely to be untruthful if they believe the researcher may hold alternative information, or have the ability to recognise a bending of the truth.

5. Information may not be provided because the respondents sometimes assume that the researcher holds certain information which in reality they do not have. Facts may be glossed over and clarification must be sought.

6.5.4.9.1. Semi-structured interviews

Early in the research process, semi-structured interviews were conducted with eighteen senior managers (See Figure 6.10). The subjects were managers holding key positions as head or deputy head of the major functions. They were considered likely to be the most influential in the implementation of QIP. These interviews, intended to obtain their views on management style and purpose, communication mechanisms in the company, and views on quality, were conducted in accordance with a time schedule. A common schedule, predominantly using open questions was used flexibly. The open nature of the questions meant the total adherence to the schedule, as written, was rarely

possible; i.e., subjects frequently anticipated questions, required clarification or had to be probed to obtain a response or further information. These interviews were allowed to develop in the direction that appeared of value to understanding the situation.

A second round of interviews, with virtually the same group, were conducted around eighteen months after the launch of QIP. These interviews followed a review of departmental progress that had been organised by the Managing Director[L1], in collaboration with the researcher. Two additional managers were interviewed in round two. They were the Director of Reproductive Studies[L7] and the "new" Head of Pathology[L14]. The former was selected for the first round but the researcher gave up after several cancelled appointments. The latter was included in round two following a change in department reporting lines in Pathology.

To corroborate information and gather new insights on the company history and the implementation of GLP, the Managing Director[L1] and Associate Director of Scientific Operations[L21] (these subjects held the positions of Deputy Director and Head of Quality Assurance respectively at the time of GLP implementation) were interviewed. In the process of preparing the interview questions, observations were recorded of the researcher's perception of the topic upon which data was to be collected. The questions were then selected to explore these topics in more detail. Questions were focused on factors related to personal style and company systems which were considered to have the potential to influence implementation of QIP.

The interviews were held in each manager's office and by individual agreement, tape recorded. The question schedule was used flexibly allowing the respondent talk freely on a topic. Respondents often answered questions in advance of them being asked or would invalidate an intended question through the information they provided unprompted, thus adherence to the schedule was loose. Throughout, clarification was sought as required and brief notes were made as a prompt to return to a point at a later stage, rather than interrupting the flow.

The tapes were first transcribed almost verbatim (some "ums", "errs" and "ahs" were removed) providing an individual record in the language of the respondent, of the *actual* questions and responses.

Subjects selected for senior manager interviews, and their position in the company hierarchy are shown in Figure 6.11.

Figure 6.10   Interviews of senior managers : Position in company hierarchy of subjects
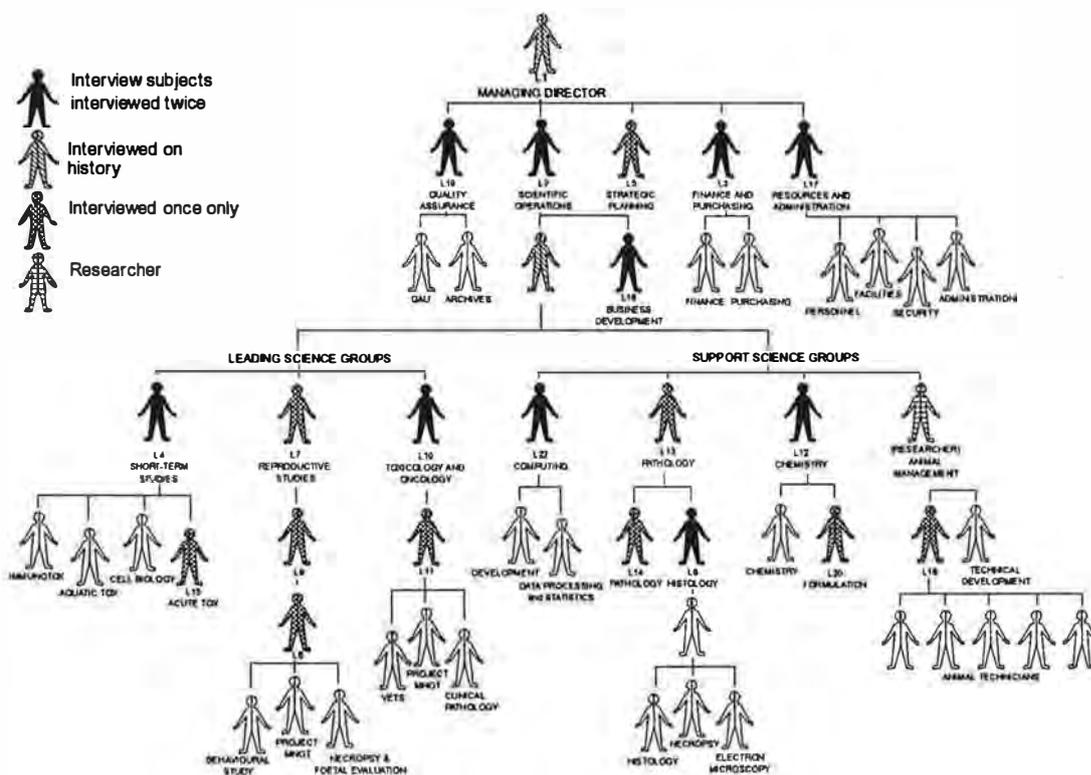
6.5.4.9.2. Loosely structured interviews

The term "loosely structured" describes the nature of group interviews. These interviews were intended to follow the same lines of inquiry as the early senior manager interviews, but it was felt that the best response would be obtained from groups, each of whom might respond personally or stimulate responses from others. A schedule of topics to cover was prepared before meeting with each group. The role of the researcher was more "facilitator" than "interviewer". Topics were addressed to the

group using such questions as "what do you think of....." or how do you feel about....." and so forth. The group was encouraged to open discussion on the subject.

6.5.4.9.3. Unstructured interviews

At the other end of the scale, interviews were used to explore and explain causes of quality problems that arose within the organisation. There was usually a dual focus, a) to understand the incident cause and effect, and b) to find out how the subject felt about the situation. Such interviews as these could not be planned as the events that they addressed happened spontaneously. As each of these interviews covered different situations that had arisen spontaneously, the area of enquiry and thus questions, could not be devised in advance. The form of the interview was unstructured with the interviewer following up on interesting issues as they arose.

Throughout the research, as data was gathered, further information was often required to throw light on an event, a document, the nature of data and so forth. The telephone was used extensively to obtain this type of information from subjects expected to know the answer to the question. Data thus obtained was often that which was required at the time when an issue being investigated was still fresh in the minds of those concerned. The geography of the site, separation of individual laboratory facilities, the need to shower and change on access to animal facilities, combined with restrictions on entry under certain circumstances, suggested that the telephone was the most practical means of communication. Whilst questions were formulated in advance of a telephone call, the calls were made spontaneously so subject normally did not know they would be contacted. At each call, subjects were asked if they would provide "a bit more information about...." or "an explanation of.......". The subjects were told that they were providing research data, thus lowering defences which are often put up if such questions are asked in the normal course of company operations. The same approach was used face to face if subjects were conveniently located.

In addition, listening to conversations in a working context, or over lunch, or just having a casual discussion provided much information. As time passed and it became commonly known that the research was being conducted, people would contact the researcher to provide information or to ask for her view on an issue. Contacts would

often be along the lines of "You're the "quality person" around here... what do you think of this..?", "I thought you might be interested in this" or "what should we do about that?" and so on.

6.5.4.10 Technique improvement survey

This was an attempt to improve the technique for taking samples of blood from rodents. A detailed, technical, structured questionnaire was developed to provide information on the blood sampling process, a brief description of which is presented in the box below.

Figure 6.11   Procedure subject to improvement : Blood sampling in rodents

---

Description of blood sampling techniques in rodents

During studies designed to evaluate the effects of a chemical substance that has been given to rodents (rats and mice), it is normal procedure to take samples of blood from a small proportion of the animals, at intervals during the study, to investigate the effect of the chemical under test.

The volume of blood required, although small in relative terms, is quite large as a proportion of the size of the animal. For example, a total of 5ml might be taken from a rat weighing 500g (1% of bodyweight). By comparison, to conduct the same tests in a human visiting the hospital haematology clinic might take 10ml (0.015%) of bodyweight for a person weighing 140lbs). The proportion of blood taken from a rodent cannot easily be reduced because the analytical equipment used for each test needs a minimum volume of blood to operate.

The physical build of the rodent means that blood vessels suitable for withdrawal of a sample are not readily located, thus alternative techniques for sampling have been developed. At the time of this research, the method of choice was to take the blood from a gap in the bone behind the orbit of the eye (the retro-orbital sinus).   This technique uses a short micropipette (a very small tube of glass about 0.5" long and with a bore of 1mm), which is inserted into the sinus and blood is withdrawn by capillary action. To restrain the animal, and to prevent distress, the procedure is performed under light, general anaesthesia.

The technique requires precision, speed and dexterity if good quality samples are to be obtained and the animal is unharmed. Occasionally, due to a variety of factors, the animals may be physical damaged or die. Whatever the circumstances, such an outcome is undesirable.

Early in this research programme, a problem with this key procedure, i.e. removal of blood samples for analysis from rodents, required as part of the protocol for toxicology studies had been observed. Because of the critical nature of this activity, whenever there was a problem, negative feedback resulted, either externally from the study sponsor or internally through line and project management. This created a strong desire to improve the technique. Steps were taken to revise training, review competence of people participating in the procedure, review the technique itself, and collect information such that there was a better understanding of the nature and extent of problems.

To aid the above objective, and to provide measurement of change, a questionnaire was developed. The use of this questionnaire was originally intended for a six month period, but early information gained was of such value that the period of use was extended for a year.

The questionnaire (Appendix 9) was multipurpose and divided into two parts. Its uses were

1. To monitor performance trends in respect to blood sampling

2. To gather data to enable identification of circumstances or actions which influence the quality of the product (the blood sample)

3. Providing feedback to enable learning

4. Improve communication between the interacting but departmentally separate groups involved in the process.

The questionnaire consisted of two linked parts. Part I was devised to provide comprehensive information about the sampling process performed by animal technicians. Part II gathered information from the recipients of the blood samples, the clinical pathology laboratory, and also served as a feedback form on satisfaction for the technician who had performed the sampling.

The two parts were linked to:

a) prevent the need for repetition of data,

b) to ensure the two responses were permanently linked, and

c) to encourage communication between the two respondents.

Part I was completed in parallel or just after a blood sampling session. It was then sent, with the blood samples, to the Clinical Pathology Laboratory where Part II would be completed.

The questionnaire was designed to limit the time required for completion to a minimum. As the majority of data to be collected was objective, providing nominal values, a tick box format was used. A few questions providing nominal data required expansion of an answer by use of an open ended question. In these cases, the amount of space provided for the answer was intended to indicate, to the respondent, the amount of information expected. Where questions required subjective responses, 3 or 4 point ordinal scales were used.

The questionnaire was piloted using a group of individuals by whom it would eventually be completed. Over three drafts, this group suggested minor alterations including additional questions and some clarification of wording.

The questionnaire was used for 12 months. At the same time, review of the techniques in use and additional training was in progress.

Response to the questionnaire was relatively easy to assure by :

a) matching completion to a planned and formally scheduled activity, thus enabling a prompted chase to be implemented should a return not occur

b) the interest that respondents had in the outcome - somewhat like receiving examination results

c) linking the two parts - the technicians who completed Part I had a vested interest in the response to Part II because the feedback, even in its "raw form" might be immediately useful, thus it was assumed that the respondent to Part I would be instrumental in assuring that Part II was completed and

c) the motivation of respondents brought about by their participation in an activity likely to bring positive results

174

The issue of bias of the second respondent was considered. This person would receive Part I and potentially be able to bias their response from information provided. The issue could have been resolved by separating Part I and II into two distinct documents. However, as most of the responses to Part II were objective, it was decided that bias would probably occur very little, if at all. Because the questionnaire was being used over a long period of time, responses could be monitored for any suggestion of bias. The benefits of linking the two parts appeared to outweigh the potential problems so the two Parts remained linked.

After one year of use, the questionnaire was withdrawn. Measurement of animals that died during the process continued. After six months without the questionnaire in place, a revised questionnaire was developed and implemented.

The majority of technical information collected with this questionnaire is of no direct interest to this thesis and therefore is not reported. The focus of this methodology concentrated on the value of feedback to the improvement of a process, what happens when that feed back is removed, and the learning that occurs throughout.

6.5.4.11 Document review: Survey of errors and complaints

This was one of three activities developed to provide an insight into failures of quality. They were:

a) this survey,

b) a point of time sampling of errors not included in this survey and

c) information gathering on "unofficial activity".

The latter two activities were an onward development of the survey of errors and complaints; they are described later.

The survey of errors and complaints was a daily review of incoming and outgoing communications (copies of letters, telexes, faxes, and records of telephone conversations and meetings recorded on "Sponsor Contact Forms"). These communications were reviewed with the intention of identifying any communication, the subject of which was notification of, response to, or exchange about any failures of quality by BFL. Adverse comments were defined as "*any record (letter, telex, facsimile, E-Mail, meeting notes, records of audits, records of telephone communications) which either indicate that a sponsor is aware of an adverse event, or that record any aspect of company performance which might be taken by a sponsor as a failure to meet explicit and implicit quality standards*".

The data was used to identify types of problems, monitor trends and to evaluate impact of problems in relation to the client.

This review was essentially a continuation of a much disliked, pre-existing "Error Report" which was originally compiled for the company's previous Managing Director by the sales department. This original report, organised by department and scored for severity, was regarded as a "black book" by departmental managers who had no input in the entries or opportunity to offer defence. In order to turn the activity into a valid research tool and to increase its acceptance, certain actions had to be taken to assure a consistent and unbiased approach to communications monitoring. The fact that this activity was possible at all depended upon the presence of a formal (by tradition) system for handling of correspondence, an activity which was valuable but very labour intensive.

On a daily basis incoming postal mail and incoming faxes were centrally sorted by a trained person. Mail was copied and prepared for distribution to the addressee and others according to defined listings. In addition, other individuals who might be interested in a communication were noted for copy. Mail addressed to the personnel office or finance group marked "confidential", and mail which was clearly of a personal nature to the addressee was forwarded without further scrutiny. All other mail was opened and reviewed. A reverse of this system operated for outgoing communications. It was a requirement of the company that copies of all outgoing letters or faxes, and records of telephone conversations between company and client, and proceedings/discussions at meetings should be recorded in writing and a copy entered into the central mail handling system.

The mail-sorter was trained to identify communications that contained information about any failure of quality. A copy of such was set aside for further scrutiny and/or inclusion in a report which was collated monthly. The researcher automatically received a copy of such mail and where necessary, would talk to the addressee or sender for further information or understanding of the issue. To assure a consistent approach, the mail-sorter and researcher would confirm interpretation and selection criterion for selected communications. In addition, the researcher, at intervals (initially weekly, moving to around every six weeks) would check the daily correspondence file to assure that her selection, matched the mail-sorter's selection.

Initially, collation involved interpretation and summary of each communication or series of communications followed by tabulation. This was a manual activity using a word processor. The collation was moved onto a DOS based Electronic Card Manager application which allowed easier edit and sorting. Finally, having found the DOS card manager too restrictive and slow, a *Windows* based *Microsoft Access* database was developed. To introduce a positive connotation to the quality feedback report the database was called "ACE" - Accolades and Errors database.

Development of the coding, required several iterations and refinement in use as each entry was coded. Early coding was performed by classifying by colour code each month's report into six major categories. They were errors related to:

1. **Science**: procedural error, differences in interpretation, delays in sample dispatch - including poor packaging, and poor data quality

2. **Protocol**: errors detected in protocols and protocol amendments

3. **Reports**: delay, errors and missing sections in draft and final reports

4. **Correspondence:** late or absent results/correspondence, wrong name(s) or address, typographical errors, damaged correspondence, errors and delays in monthly status reports

5. **Finance**: errors in pricing or invoicing. Misaddressed invoices. Delays in production/dispatch of cost estimates.

6. **Scheduling/attitude**: delays or timing unacceptable to sponsor. Complaints about quality of response.

Over time the codings were refined in an attempt to focus the output to reflect the type and variation of comments. The major categories were subject to minor change; they were extended to ten major categories and a maximum of three further minor categories, culminating in a four-part code. Entries from 1989 onwards were ultimately classified directly on the ACE database using the codes presented in Appendix 6.2.

To assure consistency, all of the coding was performed by the researcher; frequent checks for coding consistency were applied.

Over the duration of this project the mechanism for production of this report changed.
   a) the title of the report was changed from "Error" to "Quality Feedback"
   b) positive comments were included
   c) a draft version of the final report was circulated for comment before formal issue and disputed entries discussed.
   d) after the introduction of ACE, the format of report circulated in the company varied in format. Sorting was ordered to highlight interesting categories and to provide comparative figures for previous months or periods. This variation was intended to heighten interest in the report.

6.5.4.12   Sampling of documented errors

As the data on errors accumulated from the survey described in 6.5.4.11), because of its focus on errors that might influence customer view of the company, it was apparent that the database did not capture all of the errors that occurred in the company. To get a feel for whether just the "tip" of the iceberg was being captured, or a greater proportion, two samplings were taken with a three month interval between them. These samplings gathered information on all of the documented errors that occurred in six animal facilities and the pharmacy unit. The problems of interest were those of enough significance for formal documentation in study data.

These two areas were selected because:

1.   They were regularly cited in the ACE Quality Feedback report

2.   The design of their work, and the style of control of that work, would make it certain that problems would be documented. The nature of error is usually black and white - it is unusual for there to be debate upon whether or not an issue is subject to documentation as a non-conformance activity.

3.   Both groups provided a cross company service, thus the sampling covered a wide range of study types.

4.   The types of errors were expected to be in the area of technical competence - the nature of such problems means that they occur and are normally reported as a "one-off" - they are generally not part of a continuing saga as might be the case with, for example, late reports or methodology problems.

5.   In terms of number of staff, combined the two groups represented 25 - 30% of the technical/scientific staff.

Consideration was given to the extent of which the findings in these two disciplines could be considered to be representative of the whole. As the groups involved represented such a high proportion of the scientific/technical staff, their work covered a broad spectrum of studies and there was no observational evidence to suggest that either animal management or pharmacy standards of performance or behaviour were

179

outside the norm for the company, it is argued that for the purposes of this sampling, the two groups are sufficiently representative of the company as a whole. Other technical groups performing bench work do have equivalent levels of documentation, but are far smaller in number (eg Immunotoxicology, Cell Biology). To do an equivalent evaluation in respect of other types of errors, such as errors in reports or absence of communication did not seem feasible.

The groups that participated were six animal facilities and the pharmacy unit. They were asked to keep a cumulative record for the month of errors or problems that needed to be drawn to the attention of the study director. The records included:

1. Date of problem

2. Study reference

3. Description of problem

4. Action taken and where it is documented

6.5.4.13   Hidden shortcuts survey

This survey was conducted to increase understanding of the origins and causes of error. Investigation into some of the errors recorded by ACE, and other documented errors, led to questioning of the work practices of some technicians. The researcher had a hunch that when errors appeared to have no logical explanation, there might be undisclosed factors implicated, which could include malpractice.

This was a very sensitive informal survey where technicians were asked

1.   To reveal and describe shortcuts that they took in the course of their work.

2.   Why and in what circumstances they might take short cuts

Shortcuts were actions contrary to Standard Operating Procedures. This type of activity, if identified formally, would at least be subject to comment and correction and at worst, the subject of formal disciplinary action. Thus to assure cooperation it was important to maintain anonymity of the respondents. No attempt was made to identify providers of information and a guarantee was given that no disciplinary action would be taken - this also meant that immediate formal moves to tighten up on the relevant procedure to eradicate the shortcut could not be taken. Providing such a guarantee was a dilemma for the researcher because, in her formal manager role, action would certainly have been taken to change poor practices had they come to light.

The information was gathered by a cascade process, whereby each person was asked to write down their "observation" by their supervisor. It was felt that co-operation would be greater if the each person was convinced by their direct supervisor that they should provide the information. Those starting the cascade process were told not to use coercion to force response where it was not offered.

6.5.4.14 Organisation Standing survey

Two surveys were conducted amongst senior managers to solicit their feelings about the standing of the company in respect of quality management. The surveys, both based on published literature on quality management, were intended as a stimulant to keep managers alert to QIP and quality management in general, and to give consideration to the "quality journey" that the company was supposedly travelling. The actual standing of the company in the eyes of these managers was of interest but of lesser consequence. The first survey was conducted following the introductory seminar launching QIP (November 1989) and the second in December 1991. The surveys were:

1. Managers were given a chart upon which comparative characteristics of organisations ascribing to Quality Control, Quality Assurance, Total Quality Control and Total Quality Management were placed in random order within each of twelve rows. (see Figure 6.15) This chart was based on ideas developed by Garvin (1988) and developed further by Foster and Whittle (1989).

   Managers were asked to circle the description they felt was closest to the current position of BFL. The number of descriptions circled under each heading could then be sorted and totalled to provide an overall opinion of how senior managers viewed the company quality status of BFL at the start of QIP.

2. The second survey asked managers to read an article "Levelling out the Future" (Dale and Lascelles, 1991) and using their descriptions, state at which of Dale and Lascelles' six levels, ranging from "Uncommitted" to "World Class", the company sat.

Figure 6.12 Chart used for first survey of organisation standing

At which level of quality do we sit? Circle one description in each row that you think best fits the current status of this company

	1		2		3		4	
Philosophy	Managing quality in.		Organising quality in.		Inspecting quality in.		Building quality in.	
		d		c		a		b
Goals	Defect detection		Habitually and competitively meeting customer requirements.		Activities to meeting "design" specification. Defect prevention.		Cost reduction and conformity to specification through continual improvement.	
		a		d		b		c
Responsibility for quality	Organisation-wide responsibility through devolved strategic vision.		Systems and operations. Through design and installation controls.		QC department. Individual inspectors		Centralised Quality Assurance Unit.	
		d		c		a		b
Quality application	Holistic.		Production process monitoring.		Post production inspection.		Total operational control.	
		d		b		a		c
Cost and Price	Specified cost at specified quality.		Cost reduction through quality improvement.		Cost reduction through quality improvement. Customers will pay for added value		Trade-off between cost and quality.	
		b		c		d		a
Improvement gained through	Project based activities to "do it right first time" and correction of own errors.		Increased inspection.		Customer driven habitual improvement.		Improved product specification and Statistical Process Control.	
		c		a		d		b
Driven by	Control.		Control and co-ordination		Vague system		Culture.	
		b		c		a		d
Focus	Meeting customer specification.		Customer focused. Meeting needs as perceived by the customer. Enhancing quality.		Production/system focus.		Product focus.	
		c		d		b		a
Customer	External.		Uncertain. Little concept of customers		External customer, Internal customer, Quality chain.		External/Internal customer boundary no longer valid; everyone is a customer.	
		b		a		c		d
Suppliers	Inadequate supplier inspection.		No supplier inspection. Supplier quality reliability company wide.		No supplier inspection - supplier quality reliability in all production process I.e., equipment, packaging, distribution etc.		Some supplier quality agreement plus inspection.	
		a		d		c		b
Tools and techniques	Product specification itemised costing. Rework.		Problem solving and quality analysis tools. Calculate cost of quality		Establishing QM structure. Culture of quality using measurement and monitoring as appropriate.		Procedures manual. Statistical based inspection processes and some analysis tools.	
		a		c		d		b
Company vision	Those with market leader's vision, competing on quality first, looking for sustained growth and increased market share.		Those who do not know any better.		Those with need to comply with regulations for survival.		Those competing on cost and quality with long-term profitability goals.	
		d		a		b		c
Column Totals	a		a		a		a	
	b		b		b		b	
	c		c		c		c	
	d		d		d		d	
Total	a		b		c		d	

6.6 Overview of methods at SciTec

In the corroborating organisation, the above methodology would clearly be impractical because of the extent of time and access constraints. Thus the methodology in the second organisation was restricted to interviews. This method was selected in collaboration with SciTec where it was considered that one-to-one interviews would be more acceptable to the subjects, and thus provide a better response than a questionnaire or survey.

The need for collaboration in agreeing the conceptual framework for research is absolutely critical when a researcher enters a competing organisation. The basis on which access and information is granted is trust and openness. Whereas the primary client system will benefit from the action research project, it is less clear as to how a corroborative organisation benefits. Coincidentally, at the time of the research interviews at SciTec they were at a cross-roads with their TQM programme and in the process of debating the direction forward. Thus a research intervention served to focus the minds of managers on the topic. TQM is frequently presented as a strategy for competitive advantage, thus information on SciTec's approach to TQM, or certainly any evidence of failure of quality in its broadest sense, could have been used to benefit BFL. Where the organisations are well matched and compete for many of the same work contracts, the risk to the corroborating organisation increases.

The methodological issues that had to be addressed were as follows:

1. *Endorsement to participate:* Permission to access SciTec and arrangements for this research necessarily had to be negotiated at top management level (with the Managing Director and Director of Administration and Personnel). Communication with SciTec Staff was made via the Director of Personnel thus demonstrating that the activity had top level support and effectively requiring the participation of selected subjects. Without this endorsement it is assumed that some subjects may have been unwilling or reluctant to participate.

2. *Selection of subjects for interview:* in most research it is preferable for the researcher to retain control of selection of participants. In the case of a

researcher as an employee of a competitor, this is not always feasible. In the primary client-system the researcher was free to approach any member of the organisation to participate in the research. Being exceptionally familiar with the organisation structure and staffing practices it was relatively easy to check selection for balance, stratification and distribution. In the corroborating organisation, the final selection of exactly who was interviewed was not the researchers decision. Not only did subjects have to be available at the time of the interviews, they also had to be selected by the person responsible for the collaboration. That the selection is representative is a matter of trust.

3. *Censored input*: most managers will have a natural loyalty to their organisation and to their own area of control. It had to be assumed that there would be a tendency to edit out any information which might damage either themselves or the organisation. Also, although managers may be happy to discuss negative aspects of their activities, the researcher's experience of handling visitors from competing organisations at BFL suggests that pride in an organisation leads participating individuals to ensure that the visitor sees and hears about the positive attributes of the organisation, such that they will feel worried about the competitive strengths of their opposition.

4. *Time constraints:* the researcher needed to organise times to visit SciTec to carry out research. Unlike the situation at BFL where people could be contacted repeatedly over a prolonged period of time, the information to be gathered had to be obtained within the timeframe agreed. Care had to be taken not to over extend the hospitality or test the boundaries of reasonable collaboration. In addition to time constraints in respect of visiting the organisation, it also had to be appreciated that the number of people who could be interviewed would be restricted by the time each interview took and the overall demand (disruption to operations and loss of productivity) at SciTec.

5. *Methodology restriction*: the selected method had to be that which would obtain the most valid and fullest information in the time available. Given the constraints of time and access discussed earlier, it was decided that semi-structured interviews would provide the richest source of data. The

subjects were selected to give a broad selection across the organisation but were restricted to staff in managerial and supervisory positions. In an ideal situation with unlimited access, the methodology of choice would have mirrored that used at BFL but even had this been the case, it would be unrealistic to presume exact duplication because of differences between the organisations. Because of this restriction, it was decided to use SciTec as a point of comparison and to test out information gathered at BFL. Given more time, it is considered that the data would have been enriched if discussions with groups of technicians had been held. However, to conduct such discussions would have been unreasonably disruptive of operations.

6. *Manipulated information:* although not apparent during the interviews, when researching in a competing organisation, the possibility of misinformation, vetoed topics or taboo subjects has to be considered. To avoid this scenario, which may well be contingent upon the personalities involved and their mindset, developing a relationship of trust is key. The researcher provided SciTec with background to the research objectives and was prepared to disclose research findings at BFL. During interviews subjects that were thought to be commercially sensitive or likely to be known only in confidence were avoided.

7. *Researcher Preunderstanding:* to conduct effective interviews of managers, the researcher has to quickly gain the confidence of subjects by asking questions relevant to their situation. Any suggestion of failure to understand the subject area or the activities of the organisation may be met with derision, or answers may be given to mislead. To some extent the employee-researcher from a competing organisation has a significant advantage over other outside researchers in that they do have an in-depth understanding of the nature and business of the organisation in which the study is being conducted. However, research subjects may expect evidence of that knowledge - should it not be apparent, responses may be framed to address the perceived calibre of the researcher.

CHAPTER 7
BIOFARM CASE STUDY
MANAGEMENT REACTIONS

Introduction

In this Chapter the results of the research activity intended to look at management responses to TQM at BioFarm Laboratories are reported. The research activity is that represented as box 3 in Figure 7 below. The interlinkage of the case study activities makes segregation of individual elements impractical therefore, although this chapter predominantly presents the results of the empirical activity (box 3 of figure), it does so within the context of the change activity (box 2). The data reported is that which pertains to box 4.

Figure 7.1   Conceptual model of action research case study at BioFarm
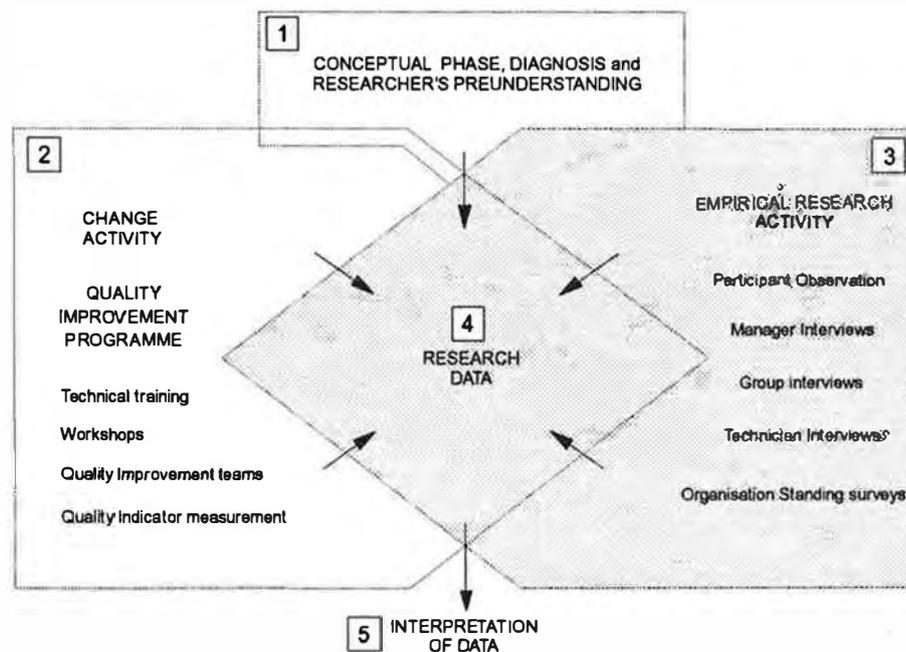
In this Chapter an overview of the findings and the responses to QIP are given, followed by a report of manager interviews and two surveys on BFL's standing in respect of managers perception of the level of quality management.

Organisation of Chapter

The sections in the Chapter are organised as follows

7.1   Introduction to case study findings

      7.1.1   Summary of BFL case study findings

7.2   Statement of Results - empirical research.

      7.2.1   Interviews - senior managers

            7.2.1.1 Interview purpose and respondent selection

            7.2.1.2 Respondent selection, profile and position in organisation

            7.2.1.3 Overview of interview findings

            7.2.1.4 Summary of Responses

                        Management Style

                        Autonomy and Standardisation

                        Workload and scientific development

                        Delegation

                        Communication

                        Formal communication mechanisms

                        Committees

                        Training and development

                        The company product

                        Identification of failures of quality

                        Issues linked to change

7.3   Organisation standing survey

      7.3.1   Timing and purpose of surveys

      7.3.2   Survey 1 - Organisation Quality Standing - Results

      7.3.3   Survey 2 - Results

            7.3.3.1 Summary of responses

7.4   Summary of main findings of interviews and surveys

7.1   Introduction to case study findings

The case study at BioFarm Laboratories produced a considerable amount of rich information from which the essence of the research data had to be distilled. Participant observation provided the dominant linking activity of the specific activities utilised to introduce TQM. The researcher had full-time involvement within the organisation both in the capacity of formal information gatherer and as change facilitator. Participant observation, as a descriptor of the information gathering process, is something of a misnomer in that its elements consisted of a mix of observation, physical data collection (written documentation produced within the body of the organisation as research evidence) and informal interview and discussion. The observation activities were supplemented by a number of measuring rods which were used to evaluate longitudinal activity. These measuring rods were described in Chapter 6; they provided quantitative data on the success or otherwise of a number of different aspects of quality improvement and provide the sort of "proof" of TQM effectiveness sought by many surveys on the subject. Later in this chapter the results from these various organised measurements are reported. To a major extent, the researcher feels that the use of measuring rods served to demonstrate exactly how difficult it is to understand the true nature and extent of change in a community when relying upon a predominance of formal tools of measurement. It was the immediate involvement, sharing in the experiences and observation of the organisation community and its varied responses to change that provided the greatest insight into the factors that influenced the implementation of TQM.

7.1.1 Summary of BFL case study findings

The data suggest that there are particular characteristics of a professional scientific organisation in respect of the profile of its people and customers, the nature of its "product" and the regulated environment in which such organisations operate, that complicate and sometimes frustrate the implementation of TQM.

At the commencement of the process of TQM implementation in the form of QIP, there were found to be inconsistencies across the organisation of a number of factors, in particular the extent of commitment to the process, the measurable contribution and the

189

achieved quality of work within a function or department. Similar inconsistencies, in terms of the gap between groups, remained at the end of the end of the research period. However, the data suggest all of the groups had progressed in the desired direction albeit that the achievement was unequal.

In the presence of top management commitment, the most influential factor in the extent of the acceptance of TQM principles and implementation was observed to be the style of management adopted by the senior person in each department. The attitude of that person to TQM was considered to be linked to a number of factors, most significantly these included the personal role that he or she perceived they had in contributing to the organisation and the nature of activities of the particular discipline. In turn, that contribution defined certain characteristics of the person such as age, scientific education and training, and external professional standing which, in their turn, were considered to be influential on the individual's mindset and the extent to which he or she viewed the necessity to change. Of only marginally less importance was the personal management style of other individuals and the degree of freedom that they allowed their subordinates to change practices in pursuit of improvement. It was observed that the control of BFL managers in this respect covered a broad spectrum from manifest encouragement through to reprimand for attempting change.

Commitment and action at the senior manager level remained uneven throughout the period of the research with levels of activity of some at the minimum level they could give without attracting too much adverse comment. Towards the end of the research process, most managers were able to identify differences in commitment to QIP albeit that none claimed lack of commitment themselves. Interestingly, at least three senior managers argued that the measure of success, based upon hard evidence of involvement and of improvement through measures, undermined the true purpose of TQM, i.e., to change the behaviour and way of thinking of individuals. They argued that estimation of their progress on the basis of hard evidence was *"insulting"* to the actual progress they had made in terms of changing the mindset and attitudes.

> *It's very easy for me to look at the numbers of slides the pathologists reads - it goes up all of the time - but it's not so easy to measure professional development which achieves improved quality but does not have the label of QIP. Personally I feel that professional development of staff has far more*

> *value than producing reports claiming how good you are or sticking up*
> *pretty, but probably statistically useless, charts on the wall* [L15] (Senior
> manager interview, November December 1991)

It was found that the impact of the Quality Improvement Programme was particularly effective in respect of breaking down of departmental barriers and the development of a culture of cross-functional cooperation. These improvements were most prevalent amongst middle managers, the level at which failures of communication, both across and within function, was previously observed to be relatively common. It was also found that the TQM concept of the "internal customer" was readily accepted although there was ample evidence of the failure to apply that concept.

Good Laboratory Practice (see Chapter 5), the long established obligatory quality compliance standard of PSOs, was found to be a particularly important influence on the quality improvement achievements of the company. GLP was considered by the researcher to provide something of a dilemma in that it provided the means for constant monitoring and rigour in the organisation and conduct of the scientific operations of the company, yet through those attributes and by design, it was thought to stifle the creativity and spontaneous change which may motivate individuals to feel in control of their job. GLP was also noted to emphasise a division in the understanding of the notion of continuous quality improvement between those employees who had been subject to its influence for many years (the scientists and technicians) and those of non-scientific and administrative disciplines. An interesting observation was to do with the extent of the difficulty that the Quality Assurance staff experienced in their acceptance and contribution to TQM. The group had the greatest insight and cross-organisation perspective within BFL of the achieved standards of the planned organisation of science, methodology and data quality, yet they were reluctant to share this perspective with others. They were generally negative in outlook tending to be the critics and purveyors of doom within the organisation and felt that they did not want to be seen in a central quality policing role. A particular worry was the potential of TQM to generate "new thinking" and encourage initiative, consequently resulting deviation from documented procedures and thereby non-compliance with GLP. Despite these worries, there was no evidence that TQM thinking in any way damaged GLP compliance or followed a divergent pathway.

191

Differences were experienced by disparate functions in their ability to identify targets for improvement (termed *Quality Indicators*). Overall it was considered that these difficulties were associated with the nature of the activities and "product" of a group and/or the failure of a group to understand the purpose of measurement. The "real time" unique nature of the major part of the organisation's product, that is *in-vivo* (live animal) testing, was considered to provide a major barrier to the application of widely used quality improvement techniques. Problems in this area generally related to the need to refine or develop complex techniques to gain improvement, pre-existing high levels of satisfactory performance and lack of identifiable volume of "common" countable entities that could be considered as candidates for improvement. Activities which were widely perceived to be in need of improvement were those of a complex nature, an example being the timeliness of the scientific reports, the improvement of which was under the direct or indirect influence of a number of different disciplines. The concept of measurement of improvement at a personal or system level appeared never to be fully accepted where many individuals continued to see measurement as an unwelcome, uninteresting, time consuming exercise that provided little value to the TQM process. An example of this mindset is given by one of the organisation's toxicologists

> *Some of my colleagues, I imagine, are happy to talk about masses of Quality Indicators and activities but I am more interested in talking about attitudes and concepts - I find the mechanics rather dry and boring. Who wants to know about quality indicators - the details are of little relevance to people outside the intimate circle of the recorder. I keep my own measures - I have done for years, but these provide me with information - they weren't started to measure quality* [L11] (Senior manager interview, December 1991)

The disciplines that found improvement processes the easiest to identify and apply were the organisation's two large technical groups, Animal Management and Histopathology. These groups were observed to be enthusiastic to participate in companywide activity. In addition to looking to improve their departmental product, they were also noted to provide positive influence of those groups that exhibited less enthusiasm but necessarily worked in partnership with the technical groups. The so called "leading science" groups, principally those with major responsibility for project management and with direct accountability to the external customer (the client), were observed to be

considerably more reserved in their acceptance of the TQM philosophy and failed to provide much evidence of active participation. The basis of the difference was considered to relate to two main factors, 1) the "product line" activities of both groups and 2) the style of the management and strategies applied to motivate larger technical work groups.

Although the non-scientific disciplines moved forwards from their relatively retarded starting point, it was noticeable that a proportion of staff within these groups experienced some problems in understanding the notion of quality improvement. In groups such as Finance and Accounting, where considerable effort was made to improve quality and provide an improved internal service, disillusionment was observed after some months because of their relationship with the scientific groups. Staff of the scientific disciplines tended to take on a superior attitude and emphasise failings of the non-scientific groups when the opportunity arose. They viewed these groups as erring servants who were employed to serve and not to question. The attitude is demonstrated in the following interview statement from a senior scientific manager

> *If I had any choice, there are some departments that I would chose not to work with. If they were responsible for earning money for the company, they might think a bit harder before they give their customer such a load of rubbish as I was given the other day* (An estimate of project costs and selling price). *The incompetence of some of those people in finance belies belief - sometimes you'd think that they have never even heard of quality or customer satisfaction* [L7] (Senior manager interview December 1991)

The researcher's further investigation into the basis for the above comment elicited the following response

> *(He) deliberately doesn't give us the information that we need to do the job properly. We are just trying to pull a price together and we don't understand all the fine details of the science. We are told at the very last minute that the price is urgent - if we have to price a rat study, how are we supposed to know that these are special ultra-expensive rats that we haven't used before or extra investigations to the standard protocol. We just think he likes to make us feel silly and incompetent - It's like a game with (manager* [L7]*) trying to trip us up - he knows there are hidden activities and then he shouts at us when we under-price. I think he does it deliberately. I think we should have a bit more consideration of what we need to do a job right because we are not idiots.* (Finance manager interview, January 1992)

On a number of occasions conflict was noted to occur between work groups within functions and between functions. The conflicts were found to emanate from several sources, most notable was the competition for recognition and the dispute over authority for control. The former was observed within technical groups and was predominantly linked to competition over improvement measures or disputed "ownership" of improvement initiatives. In the second case, conflict was noted between the study director groups and animal management. It originated from the desire of animal management staff to change procedures and systems at a less controlled and considered rate than the study directors thought appropriate. The resultant "stalemates" frustrated both groups. One animal technician explained her frustration in trying to agree a change in a technical procedure which she considered would be highly cost effective for the organisation thus:

> *They (the study directors) just try to block any move that did not originate from them, however good the justification"* and to *"fail to understand the business implications of their refusal to change .... we have worked for hours on the new format for clinical signs - we've done the SOPs and we produced a report and justification... we've not just sat down and made up an idea - it's taken ages, months and months .... I don't think they even bother to read it".* (Technician group discussion February 1991)

Conversely the study directors felt that the animal technicians failed to understand all of the implications of what they proposed. They considered that the animal technicians were far too motivated to achieve more efficient working practices that they failed to understand the science behind decisions or the implications of change on individual projects. The Study directors felt that they were often placed in the unreasonable position of having to explain problems to disgruntled clients and as such considered that the benefits of a proposed change should be manifest and proven before implementation. A feeling expressed by one study director and widely supported by others of the group in a group discussion was:

> *The animal technicians don't have to answer to the clients if things don't go to plan. Sometimes we think they don't realise just how difficult it is to get the clients to accept change. It takes up a lot of time and after the client has agreed, we then have to go back and explain why it (the improvement) didn't work. It can make us look like real idiots and the technicians just don't understand that .... sometimes we just get worn down and we give in - that doesn't mean we think it's right - just that the continued debate wears us down. We just have too much to do to spend more time more arguing...."*
> (Toxicologist group discussion, February 1991)

194

Activities such as elimination of error were observed to be complicated by the scientific nature of the business and the business base of the organisation. It was noted that many "failures of quality" (any activity which caused a sponsor disquiet), were often incidents of a singleton nature, which were not easily repeatable, and which could result from one or a mixture of factors including differences in scientific interpretation, the "experimental" nature of a technique or very frequently, the unwanted influence of unknown variables. As such, the familiar messages of quality improvement such as "get things right first time" or "aim for zero defects" or such tools as performance measurement of improvement, did not readily apply.

The pressured nature of the contract business was observed to influence resource availability such as adequacy of space, equipment and in particular, skilled staff. The two most frequently cited barriers to improvement were related to resources. One was "lack of time to do the job properly". Individuals frequently displayed positive attitudes but felt that the volume of work that they were compelled to handle made it almost inevitable that avoidable mistakes would occur. One technician gave the following view of the impact of work volume versus quality improvement

> *The demand for quality work is unfortunately greater than it was in the past. I say "unfortunate" because it should always have been there. You can't switch off - you are always looking for an avenue to switch off but you can never find it. Everything seems to take much longer than it did in the past because of the care that you have to put in to meet the quality expectation. The pressure is much higher and the demand is much higher -everyone must produce better quality work. The team leaders have so much pressure - they spend much more time worrying about planning and administration.*
> (Technician interview, May 1992).

The second was inadequate investment in information technology, predominantly electronic data capture, processing and reporting systems for the core business activity of toxicology. Amongst a number of other factors that toxicologists thought required attention, they particularly called for investment in more IT

> *(we need) more computers and electronic data capture. If you think about it, the central activity we perform, it involves the collection of data - mostly manual, entering data onto the computer, processing it, analysing it, turning it into graphs, regurgitating it, checking it time and time again, QAing it, reporting it. We are absolutely screaming for more efficient ways of doing that and computers seem the obvious answer......*
> (Toxicologist group interview, February 1991)

195

As the research progressed, so too did the economic recession of the early 1990s. Towards the end of the empirical research period the influence of external economic factors was observed to place stresses on the organisation. Such stress factors included reduced profitability associated with a reduction of market size, tighter competition and increased control over expenditure within the organisation. In the case of BFL upper management called for a freeze on employment of new and replacement staff and increased focus upon revenue earning activity. Non-revenue earning activity such as training, internal meetings, attendance at scientific meetings was considerably reduced. This resulted in a reduction of organised training and the type of gathering that had served to erode departmental barriers and facilitated the discussion of and introduction of quality improvement initiatives. A change of corporate structure and new executive management resulted in a change of corporate strategy and the engagement of management consultants to implement Business Process Reengineering. Although it can be argued that TQM and BPR are based upon many of the same principles, in the case of BFL the two appeared incompatible. The problem for the organisation was that QIP was internally sponsored and driven whereas the BPR process was externally driven, demanded by BFL's corporate masters for BFL and others of the newly merged company. Conflicts of philosophy, strategy and time meant that it did not prove possible to run the two programmes side by side.

7.2   Empirical Research - Statement of results

7.2.1   Senior Managers interviews

7.2.1.1 Interview purpose and respondent selection

Interviews were conducted with eighteen senior managers between April and July 1989. Using a common schedule of open questions their views upon the following issues were sought:

1. Personal management style and delegation
2. Communication
3. Effectiveness of management committees
4. Staff training and development
5. Perceptions of key quality issues and blocks to resolution

To form the interview questions and provide focus, pre-interview observations were recorded (Appendix 7, 7.1)

7.2.1.2 Respondent selection, profile and position in organisation

The selection of respondents was based upon their seniority in the company hierarchy, membership of management committees and extent of influence over people and company strategy. The intention was to interview managers of all functions thus obtaining a broad cross-section of views from those considered to have greatest potential, through their actions and attitudes, to influence the implementation of QIP. Respondents are listed over the page (Figure 7.2) and their position in the company hierarchy is shown in Figure 7.3

Figure 7.2   Listing of interview respondents

Subj Ref.	Pseudonym	Position in Organisation	Membership of Committees	Academic Qualification	Joined BFL
L2	George Cross	Director, Scientific Operations	POL. OPS (chair), FIN	BSc	1975
L3	Ben Nevis	Financial Controller	FIN(chair), ADM, POL		1984
L4	Boris Grant	Head, Short Term Studies	OPS, SCI, BUS	BSc, MSc	1979
L5	Richard Rogers	Director, Strategic Planning	POL	BSc, MRPharmS	1978
L6	Ron Dyke	Head, Histology	ADM, BUS	MSc, BSc, MIBiol, CBiol	1977
L8	Malcolm Mack	Chief Teratologist, Repro Studies	-	BSc, MIBiol, CBiol	1974
L9	Robert Bruce	Deputy Head, Repro Studies	-	PhD, MPhil, BSc, DABT	1976
L10	Michael May	Head, Long Term Studies	OPS, SCI	BSc, MSc, PhD	1980
L11	Mark Gorman	Chief Scientist, Long Term Studies	-	BSc, MIBiol	1973
L12	Steve Emory	Head, Chemistry	SCI, BUS	PhD, BSc, CChem, MRSC	1989
L13	James Swift	Head, Pathology	OPS, SCI (chair)	PhD, BMV&S, FRCVS, DipRCPath, MIBiol, CBiol	1984
L15	Len Loval	Section Head, Short Term Toxicology	-	BSc	1974
L16	Larry Kissinger	Head, Business Development	BUS, SCI	PhD, CChem, FRSC	1983
L17	Keith Holloway	Director, Resources	ADM, POL	BSc, MInstAM(Dip)	1978
L18	Chris Crabtree	Deputy Head, Animal Management	-	FIAT	1975
L19	Brian Snell	Head, Quality Assurance	-	BSc	1979
L20	Bert Richards	Section Head, Pharmacy	-	BSc, MRPharmS	1985
L22	Kevin Evans	Head, Computer Science	OPS	BSc	1980

Key: OPS = Operations; FIN = Finance; POL = Policy; ADM = Administration; SCI = Scientific;

BUS = Business Development (Sales)

Figure 7.3   **Senior Manager Interviews: Respondents and their position in the BFL hierarchy**
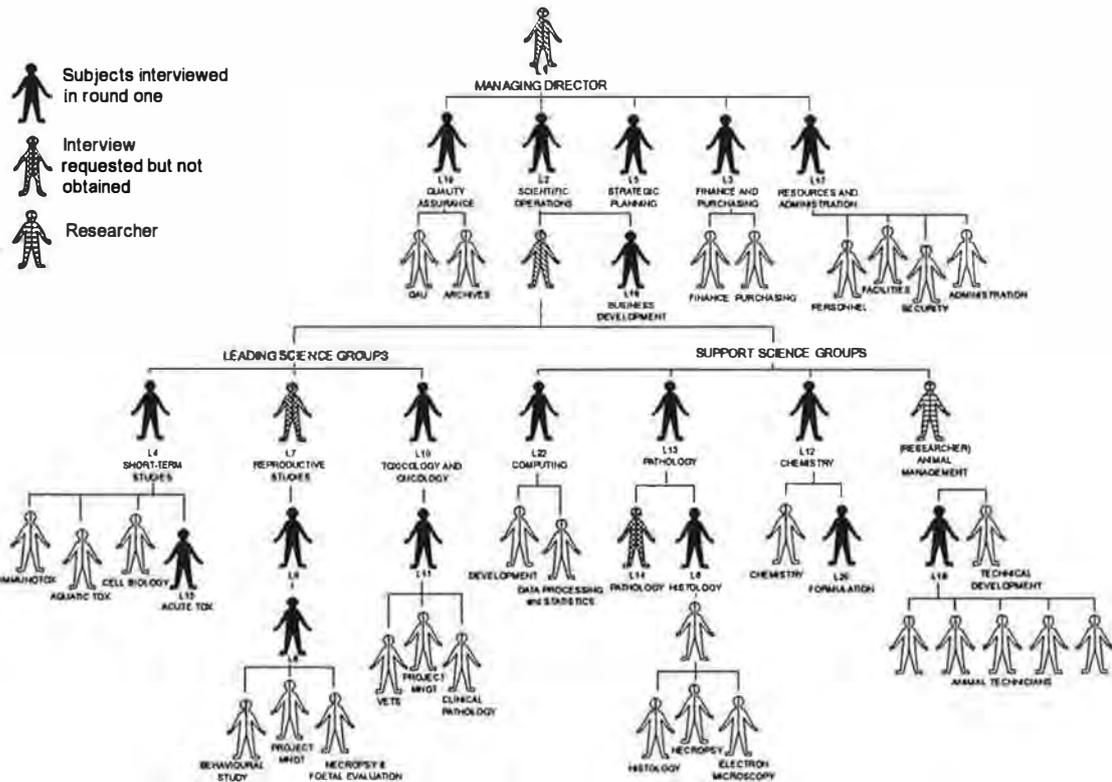
Of the managers selected, all agreed to be interviewed. In the event, Dr Harry Hill, Director of Reproductive Studies [L7] failed to be available on four planned occasions thus no interview was obtained. From the functional point of view this loss was of little consequence because the next two in line of seniority in the department were interviewed. However, the loss of the personal views is unfortunate as Dr Hill Harry was known to hold strong views on standards of achievement, and was observed to have an interesting dominant management style. He was also one of the longest serving senior managers (17 years) and sat on four of the standing management committees. Interestingly, although Dr Hill was not interviewed, his style, actions and achievements were frequently cited by other managers as examples of extreme behaviour. No other managers received similar citations.

7.2.1.3 Overview of interview findings

The data obtained from these interviews provided the backcloth against which the Quality Improvement Programme was introduced at BFL. This picture was of importance for the design of other elements of the research programme and for the final shaping of the Quality Improvement model to be implemented. The reluctance of the managers to accept the TQM programme proposed by a TQM consultant in 1987 had been replaced by a willingness to recognise the desirability of a quality improvement programme. TQM, as originally perceived by most of the group, was still considered to be a concept that was inappropriate for the type of business and culture of BFL.

Respondents gave a consistent picture of the problems of BFL and the barriers likely to interfer with progress. Barriers included communication, seen as a major cause of error and poor interdepartmental relationships, high staff turnover and resource deficiencies - in particular, lack of skilled staff and the need for more use of Information Technology. The element of the company product considered to be most wanting was widely recognised as late reporting to clients; this aspect of performance had been the subject of historical monitoring and was known to be far less than desired. The scientific/technical performance of the company was seen to be at the top of the market

Responses were open and at a depth of consideration appropriate to the level of intellect and experience of the respondents, all of whom had extensive experience and were educated to graduate level and above. The benefits of improvement were acknowledged, most commonly through recognition of the need to be competitive in a reducing market place. There was no suggestion of non-cooperation or reluctance to progress the company although even at this early stage, differential quality achievement levels across departments were recognised with around half of the managers indicating that they saw failing in others. Responses to questions on receptiveness to change suggested to the researcher that reservations existed on the likely success of any change effort. These reservations stemmed from the company's relatively poor track record of seeing through initiatives. In respect of the respondents personal desire for involvement, a range of responses from ambivalence to enthusiasm were noted; there was a preference for an evolutionary rather than a revolutionary pace.

7.2.1.4 Summary of responses

Respondent views of their Management style

The words and phrases used by the respondents to describe their management style are presented below. They are placed in three columns to give an indication of the leaning toward either people involvement or towards autocracy. The selection of this axis is based upon the viewpoint that a management style characterised by openness and involvement of people, may be more successful in the implementation of quality management than the closed, autocratic style. The axis has an imprecise scale and placement is subjective based on nothing more than the researchers association of the word or phrase with leaning towards one direction or the other. Nevertheless it does provide a useful visual way of viewing the spread of styles. It was noted that several managers used words which fell in more than one column.

Figure 7.4   Phrases used by respondents to describe their management style

<-------- Toward people involvement		Toward personal directives -------->
Open (L16)	Approachable (L16)	Quite closed (L4)
Open door (L9)(L11)	Fairly /reasonably open (L2)(L3)(L11)	
Communicative(L17)		
	50% People orientated (L17)	
	50% Task/procedure orientated (L17)	
Democratic (L6)(L9)(L12)(L22)	Flexible (L16)	Autocratic(L11)
Consensus (L2)	Democratic to some extent (L15)	Not democratic (L8)
		"the boss is the boss"(L12)
Team based (L12)	Involved (L15)	Persuading (L4)
Participative (L13)	Motivating people (L4)	Leading from the front (L3)
Consultative (L5)(L12)		
Relaxed rather than contrived manner (L17)	Fair (L8)	Stern (with juniors)(L20)
Fairly relaxed (L18)		Strict (L6)(L20)
Fairly relaxed with seniors(L20)		Arrogant (L6)
Relaxed (L19)(L22)		Uptight (L20)
	Oiling the wheels (L10)	Putting my ideas into action (L10)
	Change hat according to situation (L18)	

201

All managers described themselves in a style recognisable to the researcher through previous observation, although they generally restricted themselves to a few words. They tended to emphasise positive or neutral characteristics leaving out negative features of their style. Descriptions were often preceded by phrases such as "*I think I'm...*", "*I like to think of myself as....*", " *I have never really thought about it...*" suggesting that consideration of one's way of managing was not particularly important.

Only two managers (L12, L8) stated with any confidence that staff reporting to them would described them as they described themselves. Others thought that there would be variation of view according to such factors as seniority, frequency of contact and capability of the observer.

Those who spoke about consultation (10/18) gave the impression of a desire to share ideas, allowing people to disagree and criticise. This group clearly believed in the value of consultation and participation but nevertheless indicated that at the end of the day, it was they who retained responsibility. Illustrative statements include

> "*Although I have strong views about things, I encourage everybody to argue with me or disagree*" [L4]

> "*I ask for people's opinions but I think that the man at the head of a particular department has to make the decisions*" [L5]

It was noted that several managers recognised that they adopted different styles according to whom or what they were relating at the time. In one case (L20) this change of style, based on the seniority of the contact, had been observed in the field as inconsistent and counter-effective in achieving results. In the other case (L18) it was observed to be an effective way of commanding a situation and achieving desired results.

Views on whether management style would influence the adoption of QIP varied. The consensus was that management effectiveness mattered more than management style *per se* and that there were many different styles that could be effective. Dr Steve Emory [L12] felt that what goes on in a department is:

> "*a reflection of the HoDs management style and personality and that includes the way in which the whole department reacts to initiatives such as QIP*".

He mentioned the differing styles of departments ranging from those *"very, very autocratically run"* to those that are run *"flexibly, in a relaxed style and very democratically"*

Ben Nevis, the financial controller, segregated management and quality thus.

> *"In my view management is management and quality is quality"* [L3] .

He felt that provided the desired endpoint was reached, the style of the individual manager was irrelevant

> *"The method of achieving (that) quality, whether it is an aggressive go-getter attitude or a relaxed, philosophical "lets lay back and think about quality" doesn't matter provided it is what the company needs...."* [L3]

Richard Rogers [L5] used metaphor to demonstrate the same point

> *"Management style is not everything. Management ability is more important.... you cannot say that one particular school of painting is better than another; it's a matter of opinion. What you can say is that it is possible to paint very well or very badly in any of the different schools. The same is true for management style...."* [L5]

Several respondents (L9,12,17,13, 22 and 10) commented upon negatives aspects of the influence of management style.

Dr Robert Bruce [L9], deputy to Dr Harry Hill (not interviewed) raised the issue of the ability of management style to stifle initiative. In his experience, a manager who controls too tightly and is often critical, reduces staff motivation and their desire to improve, consequently making them inhibited about trying to change things. Robert was clearly talking about an issue close to home:

> *"The real problem is that when you have worked in a department with the same boss for years, you unconsciously or even consciously, begin to adopt his style because that keeps you in favour. I am sure none of us like to admit that we sacrifice some of our own style but I think we do. I think this will have an impact on QIP because if your boss doesn't appear to want it, then you either have to be very brave and resist or you are forced to follow"* [L9].

His comment supported observation of the style of Harry Hill as a powerful autocratic scientist, controlling all activities in his department. This "cloning effect" was evident in other departments where, depending upon the style of the head of the group, it had either negative or positive consequences. In the department of Toxicology and Oncology, the group were observed to be resistant to new ideas and generally cautious of change. This followed the style of the head of that group Dr Michael May [L10], who

was frequently exhibited signs of reluctance to adopt new concepts and procedures. In the context of selling QIP to the company, he somewhat negatively recognised the difficulty of transcending the layers of the hierarchy to deliver a message to all staff. He noted that:

> *"You cannot sell it (QIP) to the department heads and expect them to pass it down the line...... It will be very, very difficult to get across, and I'm not sure any of us knows how. I hate to say it but I think the consultancy sell approach is what is needed".* [(L10)].

Michael's observation was indicative of his general mindset; he was observed to frequently put up hurdles, often describing why something couldn't or shouldn't be done, rather than finding ways to do it. What he was effectively saying is "you haven't sold it to me so don't expect me to sell it to others"

The issue for QIP was whether the negative impact of "cloning" could be overcome such that the consensus view of the need to improve quality through QIP, would be adopted. This was state was described by George Cross

> *"There are a variety of people involved, all of whom have been used to a fair bit of autonomy and some of whom are more interested in what affects them immediately than what affects others. There are some people who are less likely to reach a compromise or accept a consensus view than others. These are people who ignore the consensus view and go their own way....... I would like to have a bloody great row with Harry Hill about it, but I can't as Greg Holmes (the Managing Director) won't support me"*[(L2)]

For QIP to be successful, it was clear that some changes in management approaches and style would be necessary. Richard Rogers presented the view that it might be very difficult to influence the style of somebody who had been an autocrat for many years.

> *"I think there are people who adopted their present style so long ago that it would be very difficult to change them now - they have probably gone too far"*[(L5)].

Ron Dyke[(L6)] observed to be a radical thinker and often forthright, if somewhat emotional in his views, felt that affirmative action might be required:

> *"We are going to have to sort this one out - egos might get bruised but eventually people will just have to get used to it. If someone sits there and says "I want all of your views" that probably will not work.... It's going to have to be someone, George Cross if you like, saying "I am telling you, this is how it's going to bloody be - I don't care if you like it or not - that's it!. In the long term, that approach won't build good relations. It starts to be like management disciplinary action - and very counter to QIP"*[(L6)]

Views on autonomy and standardisation

The autonomy that departments had historically been permitted was generally liked by those at head of each group but was observed to be one source of non-cooperation between departments. The style of QIP was devised to avoid the resistance that was anticipated to any overt reduction in autonomy through imposition of centralised structures. However, it was felt that this approach provided a gateway of opportunity to opt out of QIP. Autonomy allowed individual styles of management, and individual approaches to work style and organisation to be perpetuated. Observation suggested that whilst there were benefits to the company in terms of such desirable attributes as focus on clients needs, these same attributes could work in reverse where, for example, a client assumed a communication would be shared and it was not. The aim of QIP was to retain the benefits that had accrued from autonomy, yet breakdown barriers to promote cooperation.

Before QIP had been formally launched, there had been initiatives directed at greater standardisation and simplification of the company "product" and process. These initiatives had been targeted on two areas:

1. In-life data recording

2. Reporting style

Both initiatives struggled because they crossed departmental boundaries and questioned the value of the "old way of doing things". The Standardisation and Simplification working party was the pigeon of a group of technicians from the department of animal management. This group not only crossed departmental boundaries but was seen by the leading science departments as transgressing the "invisible" technician/scientist barrier. For QIP, this initiative was intended to identify and remove undesirable inconsistencies in procedures and simplify over-complex data recording processes. The aim was "error cause removal".

Activities on report standardisation had been directed at the development and adoption of a company style instead of different styles and formats originating from each leading science department. Essentially, the intention was to present standard information in a standard format. One of the objectives was for the company to be viewed by its clients

as one cohesive operation rather than a number of microcosms with a common name. The issue is presented diagrammatically in Figure 7.5. The figure shows the continuum of autonomy whereby the pull towards centralised control and standardisation increases the degree of "product" uniformity. The pull in the opposite direction, towards greater autonomy, results in individuality within a product and inconsistencies between products. The issue for QIP is identification of the "zone of acceptance" whereby the pull for standardisation (and subsequent error reduction) does not overwhelm the need for personal contribution and independence of the scientist. Almost needless to say, the zone of acceptability must meet the needs of the client.

Figure 7.5   Continuum of autonomy linked to product standardisation

Pull towards standardisation

Pull towards autonomy

Standardisation of product

AUTONOMY

Individuality of product

Inconsistency between products

???? ZONE OF ACCEPTABILITY ????

Centralised control

By the book activities
Standardisation of all systems,
procedures and systems,
resources

Total decentralisation. Local control

Freedom to work
independently without
reference to other groups or
central direction

During the interviews Managers were asked if they would be willing to sacrifice some of their autonomy if it achieved greater consistency. Every respondent perceived some benefit in achieving greater consistency and nobody argued that the current state of autonomous departments was of immediate benefit to the company. With questions of this nature, it was felt that respondents may have answered in a constructive manner, adopting the "company view" rather than expressing their individual view. Certainly, the well reasoned responses did not support observation of the actual behaviour of some. Opinions varied upon the extent to which autonomy ought to be surrendered. The issues that were mentioned related to the desire to retain ownership, sometimes by

making a recognisably individual contribution to the "product", the value of independence to the scientist ego, versus the acceptance that greater consistency was not a bad thing and the conflicts that arise in attaining consensus.

A tabulation of responses to the question "Would you be willing to sacrifice some of your autonomy if it achieved greater consistency?" can be found in Appendix 7, 7.2.

Summary of responses

There was not uniform agreement on the benefits that might be gained from increased standardisation. Some managers questioned the need for companywide standardisation in the context of the variable nature and organisation of activities undertaken within the different functions. Where they thought benefits might accrue in respect of report production, they were willing to sacrifice some autonomy to achieve that. But that sacrifice did not extend to the broader management aspects of the departments. Boris Grant provided reasons why he favoured autonomy over centralisation for the varied small activities in his group - Boris was observed to be a strong advocate for autonomy, believing that his small groups could function more effectively without the burden of centralised systems and company financial overhead.

Drs Swift and Bruce saw the need to retain scientific independence as an issue. Whilst this response was predicted, it is interesting because the push for greater consistency had little focus on the scientific aspects of work. It was as if this argument was used in a protectionist manner, sending out the message of "damage our integrity and you have trouble". This was seen as a subtle form of resistance to change. As it was, the company recognised the need to assure that scientific integrity was never compromised; this was in the interest of being seen as an independent organisation. It could be concluded that Dr Swift is making a statement for retention of the status quo if his view on this matter is put in the context of his comment:

> *"We all like having the freedom to run our groups as we see fit. I don't believe any of us should be forced to treat our very different groups in the same manner because they are made up of such diverse types. Some departments are made up of large groups of young technicians and other (Pathology) have older, experienced staff who want to do things their own way. Pathologists won't take kindly to the sort of hand holding that is necessary in some areas".* [L13]

The autonomy extended to the heads of departments was not necessarily extended further down the hierarchy as noted by Mark Gorman, the Chief Scientist in Toxicology and Oncology:

> *"The autonomy is obviously very welcome for those at the top of the tree - but I'm not at the top of the tree. The freedom I have is restricted to those areas about which Mike (HoD) has no experience or that he has graciously allowed me to handle."* [L11]

Mark held a senior position in the department of Toxicology and Oncology. This department consisted of two groups that had been merged into one several years previously. Mark had held the departmental head position for a brief time before the formation of the combined department. The issue within the department was still to achieve intradepartmental consistency. Observation suggested that the relationship that existed between Mark and his new boss was a disturbed truce. He felt that his boss went into meetings and agreed certain actions which were not practical and did not take into consideration the current structures. Agreeing to multidepartment Standard Operating Procedures[1] provided such an example. The frustration of getting consensus is illustrated by Brian Snell, the head of quality assurance. He provided an example of an SOP for checking that animals on study received the correct dose form in the correct amount. There was wide agreement that such an SOP was required but multiple different ideas about the process (which actually had a very straightforward objective). The practice was that SOPs that covered the same activity in several departments were authorised by the head of each affected group. As this SOP circulated, each would make an amendment, putting the process back to draft.

> *"We were four years trying to evolve an SOP for dose accounting which ought to be a pretty simple thing.... A large amount of the difficulties include resistance to change, intransigence, plus everyone wanting to keep their autonomy."* [L19]

Ultimately, the SOP was signed by a single signatory at Director level and was thus regarded as an imposition. Mark Gorman's view was:

> *"I'm not sure it is essential to have full consistency on SOPs, for example. The only way this could be achieved would be to have fixed guidelines as to what an SOP should or should not contain....... A lot of time and effort is spent on making SOPs consistent and I question whether all that effort is cost effective."* [L11]

---

[1] A Standard Operating Procedure is formally authorised, written methodology that describes the exact way that a technique or process must be conducted.

The issue for QIP was the level at which decisions on changes were to be made. Those involved in hands-on work and in the thick of operations were often better informed than their head of department about the appropriateness of a proposed change. Heads of department were often poor at delegation, in some cases because they wished to retain control, and in other cases because of their perception of staff capability, thus decision making tended to rest with the upper echelons. However, implementation of those decisions often rested at the next layer down. They expressed such opinions as:

> *"Sometimes, when suggestions for standardisation arise, they are not well enough thought out and there is a good reason why the suggestion is not appropriate but sometimes, it's just sheer bloody-mindedness - not invented here."* [L9]

It takes little to see how the so called "sponge layer" of middle managers developed whereby agreement to act did not translate into action.

Views on workloads and scientific development

The interviews provided insight into:

a)   managers view of their own workloads

b)   the perception of shortage of man-hours as a barrier to quality

c)   the issue of scientist development

A major reason for the rejection of the consultant led "traditional" TQM programme had been the lack of available hours at management level to drive the programme and at operational level, to be involved. That concern had originated from a subset of the group interviewed. QIP was envisaged as far less time-demanding but nevertheless, still requiring sufficient input to develop and maintain momentum. In other words, managers would still have to put in appropriate time, but could control when and how much.

A summary of responses to question on workloads is provided in Appendix 7(7.3).

It was found that most respondents felt that their personal work required more hours than those available in the standard working day. Most of these respondents were holding positions of authority whereby they had the freedom to control their work load through delegation and their local organisation and systems, yet most had not

maximised the potential of the opportunities. Only two, Chris Crabtree [L18] and James Swift [L13] felt that their work load was about right. Chris Crabtree noted this as a change from the past whereas James Swift, who described his work as *"achieving what I am expected to achieve"* took the approach that any failure on his part would cause him to look at his pattern of work with a view to further optimisation.

Other respondents managed their work loads by regularly working additional hours and/or taking work home. Some managers saw the work load as detrimental to the quality of output. Overall there appeared to be an acceptance that high work volumes were inextricably linked to the role of a manager in a contract laboratory. In general, respondents rationalised the work volume in this way rather than looking to their style of work, systems or more effective delegation. Feelings about the work load range from acceptance, to coping, to frustration. There was some recognition of improvement in some areas.

The matter of workloads is interesting because it throws light on the culture of the company. The growth of the company had been characterised by a dedication to getting the job done through sheer hard work, long hours and dedication. With resources and expertise in short supply, it was common for scientific staff (this included the founders of the company) to work extensive hours. The struggle to get a foothold in the market and the nature of the work, governed as it is by tight deadlines, meant there had been no other option. This strong work ethic persisted beyond the time when it was absolutely essential for survival and growth. For example, the Managing Director set a behavioural norm by arriving early in the morning and rarely leaving before 7 o'clock in the evening. As one manager put it:

> *"Working excessive hours becomes habit forming. You do it because you always have. You do it because others do it - you certainly don't want to be seen to be shirking by leaving work, heaven forbid, at the end of the normal working day. And you do it because sometimes it is necessary - in the past it has been essential. Even though the pressures have eased up from the early days, we have not really changed our habits. You just have to look at the car park after hours to see evidence of that. I suppose when the day comes that the car park is empty at 5.30pm, that will be evidence of a move away from the solid work ethic that has taken to company to where it is now."* [L9].

210

The way in which work hours are to be filled has significance for the adoption of quality management practices in that a shift is required away from the firefighting mindset to one of proactive thinking and planning. Several respondents talked about the "addiction" to work, the shortage of people, and consequently time, for the more proactive aspects of management. Examples are this are:

> *"... at times there is an element of guilt in the fact that you might say to yourself, well maybe I ought to spend three hours thinking. Thinking does not appear to be very productive - somebody wanders in and catches you thinking, they are likely to think that you are not actually working."* [L17]

> *"People are quite uncomfortable with sitting around and chatting because of the legacy of hard graft in the past leads them to think someone will shop them for not doing anything"* [L18]

The interviews found evidence of potential problems in making that adjustment and an attitudinal shift whereby employees' expectation of how they gained job satisfaction was changing. In particular the issue of career development for scientists was increasingly a point of discussion. The issue was the shift from science as a production activity to meet the changing expectations of scientifically qualified staff. George Cross[L2], Director of scientific operations saw the expectation of change thus:

> *"As long as I have been at BFL, anyone doing a scientific job supervising studies has always had 25 hours of work a day. Basically there has not been time allocated to things like reading around the subject - we have saturated them with work. We are now at a peak of that saturation and we are seeing an attitudinal change which is saying that these people have got to be fulfilled as well as knackered by the end of the working day. They want to feel that they are contributing to the science and soaking up the science at the same time - this is a considerable change"* [L2]

In some areas there was a unspoken disapproval of the operational and business pressures on scientists. Dr James Swift, Head of Pathology, who was observed to be an advocate of personal development through education, viewed the intensity of "production activity" in a negative manner:

> *"When I first came here (and Paul Furness felt the same way), we felt we were squeezed dry by the company. We came in with a certain amount of experience and academic qualification and we were expected to give, give, give. We gained some experience back but there was no way at the time of keeping oneself up to date. It's almost as if the company buys in scientists who already have the standing, reputation and knowledge, and then does nothing to nurture them. It's very hard for a scientist to stay up at the forefront of his subject - he's so busy. There's not even a decent library at hand. It's like taking a plant from a nursery and planting it in rough soil. It will crop for a time...."* [L13]

211

One of the underlying issues for the company lay in its ambitions to be seen as the "best in the market" in respect of scientific standing and expertise, versus the extreme difficulties of attracting, recruiting and retaining the high calibre staff required to meet that objective. There were those who believed that the focus of the company needed to move in the direction of increased personal development and reward (this is in line with the TQM culture), whilst others preferred to adhere to the values of the past and a work ethic which viewed personal development as essential but as a matter of individual, rather than company, responsibility.

Dr Swift was a pathologist who, by his own words, was one of a group who "........... *above all people, have a supreme ego*". Satisfaction of that ego required recognition and the opportunity to increase professional standing both inside the company and by the scientific community at large. He took the view that achievement of company objectives for improved quality required attention to be placed upon development of the skills, knowledge and experience of the individual in their discipline. Through this approach the company would improve in its professional standing in the market place, and thus attract more customers willing to pay a premium price. To do this was the company's rather than the individual's responsibility.

By comparison, Boris Grant [L4] seemed so focused on serving the customer and firefighting that he tended to dismiss the views of those in the company looking towards a more proactive style. He saw these views as evidence of increasing introspection, detracting from the goal of client satisfaction through delivery of good science. Boris's mindset extended to seeing himself primarily as an agent of the customer, placing allegiance to the customer above allegiance to the company:

> *"I set the example of wholly working for the client - I don't feel as if my first allegiance is ever to the company..... I hope my staff feel the same way"* [L4]

He was observed to amplify that commitment to the client through overt demonstration of disdain for formal company structures by, for example, taking client-based work to management meetings, handling correspondence and allowing "urgent interruptions" by his support staff. His view was:

> *"There's always clients to serve and fires to put out. You might have noticed that I take my work to meetings so **they don't interfere too much with my activities** ..... but that's life in a contract lab..... I wouldn't like not to be busy because that means we are probably not winning work fast enough"* [L4].

The views of Boris and James have to be examined in the context of the nature of the core business, the stage of development and the business objectives of the company. George Cross, who had joined the company as a toxicologist in 1975 and had progressed to the position of Director of Scientific Operations, took a more business focused stance and less insular view. Insofar as the pathologists went, he expressed his view as:

> *"This may sound rather cruel, but it is not actually important in the work we do, that they keep up to date with their field in the wider sense, because most of their activities are performed to a specific format. OK, they have to interpret the findings but that interpretation is based upon classical knowledge, not anything that is novel. It may be that on the very rare occasions that a client wants them to be more involved in discussions over a particular class of compound, then it is a failing not to be up to date - but it's probably more of a failing in areas such as mutagenicity where things are moving rather faster than in pathology.*
>
> *Some of us may like to think that we are a centre of learning and high science akin to academia, but in reality we are not. We are a commercial scientific company that happens to employ scientist to provide the level of expertise required to run toxicology studies".* [L2]

The different allegiances of Boris, James and George provide an interesting insight into the organisation and the disharmony that existed at the time of the interviews. They are illustrative of the autonomy that each manager held in running their own departmental affairs. If we look at these allegiances in terms of the objectives of TQM, then Boris' allegiance to the client appears laudable. Yet the failure to give due consideration to the aims of the company and to contribute as one of the team does not fit the TQM paradigm. Likewise, James' allegiance to the science, and specifically to his profession, are of benefit to the conduct of the company's core activity - but there appears to be a failure to look at the broader business picture. George Cross provides the allegiance to the company and sits in a senior position to the other two, thus has influence by virtue of position, but was not convinced of the value of TQM:

> *"I'm worried about Total Quality Management programmes because to me it seems not far short of basic hype. Everyone you hear about is doing TQM; it's this year's flavour of the month. That sort of thing worries me and to that extent, I think we are going about it in the right way to satisfy those other sceptics around us, i.e., not overt or brash."* [L2]

213

Delegation

It was found that the company work ethos was not characterised by universal effective delegation although there was a general recognition of the value of the practice. The reasons for delegation, against delegation and the affect of poor delegation provided no startling insights and read much like the standard texts on the subject. There was no evidence of extremes of practice, either good or bad.

There were two key issues, neither widely mentioned, negatively impacting upon quality. They were a) inappropriate delegation to people not capable of the task and b) related to failure to delegate final report editing and review. In the first case, it had been noted that cause of technical error too often related to inadequacy of training. In other words the person asked to conduct a task did not have the capability to do it and should not have been asked.

The matter of failure to delegate report editing and review was significant because bottlenecks were created at the top of the two leading science departments; reports produced so far in a timely manner, might sit in a queue awaiting attention of the departmental head, thus becoming delayed. Timeliness of reports was one of the key activities upon which the quality of the company was judged by its client base. Extracts of responses are provided in Appendix 7 (7.4).

Communication

The focus upon communication for these interviews lay in the view that it was just one of numerous influences on the company culture. However, it was considered to be a particularly important influence because of its significant impact upon the quality of the science, relationships within groups and across the company, and the control of activity. The interviews gathered information upon three facets of communications as shown in Figure 7.6. These were

1. The formal processes required to conduct the business

2. The informal processes and networks that influence relationships

3. Potential for dissemination of QIP objectives

Figure 7.6   Three facets of communication
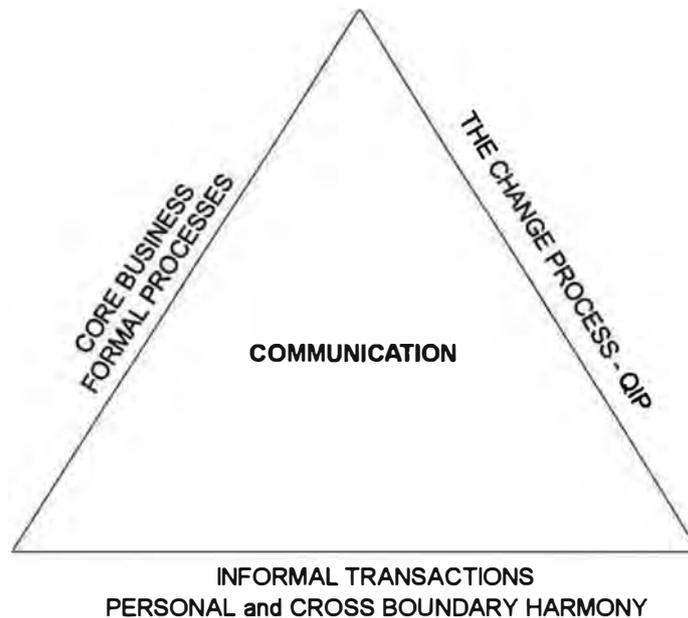
The core activity of toxicology requires a copious amount of internal and external communication for the effective conduct of studies; indeed a key part of the company product is communication. In this respect communication is taken to include written instructions such as study protocols[2], and other documentation created for the purpose of conveying information. In such transactions Good Laboratory Practice demands a high degree of formality with actual communications or records thereof documented and retained for future reference.

---

[2]   A protocol is the written methodology for an experimental study

215

Such is the importance of the formal channels, that the informal channels may be neglected. It was generally recognised that failure of these formal mechanisms often provided a contributory cause of errors. This observation suggested that communication mechanisms *per se* were a focus for improvement.

A wide range of communication forms, channels, opportunities and constraints and were mentioned by the respondents. These were organised by form, channel, resources and geographical and physical environments, into a Cause and Effect diagram shown in Figure 7.7

Figure 7.7   Factors influencing effectiveness of communications
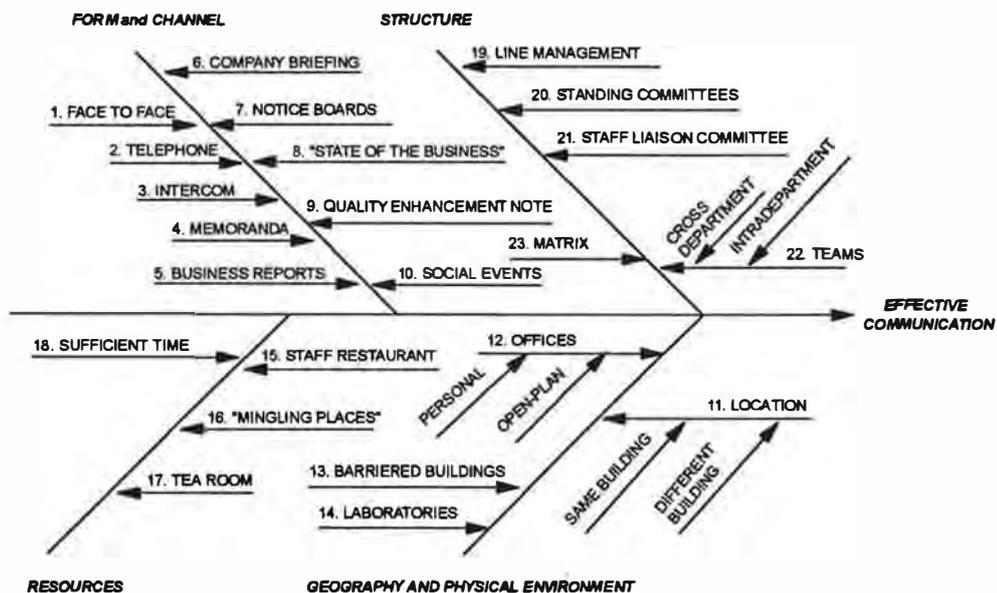
Barriers to effective communication

It was clear that communication was regarded as less than optimal, such that it was identified by two respondents, Chris Crabtree [L18] and Brian Snell [L19] as the company's major failure of quality.

"It is without a doubt, communication, and communication at all levels."[L18].

The conclusion of these two rested upon their observations of, and involvement in, the variety of communication channels around the company. Even though other respondents did not put communication at the top of their list of failures of quality, it was apparent to the researcher that they perceived significant deficiencies.

216

The frequency of personal contact with peers, superiors and subordinates was examined. It was found that contact time was widely considered to be less than desirable. Difficulties in making contact included the geography of the site (where respondents were located relative to each other) and lack of available time. The issues most widely mentioned were the impact of heavy work loads, the absence of an informal layer of communication below the business level and the difficulties imposed by distance and location or access constraints. Illustrative observations of the respondents are given in Appendix 7(7.5)

Form of communication

Views of the respondents varied quite widely in respect of their preferred form of communication (1-5 in Figure 7.5). The favoured methods were of a continuum from informal, face to face transactions, to formal written memorandum. As might be expected the choice of medium varied according to the communicators preferred style, what was to be communicated and to whom.

The favoured methods divided respondents broadly into two groups

1. Those whose job it was to work at the strategic level making proposals, analysing practices, implementing policy etc., and who frequently needed to put over complex messages to large numbers of people - the expression of authority, the desire for accuracy and a need to put over a consistent message pulled this group towards a preference for written communication.

2. Those who managed day to day activity, directed people, called upon resources and required frequent interaction with others, often requiring negotiation of response - this group had a strong preference immediacy of response and interaction, thus tend to favour face to face or telephone communication.

In general, although respondents were asked to declare their preferred method of communication, the actual method selected was that which they considered appropriate for the immediate purpose, not always the favoured method.

Illustrations of views on written communications are presented in Appendix 7(7.6).

217

It was noted that departments where the respondent was antipathetic to written communication were those where the dissemination of information was observed as weak. This observation was supported through discussions and training sessions with individuals of these groups who stated that information did not cascade. The exception to this was histology headed by Ron Dyke [L6]. Although Ron expressed a personal dislike for memoranda, such communications were widely and effectively used by others within the group.

The objection to written communication is interesting because the expression of dislike actually related to instructions, rebukes, and announcement of policy issues and changes in procedure, where recipients felt that there had been inadequate consultation.

> *"Senior management goes too much by paperwork these days. There are too many memos - there's too much discussion by memo - actually, it's not even discussion, it's primary communication."* [L4]

Such aversion did not exist where the communication included useful information or provided the basis for consultation. However, in both of the following illustrative responses, there was a suggestion that other communication channels were not fully effective. Both respondents came from departments where communication was thought deficient and where the researcher had particular concerns about the acceptance and implementation of QIP .

> *" I actually find that it is very useful to receive the sort of circulation that comes around to update us on a situation or something new. In a way it's often aggravating because you feel that you should have heard about it before but nobody bothered to tell us......"* [L15]

> *"Whilst I generally don't like formal written memos, I don't have any objection when they confirm something, or provide useful information about what is happening elsewhere in the company. I rely on these as being more reliable, if not as fast, as the grapevine......"* [L8]

Consultation, although it may have been both necessary and well intentioned, was not always welcomed as mentioned by Robert Bruce. An issue for him, observed to be shared widely amongst the respondents, was the imposition on his time:

> *".... One thing that does annoy me is getting sent one of those really long documents, from .... They want a response by the end of the week and the issue is not on your list of priorities. You have to decide whether to do a good job and really think about it and consult - what I often do is just scribble in the margins and return it."* [L9]

Views on formal communication mechanisms

Company briefings

Formal company briefings were generally seen as ineffective and thoroughly disliked by some. Keith Holloway[(L17)], Director of Resources and one of the few managers knowledgeable in area of human resource management and motivation theory, held the responsibility for administering the centralised company briefing sessions. He was convinced of the value of briefing and considered that failure rested with the process of implementation rather than the underlying philosophy. He stated his view as:

> *"I remain convinced that briefing is a technique, a weapon in our communications, that we should use and we should use more often. It is a team building technique as much as anything else and it should mean that the material being conveyed should be interpreted and added to as it is passed down the structure. I don't think, from my understanding of how some of us do it, that those principles are remembered or realised or rebuked.*
> *I don't know that there is anything intrinsically wrong about the philosophy of briefing meetings but I think we have a very sketchy use of it within the company.* "[(L17)]

Keith's observation was supported by George Cross who likewise, noted the deficiencies in the presenters but perceived a wider problem of deviation from company intention

> *"The basic problems with the briefings is the people that give them - they're not all trained or properly motivated. There is one dept. where briefings are given days late or not at all. The HoD doesn't think it's worthwhile."* [(L2)]

The issue with respect to QIP was the potential of the briefing process as a means of disseminating information linked to the programme. It seemed that despite Keith's considered and rational viewpoint, the process itself was discredited. Briefings did not stimulate discussion, the information provided was outdated and already known or of little interest to the company at large, and the briefing process was an imposition on valuable time. James Swift provided an extreme personal viewpoint:

> *"It's terrible. It doesn't fit in with my style. It's one person with a hidden agenda addressing another group who are almost taken cold. The extroverts hog the floor. The introverts can't speak as the extroverts take up the limited time. At simplest it's a one way communication and that's not communication - communication is a two way process."*

Where briefing was favoured it was locally, rather than company, initiated. The practice of holding regular intradepartmental meetings was quite widespread. Practice varied between departments and sections thus following the culture of autonomy.

Quality Enhancement Notes

Quality Enhancement Notes (QEN) predated QIP as a formal mechanism for any employee to report to "management" any matter which was either the cause or had the potential to be the cause of a failure of quality. The originator of a QEN was promised a response on the matter. Respondents were asked how effective they felt the QEN was as a tool for communicating quality problems.

The respondents identified few attributes of the QEN. Although some were able to see its potential, most were negative about the way in which it was used and its reception by the staff. . The key issues were:

1. The QEN was a **written document** which tended to be viewed as "a legal indictment". To avoid this image, the originator required skills in diplomacy and the use of the English language.

2. It caused conflict and strife between groups and individuals.

3. The way in which it was used tended to be accusatory, suggesting blame of an individual for an incident when the problem might lie with the system.

4. The problems reported were often not resolved - many were too complex for rapid action.

5. It was a mechanism for problem identification.

6. It was not a mechanism for problem solving.

7. The QEN did allow junior people to express a view.

8. There was some confusion between the QEN and the Suggestion Scheme.

Respondents views on Quality Enhancement Notes are summarised in Appendix 7(7.7) alongside observations and inferences of the researcher.

Views on the Staff Liaison Committee

This committee was formally constituted of elected representatives of the staff and nominated representatives of Management. Permanent management members were the Managing Director, Director of Resources and the Personnel Manager. Other Senior and middle managers attended monthly meetings on a rotational basis. The SLC potentially provided a network of operational staff who had the ear of others. It was thought that the SLC might provide a communication channel for the promotion of QIP. The interviews asked about the potential for the SLC to contribute to QIP and effectiveness of SLC. Respondents were not positive about the group, perceiving that it had problems of identity and focus combined with considerable variation in the calibre of elected individuals. The most positive views related to the circulation of meeting minutes.

Appendix 7(7.8) provides illustrative responses and researcher comment.

Views on standing committees

Respondents were asked how effective they perceived the standing committees to be, how effective would they be at implementing change and what changes they would like to see in the committee structure.

Responses suggested that the committee structure was regarded as far from optimal in respect of conduct, membership and achievement. A number of respondents felt unable to comment on some or all of the committees because of lack of personal involvement. This lack of involvement was met in some cases by concern, and others by indifference. These factors alone suggest that outflow of information and/or effective action was largely invisible.

It was found that respondents felt the committees sometimes failed to deliver what was expected. They were observed to get bogged down by numerous trivial matters, failing to tackle major issues. This was perceived by Chris Crabtree [L18] to be *"Fiddling while Rome burns."* The perception held by Kevin Evans [L22] was that while agenda items were often discussed at length, the committees were less effective at assuring that agreed action implemented. The key issue was that members might apparently reach

consensus in a meeting but then abrogate responsibility back in their departments. As Richard Rogers observed

> *"I know of several examples of different departments of where things have been agreed unanimously at Opscom[3] and two or three months later I have been chatting in passing to one of the persons in a department who ought to be acting on the decision to discover that they have never even heard of it."*[(L5)]

It was suggested that failure to communicate decisions was just one factor for this situation. Other factors included the level and authority of people on the committee in respect of their understanding of the issues, the personal determination to manage-in change and the extent to which the apparent consensus was real. One view was that people on committees were too senior and were often not intimate enough with operations to be able to discuss matters in sufficient detail to make an informed decision. One respondent (L9) expressed this opinion

> *"The people on Opscom are too senior. You probably need some senior people but also people working closer to the actual front as it were... It frustrates me at times - they question things that come up and when they can't answer they come back to me. If they had somebody with direct hands-on experience they could have answered that straight off."* [(L9)]

Not every respondent thought the membership of committees inappropriate. For example, value was perceived in retaining the operations committee (Opscom) in its existing form:

> *"I have thought about whether we need more involvement but I am not quite sure how you would select them....... No, it's nice and cosy as it is. We don't want to bring anyone in to spoil things or to upset the apple cart. It's got all its relationships worked out - we can all predict what anyone else will do or say".* [(L10)]

This issue of relationships was thought to be quite important, not for the reasons suggested by Michael but because of the need to get senior managers to relinquish some of their autonomy and work together. George Cross exhibited great frustration with the behaviour of the Opscom members such that he had considered abolishing the group. This had happened for a lengthy interval several years earlier when the then Chairman, Greg Elms, perceived that the group, who constantly worked in attack and defend mode, were incapable of working together; many of the same group still sat on

---

[3] Opscom: a non-executive committee composed of senior scientists who met monthly to discuss matter of companywide significance to scientific operations

the committee. However, George decided there was some benefit in at least retaining the communication channels.

> *"There is value in retaining the committees for communication purposes and in the hope that eventually people will realise that co-operative effort is more likely to succeed than a load of individuals running around like a load of chickens banging their heads together."* (L2)

The quality and volume of outflow of communication from all committees was poorly regarded. Respondents observed that there was minimal feedback and decisions were inadequately explained and/or made by individuals who were distant from the action. Illustrative responses include:

> *"The worst thing is for decisions to be made in apparent isolation so that people are told to do things and they don't really know any of the background behind them. Often there is usually perfectly good reasons why decisions are made but it helps the people who have to accept them if they have a bit more background about what the problem is and how the thing is going to be resolved."* (L15)

By way of increasing the effectiveness of the committees, Keith Holloway looked to broader circulation of minutes. He saw the sharing of information as a means to encourage involvement and harness enthusiasm as the company moved along the quality improvement path.

> *"Broader circulation of minutes would be a good idea providing that we do not deluge the organisation in a vast flurry of paper. The more people who can be aware of thinking and ideas and can contribute to them, the happier I am because in the final analysis, we are dependent upon involving our staff and we have a vast untapped reservoir of ideas. And if we can harness that reservoir of ideas and apply it, we will have an incredibly useful force for driving the company forward and for introducing more widely into work culture, the idea of quality."* (L17)

There was some, if limited recognition of positive achievement. It was felt that the committees were conscious of some of their shortcomings and were taking action to remedy. Boris Grant, who was observed to be one of the more cynical and controversial members of senior management commented positively on Admincom[4]

> *"The committees may be as effective as committees can be. From what I hear about Admincom, it suggests that it may have value...there was a huge gulf between central administration and personnel and the rest of the company... there still is quite a reasonable gulf and misunderstanding but Admincom is helping close the rift."* (L4)

---

[4] Admincom: a non-executive committee with a membership drawn from major technical groups and administrative functions. It was intended to bridge the gap between scientific and non-scientific functions

Views on training and development

Respondents considered that scientific and technical training provision varied according to the commitment of each department to the process and the resources available. The two large technical groups, Animal Management and Histology, employed training officers and placed considerable emphasis on development of skills through work based training supplemented by college education. They competed with each other for new recruits - an issue that caused friction between the groups - and both "sold" their training programmes to attract recruits. These two groups tended to recruit school leavers had always had a need to provide training and education to develop technicians. In the smaller specialist areas that lacked the resources for training of the larger groups, training was seen to have deficiencies - the smaller numbers of staff meant that staff turnover in these areas had a greater impact than in the large groups

> *"In my department our technical training's grossly deficient because of pressures of time and so on. We don't allow enough time or resource for training. I think we're entering an era where people don't want to be technicians any more. Technician as a name has become disreputable - there just aren't enough experienced technicians out there any more ......we try to occasionally buy a few and let other ones grow up by dint of experience, but without programmed training. I couldn't honestly say that we would ever turn out a fully trained rounded tissue culture technician or a fully trained fish technician in the way that we would like to. But that's the nature of the game to some extent in contract labs.* "[(L4)]

Historically the company had taken the view that it had a responsibility to educate those employed at science technician level up to graduate level but did not extend that privilege to graduates or postgraduate level or to staff in administrative or other non-scientific areas. However, as the company developed, became more prosperous and staff expectations increased, respondents noted that the approach changed and opportunities became more widespread

> *"The company is more liberal in it's attitudes to the attendance of staff at external courses. In other words if individuals have ideas of what they want to do, the company will let them do it."* [(L5)]

On the scientific front respondents suggested that they were less happy with training and development, recognising that what was satisfactory in the past no longer was so.

> *"We don't consider the current level of training to be sufficient. It has proved sufficient in the past, but as the company has grown the need to hold on to new graduate staff is more acute and more difficult because they see themselves as a smaller cog in a bigger organisation."* [(L11)]

224

> *"The complaint from toxicologists is that we use them as pairs of hands to deal with report preparation and do menial tasks far below that that they require to get job satisfaction. They tend to leave if they are not satisfied with what they are doing."(L10)*

Observation suggests that the latter comment may have more to do with organisation structure, work organisation and delegation than the quality of training provision but is nevertheless pertinent to the issue of staff motivation and their response to quality improvement. To provide greater career direction for toxicologists, an advanced course was made available. This was welcomed by those looking for career development and expansion of their knowledge, but it created certain problems

> *"We had decided that it would be of benefit to BFL to have people with the DipTox qualification. Our clients will like it because our toxicologists will have a broader view of what they are doing ....they will come across better. But we haven't thought about the actual product and we haven't thought how those people, when they get the qualifications, are going to feel......We are broadening peoples horizons without thinking .... how we're going to satisfy them. Obviously, with that qualification they are attractive to the outside world so we've shot ourselves in the foot." (L2)*

Another issue mentioned by several respondents was that few staff received supervisory or management training. This was felt to be a deficiency for a company wishing to move towards total quality. One view was that the company had become too hung up on education and effectively ignored training. Observation suggested that this view was something of an overstatement in respect of the skills development required to perform the core business of toxicology but did have validity in the broader areas of man-management and business skills. It was felt that basic supervisory management skills, such as personal relationships and dealing with people, were largely absent. Keith Holloway presented the view that

> *"One of the keys to our future as a company, our future as a Total Quality company, is an investment in training - by which I am talking about supervisory training. Until we can provide individuals with some of the skills and techniques of managing people we can't hope to grow the seeds, for example, of Total Quality. I think it is one area where we have got an awful lot more work." (L17)*

Supporting this observation was Bert Richards and Kevin Evans

> *"What we provide is barely adequate. We take people through the process of learning the tasks they have to perform at the bench but not through the supervisory management side of things and that is where we have our problems."(L20)*

225

"It is at the level of personal interaction that the real deficiencies in training lie. People who deal with other members of other departments, like at meetings, could benefit from a general overview and how to interact with other people, like the people they work with within the company or even outside. We may be brilliant scientists but we are lousy managers and staff are looking for help and guidance."[(L.22)]

The Modular Induction Training Scheme, a series of presentations designed to introduce staff to all aspects of company activities was explained in Chapter 5. The importance of the scheme for QIP was threefold. It:

1. mixed staff from all disciplines thus aided the breakdown of barriers that acted as inhibitors to improvement

2. provided an overview of all company activities so that individuals could see where they fitted into the broad picture and their role in serving their customers

3. provided the basics of quality philosophy and an introduction to QIP.

The interviews aimed to gather information on the extent of senior management involvement in the scheme and their views of the response of staff. Most of the respondents had been involved in the conception stage of MITS and had apparently given it their support, albeit that withdrawal of enthusiasm during that phase had resulted in the scheme being forced to fruition by George Cross.

A summary of respondents observations suggests

The scheme was of more value to the company than to departments.

Managers felt that it was "the right thing to do" and worthwhile despite negative feedback from some attendees.

Many attendees felt that they received too much information too rapidly, especially at the very early stages of their career.

In general it was felt that modules were of greater value to established staff who had not previously had the opportunity to familiarise themselves with the whole company, than to new staff

Presenters had problems in pitching information at an appropriate level - the educated layman. They felt that the more intellectually capable became bored.

226

Some presenters were frustrated at their inability to spark the enthusiasm of some groups. This was particularly noticeable with new staff.

Some established staff, especially those who already understood the broad nature of company activities, questioned the value of attending some core modules twice.

Attendance was poor. Some managers allowed absence where departmental work pressures were high.

There was no quantifiable evidence to assess the benefit in terms of improvement of performance or reduction of staff turnover.

There was subjective evidence that indicated an enhanced community spirit and greater company and scientific awareness.

The intention of respondents to show support to the scheme through their own attendance varied from those who intended to attend the complete programme to those who had no intention of attending modules other than those they presented.

Perception of the company product

There were no fundamental differences in the perception of the "product" although respondents chose to describe it in a variety of ways. In their descriptions they referred to content, form, attributes, purpose and the input skills.

There was wide recognition of the concept of satisfying customer needs and that to do this, it was essential that regulatory needs were also met. The understanding of the total service ethic was strongly represented as was the understanding that it included personal contact, level of expertise and quality of facilities and work therein conducted. The focus upon satisfaction of the client was not surprising because most respondents had regular direct contact with those clients.

Interestingly, the descriptions were always outward looking, perceiving quality as focused on satisfaction of the external customer. Two managers of technical groups talked about the activities and data produced by their groups as the immediate product but still placed them in the wider context of service and the report to the client.

There was recognition that the service that the company provided was not the cheapest but it was seen as offering "value for money" and was considered to be at the upper end of the market. Examples of descriptions of the product are given in Appendix 7(7.9).

Identification of failures of quality

When asked to identify the company's most important failure of quality, respondents spoke failures in terms of cause and effect. The common manifestation (effect) of various causes was late reports - the tangible output of the service and the "product" that the client received as the culmination of the service. Ten respondents mentioned late reports. No other failure of any aspect of the service attracted similar comment. The other respondents predominantly talked about matters that were contributory factors to late reports (the causes). Figure 7.8 presents a multiple cause and effect diagram showing the factors that influence late reporting as described by the respondents in their interviews.

Figure 7.8   Respondents views of failures of quality - Multiple cause and effect
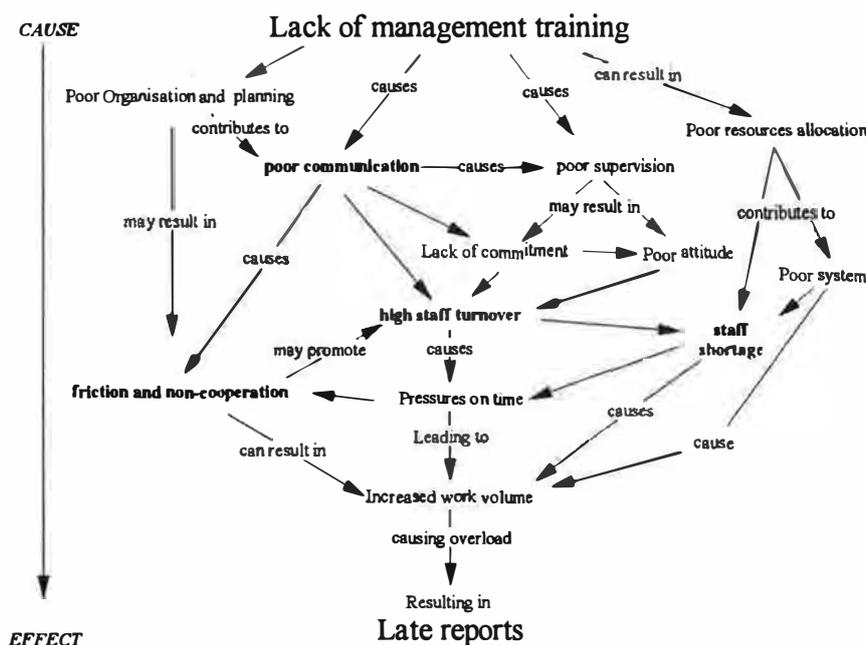
Late reporting was considered as the manifestation of *"all our inherent bad quality"*[(L22)]. Ben Nevis saw the problem as an inability to meet timelines for a variety of reasons

> *".... The problem we have is characterised by late reports but that may just be the manifestation. They may be late because of late chemistry or late pathology or all sorts of things but at the end of day it is an inability to get that element of timeliness that we actually need to achieve what we set ourselves. (the problem is) the availability of man-hours to try to complete the tasks, in a timely efficient and correct manner."* [(L3)]

Opinions on the severity of the late report problem varied from those who saw it as a perpetuating historic issue that would take considerable effort to resolve to those who saw it as a temporary glitch. The following quotes provide opposing views:

> *"We do produce a good product, and we fall down very much at the end at the moment, and almost for ever we have fallen down at the end. I can only think of a year or two when we had not had a backlog of reports. In the short term the biggest thing to overcome is to be able to produce the report to the proper standard in the correct time."* [L2]

Versus:

> *"In an ideal world we'd produce perfect reports and perfect quality, exactly on the schedule that we promised. But life isn't like that. Probably at the moment our biggest problem is getting reports out on schedule. I view that as a somewhat temporary hitch rather than as a very major fault."* [L11]

Factors that contributed to late reports were considered to sit in the domain of inadequacies in the management of manpower and other resources. The lack of supervisory and managerial skills manifested itself in high staff turnover and low motivation as mentioned by Bert Richards [L20]

> *"I am in a department of high turnover and low motivation. I'd say motivation is the biggest problem at the moment...... and not team leaders but at a general level."* [L20]

Boris Grant saw the problem as one of attitude and commitment to doing the whole job rather than working in a compartmentalised way. Communication was mentioned by Chris Crabtree, Ron Dyke and Brian Snell. Pressures of work were seen as originating from a failure to match resources with the call for resources,(L19) culminating in staff turnover. Loss of skilled staff was seen as a backward step in achieving desired quality

> *"In terms of achieving quality the problem is high staff turnover because you need people who are able to adapt to BFL's way of doing things and it can take several years before someone is reasonably competent, so to lose them at that point is a disaster."* [L15]

> *"(we need) sufficient staff to do a careful, considered job so they don't have to rush ......if we put people under pressure things start happening. If you have enough staff they can take it at a more ordered pace, pay attention to detail. A similar problem is getting enough people to get a report out on time - it is an horrendous task......"* [L9]

Looking to root causes, six respondents (L6,10,12,17,18 and L19) mentioned deficiencies of management training and ability, resulting in a knock-on effect to the scientific service of the company. Keith Holloway presented a picture of a continuing spiral, costing the company money and preventing the development of an appropriate environment for QIP to develop:

> *"we need to develop our supervisors and our junior managers so that we can have the sort of interpersonal communicative structure in which we can grow the quality ethic. Without this somewhat fundamental baseline of expertise, we will forever be going round in circles avoiding that stability we seek and pouring money down the drain recruiting and training to no avail."* [L17]

Michael May simply recognised that people were holding responsibilities for which they were inadequately equipped

> *"There is the matter of management training. I think that it is something we need to consider doing more of. Most people have had no training in that area but still have supervisory and management responsibilities."* [L10]

Steve Emory looked to his own department to illustrate the failings in supervisory skills and the consequent impact on the scientific product:

> *"In the case of my department, it is clearly lack of experienced people. We are a new group and have not yet worked out our standards, targets or even relationships. I think that where I do have experienced people, I have no problem with their science but they don't have the faintest idea of how to communicate, motivate, or organise themselves and they certainly need guidance on organising others. So I think that our basic problem is probably back in the area of management training. This has a knock on effect in the end to the quality of things like our reports."* [L12]

One respondent (L18) who saw communication as a major issue tried to explain where he felt the origins of the problem might lie. His perception suggested that there could be a hierarchical division (a "them and us" situation) existing between scientists and technicians

> *(The most important failure of quality)" is without doubt the interdepartmental communications and communication at all levels. Why this comes about, I am not totally sure because I think we try. But there are all sorts of egos at play - there are issues of status and issues of capability. If you happen to be a junior technician and you call a study supervisor and he won't come to the phone, you begin to think you don't matter - you are a lowly being. You forget that both of you have a responsibility to do your job - that he has a responsibility to communicate with you. You tell your supervisor and he hits the roof, but feels powerless to comment. I suppose it's that old scientist technician divide again, those who think they are here to be served and obeyed and think you are the servant."* [L18]

231

Observation suggested that communications problems did not just sit between technicians and scientists but existed between the departments that might, under Chris Crabtree's scenario, see themselves as equals. Chris himself had spoken about the competitiveness that existed between his department of Animal Management and Histology, the two large technical groups of the company.

One interesting observation came from the Head of QA who believed that the current structure of the organisation exacerbated communication problems and those in turn, affected the quality of work. He advocated the formation of study teams - multidiscipline groups with representation from the scientific and technical disciplines, bought together for the purpose of conducting a study. Brian drew on his experience of working in the Antarctic

> *" within any organisations with more than about fifteen people you get groups and they will tend to compete. That can be positive and it can be very negative and very destructive. It is only very small groups than can survive without forming cliques - one of the things that they observed in the Antarctic was that if you had a base with about fifteen or sixteen people rather than a larger number, it usually stayed together as a cohesive unit - it's very difficult to form an isolated clique - the population is so small that all the cliques had to overlap. If you increased the group to twenty five, it splits down the middle and you get two opposing factions fighting for control. I think that is just human nature but I come back to the fact that we live isolated lives because of the geography of the site and this is exacerbated by the line structure. I think we should be really pushing to break down some of the barriers. "* [L19]

However, a key issue in the formation of such teams related to structure of the formal hierarchy and the perception of the relative importance, seniority and recognition awarded to the individual managers. The question was "who would head up such teams?" Brian thought that the ideal person would be a study director - the person accountable for the conduct of a study. He did, however, feel that such a person

> *"Would probably not have developed the managerial skills required to lead a group of technicians.............. and I can't imagine that the pathologists would ever want to report into a study director - they see themselves as being on a higher plain - for that matter, I can't see the chemists being too happy either - maybe its a dead-duck of an idea."* [L19]

232

Issues linked to change

Respondents were asked how they personally felt about change, their views on the reason for change, and about their perception of difficulties that might be encountered in facilitating that change.

To some extent, the latter question may seem naive in that the response seems eminently predictable, however it was felt by the researcher that discussion of the inevitable might ease some of the anticipated resistance.

The rationale that the respondents gave for improving quality followed, to some extent, the text book reasons of the need for change. They included the underlying issue of long-term survival and considered the changing market, the retention and further development of self esteem and standing within the industry group, reputation with clients and holding the competition at a distance. Extracts from responses are summarised in Appendix 7(7.10).

Perception of problems

The perception of potential problems that might be encountered in the implementation of QIP provided an interesting mix of opinion. The potential of "traditional" resistance to change was widely identified. A common thread was the notion that change would be difficult without adequate resources, people and time being the most critical. Eight classes of problem were identified below and presented with illustrative responses in Appendix7(7.11)

1. **Resentment and Denial:** the issue of gaining acceptance that there might be any problem with the current ways of working. Respondents tended to look at performance standards from the external customer perspective rather than looking at total performance. Whilst respondents may have failings, they resent them being pointed out seeing lack of quality as a *"black mark or stigma"*. The scientists mindset tends to call for proof that change is essential. If he doesn't see proof of problems, or they are not directly his problem - they do not exist.

2. **Resistance:** A problem might arise with covert resistance whereby the external veneer might suggest full cooperation and commitment but the reality is different - on the part of some managers there may be no action or intention of action.

3. **Relationships:** The recognition that barriers between groups must be broken down for progress to occur. QIP may be viewed as a vehicle for achieving greater co-operation and harmony or it may fail because of an inability to break down those barriers.

4. **Inadequate motivation:** This may result from poor attitude (attributable to a variety of causes such as, for example, inadequate direction, recognition or personal nature as suggested by Bert Richards) or it may be that individuals are motivated to move in a different direction. Isolation (by facility, discipline, numbers etc.) may lead to suboptimal motivation because the pressure of the flow of the group is minimised.

5. **Resources - staff shortage:** Respondents suggested that the combination of rapid growth and relatively high staff turnover had led to shortages of staff and associated problems of failures of quality. This was exacerbated by the fact that much work was governed by the clock and required specific skills. The mindset of some has been felt to be "lets get the staff numbers sorted out and then we'll get onto QIP".

6. **Growing pains - time shortage:** This issue links directly to the matter of staff resources and was mentioned sporadically through the interviews. Respondents suggested it was a key issue - a circular "Catch 22" situation where staff shortage causes problem, which require time to sort out, demotivate and so on. For QIP to succeed, staff would have to dedicate time they did not obviously have.

7. **Receptivity of employees:** This is the issue of communication - i.e. selling QIP effectively to the whole staff. Unless the body of employees are convinced of the value of QIP, progress at senior level alone would be of minimal value.

8. **Goals and definitions:** Several respondents spoke about the need for a good understanding of the Goals and Objectives of QIP and the definition of "quality" that the company would apply. It had been observed that the ability to debate the meaning of quality, in the context of the business of a contract laboratory, was widespread .

Personal views on change

Respondents were asked how they personally felt about change; whether they welcomed it, preferred the status quo and so on.

An interesting observation was of ability with which respondents worked around this question, providing a general, rather than a personal view. Respondents spoke about change in broad terms rather than about the specific move to TQM. Responses broke down into five groups

1. The respondents who had no objection to change provided it was not imposed upon them without consultation. They admitted that they would resist imposed change and disliked change for change's sake. They welcomed constructive change and liked to be consulted (L2, 8, 9,11,15 19, 20)

2. Respondents who welcomed change and disliked maintenance of the status quo. These were the individuals who liked to be originators of change and were constantly looking for improvements (L6, 13, 18, 22)

3. Passive acceptance. An attitude of "if it happens, it happens, if it doesn't, then it doesn't". One respondent in this category gave the impression that his reaction originated as a result of his previous failed attempt to resist what he perceived as *"unreasonable change"*.[L16] The other respondent (L10) appeared to be bemused at lack of active change around him as he perceived commitment to be present at the top of the company and at his level

4. The respondents who did not express a personal view but cogently put forward arguments for change and their understanding of how others might respond. Their presentations suggested considered and well managed change to be a

philosophically acceptable concept. These respondents looked towards design of change rather than implementation [L5, L17]

5. Respondents who couldn't imagine why the question was asked because the pursuit of improvement is one of life's natural processes [L4].

A summary of respondents comments on their personal feeling to change and other qualifying statements is presented in Appendix 7(7.12).

7.3   Organisation Standing Surveys

7.3.1   Timing and purpose of surveys

Two small surveys were conducted, one in 1990 in the early stages of QIP and the second in 1992. Both of these surveys asked senior managers to assess the current standing of BFL in respect of quality management as described in the literature of the time. The first survey, the results of which placed the company at a level between QA and TQC according to Foster's and Whittle's descriptions, served to help managers recognise that there were different levels of quality and to confirm that the company was not already at the highest level. The second survey based on Lascelles' and Dale's six levels of quality had the desired response of stimulating managers to think about the nature of progress that the company had made and had yet to make.

In both surveys, the respondents had difficulty in relating the generic description of levels of quality to the type of organisation that BFL was. This problem served to emphasise the dominant link between TQM and manufacturing and the tendency to judge progress and positioning in light of the tools and techniques appropriate to manufacturing industry. In the case of the second survey, this bias had the effect of alienating several respondents who judged that against the criteria given, BFL could never reach the upper levels. Thus the question arose again of whether TQM was appropriate for Professional Scientific Organisations. Several managers still considered that compliance to GLP should be regarded as the target quality standard for BFL; they considered that other levels of quality were irrelevant. Although there were some comments about the having to learn the language of TQM (from the QA department), in general it was evident that managers were able to relate to both language and concepts. This was seen as evidence of progression since the 1990 survey when difficulties of language were experienced.

7.3.2 Survey 1- Organisation Quality Standing - Results

This was a small survey completed by the managing director and 17 senior managers from all major functions of the company. These were the directors, department heads and senior managers who it was thought would be most influential in the success or otherwise of QIP and were considered sufficiently aware of the company state to make

an informed opinion of the quality status. Using a chart describing characteristics of Quality Control, Quality Assurance, Total Quality Control and Total Quality Management, survey participants were asked to select the descriptions that best fitted the current quality status of BFL. The participants are shown in Figure 7.9 below

Figure 7.9   Participants in organisational standing survey and their position in the company hierarchy
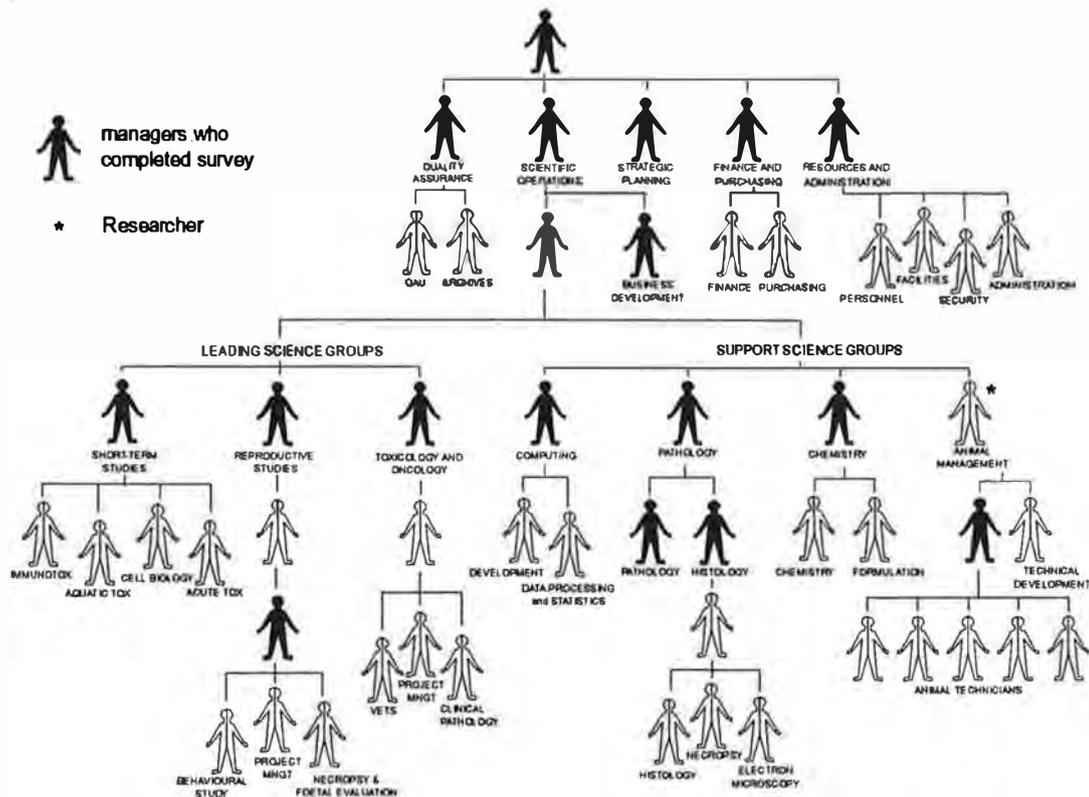
The managers were asked to complete the survey after such time as they had been introduced to the TQM philosophy but at a time when some had yet to be convinced of the need for a quality improvement programme. The survey served two purposes; apart from the tangible results which were of interest to the research, it was hoped that this internally produced result would stimulate participants to think about the real situation of the company in respect of the way in which it managed and thought about quality. It had been predicted that the majority of scores would place the company in the mid level and this would be sufficient to demonstrate that there was room for improvement.

Completion of the survey was fairly full with 210 selections made out of a possible 216. The scores are tabulated and charted in Figure 7.10 a-c

Figure 7.10a   Organisational Standing : collated survey scores

Quality Level					
	QC	QA	TQC	TQM	Total responses out of 18
Philosophy	0	7	8	3	18
Goals	1	5	4	8	18
Responsibility for quality	0	8	8	2	18
Quality application	3	7	5	2	17
Cost and Price	5	5	6	1	17
Improvement	2	4	7	5	18
Driven by	0	3	12	3	18
Focus	1	7	6	4	18
Customer	0	8	7	2	17
Suppliers	3	11	3	1	18
Tools and techniques	0	10	4	2	16
Company vision	0	2	10	5	17
Total responses at level	15	77	80	38	210
Percentage of responses	7.14	36.67	38.10	18.10	100

See Figure 7.10c for full explanation of categories

Figure 7.10b   Bar chart of total scores for each quality level

239
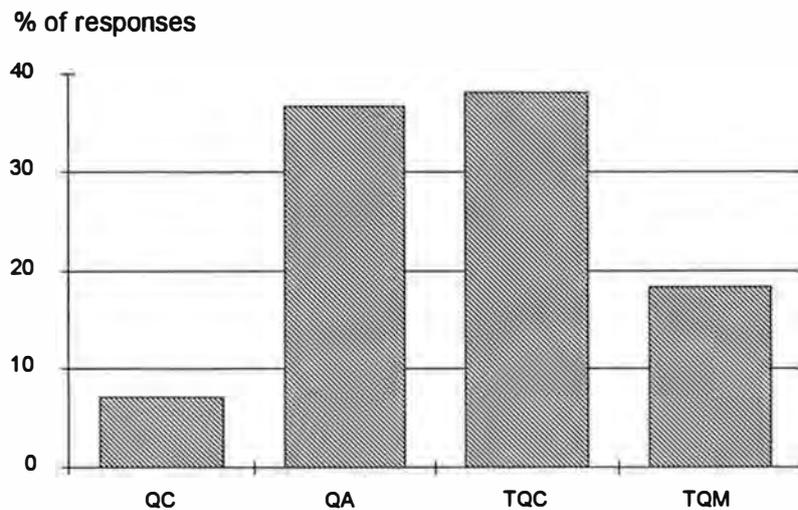
Figure 7.10c Organisation Standing : Survey master and scores

Numbers in parenthesis are the incidence of selection of the description

	1	2	3	4
Philosophy	Managing quality in.	Organising quality in.	Inspecting quality in.	Building quality in.
Score	d (3)	c (8)	a (0)	b (7)
Goals	Defect detection	Habitually and competitively meeting customer requirements.	Activities to meeting "design" specification. Defect prevention.	Cost reduction and conformity to specification through continual improvement.
Score	a (1)	d (8)	b (5)	c (4)
Responsibility for quality	Organisation-wide responsibility through devolved strategic vision.	Systems and operations. Through design and installation controls.	QC department. Individual inspectors	Centralised Quality Assurance Unit.
Score	d (2)	c (8)	a (0)	b (8)
Quality application	Holistic.	Production process monitoring.	Post production inspection.	Total operational control.
Score	d (2)	b (7)	a (3)	c (5)
Cost and Price	Specified cost at specified quality.	Cost reduction through quality improvement.	Cost reduction through quality improvement. Customers will pay for added value	Trade-off between cost and quality.
Score	b (5)	c (6)	d (1)	a (5)
Improvement gained through	Project based activities to "do it right first time" and correction of own errors.	Increased inspection.	Customer driven habitual improvement.	Improved product specification and Statistical Process Control.
Score	c (7)	a (2)	d (5)	b (4)
Driven by	Control.	Control and co-ordination	Vague system	Culture.
Score	b (3)	c (12)	a (0)	d (3)
Focus	Meeting customer specification.	Customer focused. Meeting needs as perceived by the customer. Enhancing quality.	Production/system focus.	Product focus.
Score	c (6)	d (4)	b (7)	a (1)
Customer	External.	Uncertain. Little concept of customers	External customer, Internal customer, Quality chain.	External/internal customer boundary no longer valid; everyone is a customer.
Score	b (8)	a (0)	c (7)	d (2)
Suppliers	Inadequate supplier inspection.	No supplier inspection. Supplier quality reliability company wide.	No supplier inspection - supplier quality reliability in all production process i.e. equipment, packaging, distribution etc.	Some supplier quality agreement plus inspection.
Score	a (3)	d (1)	c (3)	b (11)
Tools and techniques	Product specification itemised costing. Rework.	Problem solving and quality analysis tools. Calculate cost of quality	Establishing QM structure. Culture of quality using measurement and monitoring as appropriate.	Procedures manual. Statistical based inspection processes and some analysis tools.
Score	a (0)	c (4)	d (2)	b (10)
Company vision	Those with market leader's vision, competing on quality first, looking for sustained growth and increased market share.	Those who do not know any better.	Those with need to comply with regulations for survival.	Those competing on cost and quality with long-term profitability goals.
Score	d (5)	a (0)	b (2)	c (10)

Key: a - Quality Control, b - Quality Assurance, c - Total Quality Control, d - Total Quality Management

Figure 7.10d   Bar charts comparing scores by factor for each level of quality

241
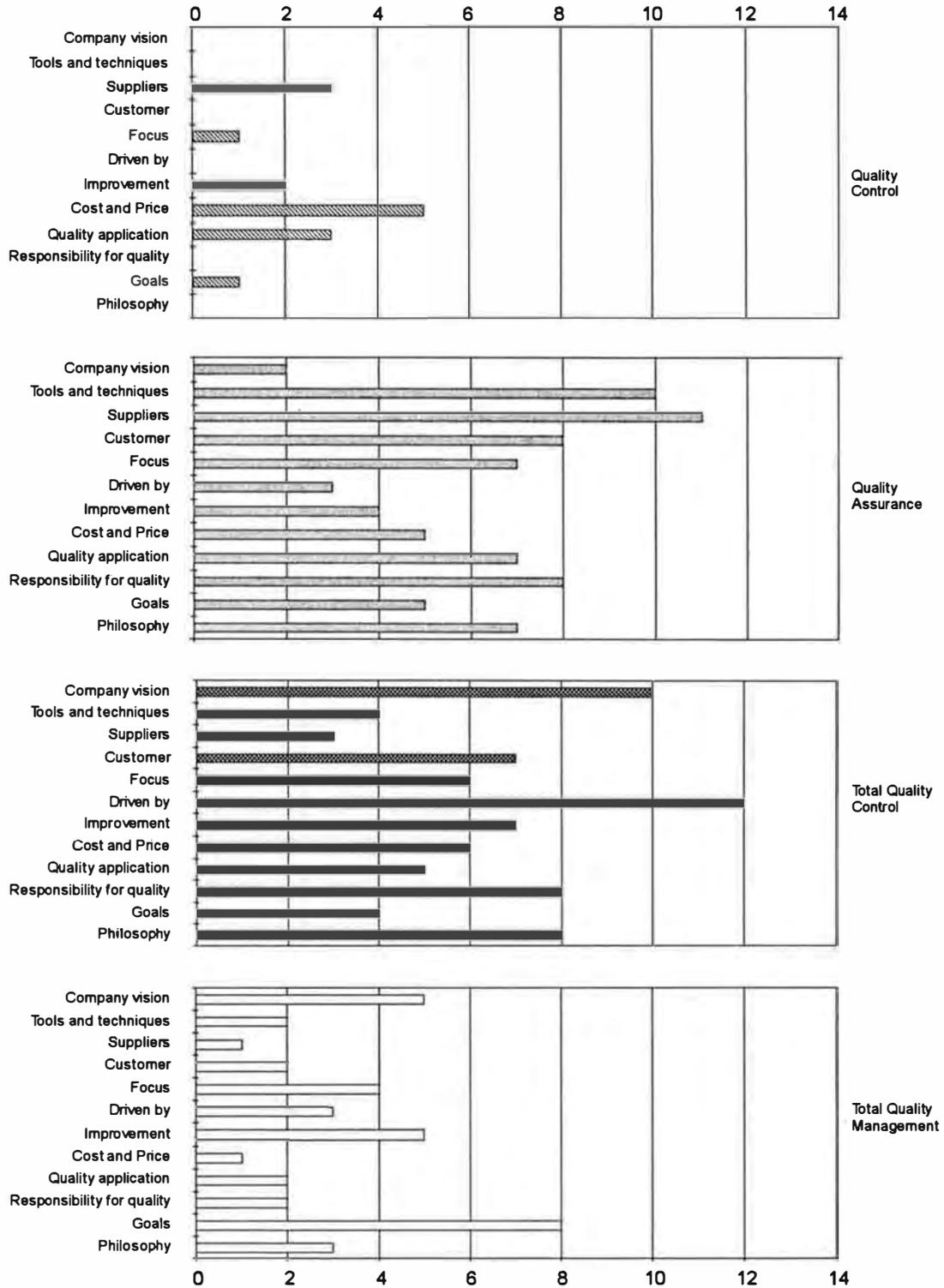
Because of the small size of this survey, no attempt has been made to look at statistical significance of the results, rather individual factors that appeared of interest are discussed. The simple format allowed for rapid collation of results and presentation of these at the subsequent seminar. Through discussion, further insights of the managers perceptions were gained.

The overall scores placed the company solidly in the QA and TQC levels (36.7 and 38.10% of responses respectively). The lowest score was for QC (7.1%) with TQM at 18.1%. As the company had long established QA practices, these scores were in line with expectation. In this survey, there are some step function improvements between the descriptions of the factors for QA and TQC, but they are not pronounced. It is considered that the two levels are sufficiently similar that the scores could be amalgamated as one, strengthening the picture of a company sitting firmly at the level of QA.

For six of the twelve factors scores were distributed across all four levels of quality. The other six were distributed across QA, TQC and TQM with zero scores for "philosophy", "company vision", "tools and techniques", "customers" and "responsibility for quality" at QC level.

At the QC level it is interesting to note that managers did not see the company as "inspecting quality in", they did not see the goal as "defect detection" but five respondents considered that there was a trade-off between cost and quality. When examined further, what they were actually referring to was the issue of late reports. The logic was that investment of more costs in manpower would allow delivery of better quality; they saw inadequate investment as a trade-off against quality.

There was agreement that most people within the company had some idea of who the external customer was, although the further away from the company-customer interface, the less insight was had. The managers felt that even where individuals working in scientific operations did not have a direct relationship with the external customer, they appeared to be aware of the chain linking their activity to the external

242

interface. The TQM description of "External-internal boundary no longer valid; everyone is a customer" was selected only twice suggesting that even if the concepts of internal customers had been accepted, the practice of co-operation required for an effective chain of customers had yet to develop.

"Company vision" brought out some of the more interesting divisions of viewpoint. The QA description of "need to comply with regulations for survival", selected by just two respondents, could have been selected by all because it was a matter of fact for the company; the company had comply with Good Laboratory Practice and the work it conducted had to meet the testing guidelines of various government agencies. The discussion revealed that some managers thought that survival by compliance with regulations could not be regarded as a "vision" and thus they did not select the description. However, the head of QA (L19) felt that there were deficiencies in compliance with Good Laboratory Practice such that he felt the need to comply with regulations outweighed the other descriptions. He expressed his view as: *"How can you have a company with a vision of market leadership that has things wrong which are fundamental to GLP, that we have been asking to have corrected for as long as I can remember"*.

Ten managers selected "those competing on cost and quality with long term profitability goals". They felt that achievement of these goals would allow the company to shift its vision, in the future, to that of market leadership. One manager (L17) who selected the TQM description under "company vision", felt that *"vision is a matter of looking to the future"*. He felt that the company could have a vision of market leadership even if it were working at the QC level; if the company failed to have the vision, it would probably fail in it's efforts to improve quality. Another manager (L5) commented on his perception of the need to view both the vision of the company and the current level of performance within a changing economic context. He expressed the view that whilst, at the current time, some people may not consider cost was a relevant factor in the placing of work, they needed to consider the event of a downturn in the economy; in such circumstances cost competitiveness might be a critical factor to sell work. It was imperative that the quality delivered would provide

value for money. He felt that the company, irrespective of whether it had the vision of being number one in the market place, had to continue to set goals based on long term profitability and thus would most safely consider itself to fall under the TQC description. However, the vision of market leadership seemed a long way off when *"We don't always deliver quality now even if we like to think we do. Sometimes the way we treat some of our best sponsors, suggests we have barely heard of quality control let alone TQM"*

In respect of the scores for TQM it was found that "goals" was the only factor where the TQM score exceeded other scores. The reason for this was thought to be the relevance of the description "habitually and competitively meeting customer requirements" to the culture of the company and managers empathy with the description.

There were some comments upon the survey descriptions where managers felt that they were too directed at manufacturing industry and the quality practices that were used in that sector. It was felt that the "tools and technique" descriptions were inappropriate because of the apparent focus on a tangible product that could be inspected and measured for quality at the end or during the production process. They felt that the means of judging quality of BFL's "product" were generally subjective but no less valid than the statistical methods.

It is considered that the survey served its purpose both in establishing managers perception of company standing, and in stimulating thought about what the results meant in respect of future activity and outlook. Useful insights were gained into the mindsets of managers who would be influential in QIP implementation and moulding the ideas of others.

7.3.3 Survey 2 - results

The second survey on organisational standing received broader circulation than the first. It was sent to 37 managers from director level to section head. The additional recipients were mostly middle level managers who made up a relatively new operational managers discussion group (OPMAN) and organisationally, sat just below senior management. The group were predominantly scientists. The distribution of recipients and respondents to the survey is shown in Figure 7.11

Figure 7.11   Recipients and Respondents: second survey on organisational standing
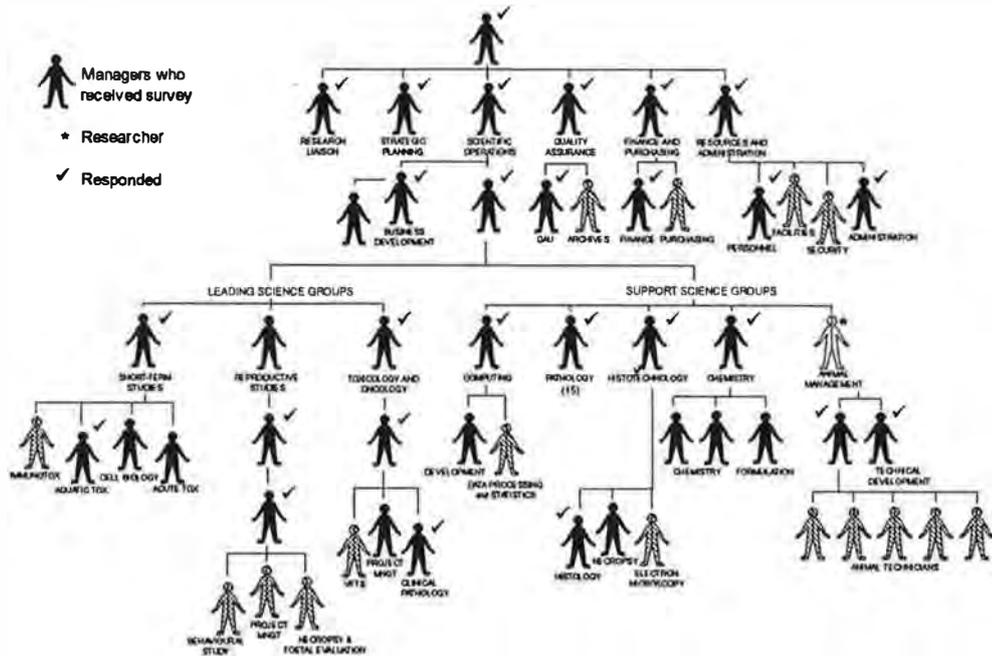
The "survey" consisted of circulation of a recently published article (Dale and Lascelles, 1991) which proposed six levels of adoption of TQM. These levels described characteristics and behaviours which organisations display in relation to TQM.

Like the first survey, the second served similar purposes. Primarily it was intended as a stimulant to the system and secondly, although the gathering of other evidence on TQM activity gave some indication of progress, it was felt it would be of interest to consolidate the picture by gathering the views of both senior and middle managers.

245

Again, like the first survey, there was no intention to do statistical analysis of results and thus it was felt that a structured format of survey, would not necessarily add value to the process.

The article was distributed via the company internal mail system with a covering request asking recipients to indicate at which of the levels described in the article they considered BFL to sit, and why they thought that to be the case. There was no structured "return survey form" - it had been observed that recipients of articles often communicated their views by annotating and highlighting interesting concepts/paragraphs and it was felt that this form of response would be adequate to elicit the requested information.

Responses were obtained from 27 of the original 37 recipients (73%). Around one month after distribution (the period which coincided with the Christmas and New Year holiday period), 18 responses, of which 16 were written and two verbal, had been received. A chase was made by telephone to elicit further responses. Initially it was assumed that all responses would be in writing but in the event several responses consisted of transcriptions of face to face or telephone communications. Although this introduced some inconsistency to the survey format, it was felt that such data should be admissible because of

- a) the subjective nature of the responses,
- b) the variation of form and content of responses that anyway would be received in writing
- c) the small survey size and
- d) the assumption that the nature of the response would be much the same whether communicated verbally or in writing.

The chases elicited another 9 responses 4 of which were written and 5 verbal.

The responses varied from very brief (level numbers and no further explanation) to half - one page memoranda. Five of the responses includes diagrammatic representations of the respondents placement of BFL The full responses are tabulated in Appendix 7.13.

246

7.3.3.1 Summary of responses

There were found to be a number of common themes that ran through the responses. These were

1. Difficulty in finding a "fit" against Lascelles and Dales proposed levels

2. Perceived irrelevance of the article and the notion of "world class" to a PSO

3. Language: Alienation of respondents because of lack of thought in the selection of labels for the levels

4. The influence of Good Laboratory Practice

5. Inconsistency of commitment at BFL

6. Avoiding pitfalls common to TQM

Further explanations of these themes are presented below:

1. **Fit to Lascelles' and Dales' TQM levels**

   Respondents appeared not to find it straight forward to make a decision upon where the company sat relative to the descriptions of the six levels proposed by Lascelles and Dale. They approached their assessment and allocation of a TQM level in different ways, providing just a numerical assessment or more commonly, a numerical assessment accompanied by short commentary on the descriptions.

   The majority opinion put the company somewhere between Level 2 and 4 (taken from 22 opinions with sufficient quantification to make a considered judgement). The general picture was that of a hybrid company, with most respondents commenting upon both descriptions that fitted and those that did not. Recognisable characteristics spread from Level 1 to Level 5, the peak sitting somewhere between Level 2 and 3.

   Not all respondents were in agreement. In the case of Level 3 for example, respondents held opposing views through the range of *"Level 3 doesn't fit at all"* [L9], *"None of Level 3 applies"* [L26] to *"Level 3 "*[L6] *"Level 3"* [L13], and *"Level 3 rings some bells"* [L17]

   No respondents felt the company was at Level 1 although three (L5, 8 and 10) each mentioned lack of investment as a recognisable characteristic. These three each offered a different example; the company's conservatism in its approach to

investment (L5)[2], manpower/time resources (L10) and a specific project which had, year after year, failed to hit high on the priority list for investment (L8). The issues were not new - these respondents had frequently expressed their views in other forums.

At the other end of the spectrum (Level 5 - Award Winners) three respondents (L5, L17 and L23) made comment terms of the company's aspirations rather than a level that it had already achieved - their comments, relating to the changing culture of the company, suggested positive development in the "right" direction.

Level 6 was seen as being beyond the company.

2. **Relevance of article and the notion of "world-class"**

    It was evident from the responses that many of the readers saw the article upon which they were asked to comment as flawed. They did not see Lascelles and Dale's descriptions as representative of PSOs, pointing out that the company was made up of scientists rather than production workers and that processes appropriate for manufacturing were not required in a PSO.

    "We are not a manufacturing company and we don't need all of the processes and systems that the article suggests are needed...." [(L14)]

    "This article seems to consider a different type of business environment. For our type of business you need a very different set of descriptors." [(L18)]

    Since the early days of QIP, the flawed axiom of "we are scientists and therefore different" has pervaded the mindset of many employees. This mindset led to a readiness to reject, ridicule and question ideas that originated from such industrial sectors as manufacturing. This was unfortunate as it tended to close the mind to the many characteristics common to all or most organisations. The article seemed to exacerbate those prejudices through its language and paradigm.

    One respondent (L22) commented on the prerequisites indicated for "entry " to the higher levels. He made the point that these prerequisites were not appropriate for PSOs and thus the company was effectively disqualified from success measured on this scale..

    ".....there are certain prerequisites needed to sit at any given level which are not appropriate to our business. .... It appears that BFL could never get to world class because it has no need for adoption of such tools." [(L22)]

There was some scepticism about the value of judging performance on a global scale, the implication being that the "big picture" has little relevance by comparison with a company's position within its own field. It was thought that these comments arose from respondents considering that the company was already well positioned within its industry, thus they considered the company to be "world class" as indicated by L18

"... we are already world class in the context of the contract business" [(L18)].

Yet by comparison with the Lascelles' and Dale's descriptions, the company appeared to barely have left the starting blocks; It was felt that respondents resented this implication.

3. **Language**

The "language" of the article had the effect of alienating several respondents. These respondent expressed strong antipathy to the labels of "Drifter" and "Tool-Pushers" applied to Levels 1 and 2. Their antipathy was expressed through such words and phrases as "took great exception", "derogatory", "insulting" and "dislike"

It is considered that the feelings expressed were sufficient to influence judgement of the level at which they placed the company. In one case at least (L13) the aversion to using the label "drifter" was so strong that, whilst acknowledging some of the features of the level fitted BFL the respondent was unwilling to place accept the term as a descriptor of the company.

" I do not like some of the names suggested .... this dislike was so strong that I had to fight the value judgements imposed by their choice...... I am most unwilling to propose the term "drifter" is an acceptable descriptor for our company" [(L13)]

Another respondent (L30), a member of the Quality Assurance staff, mentioned the frustration he felt in having to "learn a new language". These views illustrate how important language is to the scientific mindset. There is a desire for precision, exact meaning and avoidance of metaphor and analogy. Observation of the response to this and other circulated articles on management subjects made evident the tendency to focus on language and literary style rather than meaning.

4. **Good Laboratory Practice**:

Eight respondents commented upon the relevance of Good Laboratory Practice (GLP) to the current status of the company. They referred to it as of it as a long established baseline that had given the company a head start with its move to TQM. GLP provided the confidence that the company worked to the recognised principles for the industry and it was seen as providing an accelerated entry into TQM, taking the company above the basic level.

".... GLP has given us a head start"[(L2)]

"We started at a different point"[(L5)]

There was evidence that following three years of exposure to TQM, there remained a belief that attaining GLP compliance, combined with satisfaction of customers, equated to provision of the desired quality level:

"GLP is the only quality standard that matters"[(L4)]

"We have GLP so we do meet our sponsors requirements"[(L10)]

This observation suggested that the scientists continued to understand quality as pertaining to the scientific service of the company as perceived by the clients rather than looking to the effectiveness of the broader picture.

5. **Commitment**

A strong message from the respondents was their observation of inconsistent commitment across the company. The observations covered leadership - the relative strength of the Managing Director (L5, L17) versus the failure and inaction of some senior managers to realise their responsibilities in getting everybody on board (L4, L5, L6, L10, L17, L21, L22, L26).

"We have strong leadership pushing for TQM. The managing director has demonstrated that (painfully sometimes) as have you (the researcher)" [(L5)]

"There is variation in the commitment to QIP across the company. It is relatively easy to notice departmental differences......... all senior managers do not see it as their responsibility to facilitate improvement." [(L17)]

There were thought to be gaps between what was actually happening and what management thought was happening (L9). Given the richness of the Lascelles and Dale article, with all of the characteristics that could have attracted comment, it is

significant that this issue was so widely selected, suggesting QIP had failed in this respect. There was no indication from any of the respondents as to where, in departmental terms, they felt the lack of commitment emanated. It was considered, in the context of other observations and combined with the specific comments on inadequacies of senior management, that it was at the top levels of the company that the problem was perceived. However, one respondent (L10) put forward an opposing view, specifically stating that *"..... we need more commitment from the ranks"* [(L10)]

6.   Pitfall avoidance

Several respondents referred to pitfalls, often quoted as problems that companies experience in their transition to TQM. In an attempt to introduce QIP in a form acceptable to the often sceptical scientists and to avoid such problems, emphasis had been placed on avoidance of overselling, razzmatazz and anything else that might be regarded as hype. The responses suggested that the style of QIP was seen as meeting those objectives

"We never did have much hype" [(L5)]

"We are not looking for a panacea - I don't think quick fixes match our culture. We think long and deep and move with caution." [(L5)]

Two managers (L5 and L17) mentioned the lack of scepticism about QIP. These managers had given the most considered responses to this survey; they generally had a reputation for thoughtful dissertations, aiming to explore and understand the issues;

"We have been noticeably devoid of scepticism, backward viewing or "what's in it for me" as described at the tool-pushers level (so far). I think that probably reflects the sort of company we are and the type of person we employ - i.e. our professionalism." [(L17)]

However, other responses suggest that a degree of scepticism remained. Respondent L10 doubted the need for improvement and threw doubt on both the achievement and value of an improvement process;

*"I am not sure that everybody feels we need an improvement programme ....
We have GLP so we do meet the level that our sponsors require....... I see improvements all the time but they might have happened anyway ... does it really matter where we sit so long as we are keeping our clients happy?"*

Respondent L4, by stating *"GLP is the only quality standard that matters"*, effectively denounced TQM as irrelevant. L14's rebuke of the Lascelles and Dale levels on the grounds that they do not present the relationship between clients and company in the way that he perceives they should be presented, is seen is evidence of further scepticism:

"There is no mention of the standing and respect that organisations have with their clients. There should be far more focus on the characteristics that relate to the relationship between the company and the clients. I understood TQM to be about satisfying clients but there is very little about that in the levels." [L14]

7.4   Summary of main findings of interviews and surveys

Over the timespan of the interviews and surveys, the exposure of managers to the principles of TQM resulted in the development of their understanding of quality management principles but appeared to do little to gain a consistent commitment to activity focused on quality improvement. The interview and survey data were rich in managers' expressions of their feelings on complicating influences to implementing TQM in PSOs. The responses supported other documented and observational evidence; they identified several themes in respect of the factors that appeared to have most influence on the acceptance, and consequently the effectiveness of QIP. These themes provided the foundation for the models proposed in Chapter 11 and suggested areas of further investigation at BFL and with the corroborating organisation. The themes which provided the underpinning of the corroborating investigation are briefly summarised below

1. **The mindset:** The interviews and surveys found that BFL managers endorsed the "informal" approach of BFL to TQM. The dominant belief was found to be that "we (as a PSO) are different" and "I (as an individual) am different", thus TQM, as applied to manufacturing industry, is inappropriate for a PSO. Further evidence was found in expressions of dislike of hype, rhetoric, generic categorisations and over-prescriptive solutions to problems. It was initially considered that these beliefs and prejudices were indicative of the scientific mindset discussed later in Chapter 12. Investigation in the corroborating organisation aimed to establish whether this mindset was common to another group of scientists or was specific to BFL.

2. **The nature of the business of PSOs and its clients.** A common theme was the difficulties that the work itself posed upon the improvement of quality, and the additional complications that could be introduced by the extent of interaction between company and client.

3. **Inconsistent commitment:** The interviews served as a source of managers expressions of commitment that could be gauged against observed behaviour and other documented evidence of activity. Some managers openly expressed views that suggested that they were unlikely to be effective at driving improvement. In other cases, views were consistent with observed behaviour

but suggested that achievement would be limited; there were also managers that had positive attitudes to TQM that were supported by activity. This inconsistent picture was corroborated at SciTec (Chapter 10)

4. **Management Styles**: Through statements about self and observations of others, the interviews provided a rich insight into management style. This was found to be a key influencing factor in the amount of effort and direction that departments put into TQM. Different attitudes to the approaches to quality improvement were evident. The measuring rods reported in Chapter 8 and 9 provide documented evidence of participation that supports the observations of the impact of different styles. These findings formed the basis of the TQM management styles model reported in Chapter 11

5. **Influence of Good Laboratory Practice:** It was found that the influence of GLP persisted throughout the period of QIP implementation. What the second survey in particular showed, was that a few managers clung to the belief that GLP represented the only valid quality system for a PSO - this was taken to indicate ambivalence to TQM. The second survey on organisation standing suggested to the researcher that the strength of support for GLP had strengthened in some areas although there was also evidence of a greater understanding of different quality levels and the management of quality in the broadest sense.

6. **Communication**: Identified as a barrier to TQM during interviews, observation and group interviews provided evidence of improvements in communication, particularly that of a cross departmental nature. Reduction in the extent to which communication was criticised was regarded as indicative of breakdown of departmental barriers and increasing cooperation.

7. **Conflict and reward:** The interviews and observation found a destructive link between the use of reward which tended to invoke conflict. It is suggested that the approach of congratulation and high profile recognition used in many TQM programmes was misjudged and is likely to be counterproductive in the conservative culture prevalent in professional organisations.

The value of the organisation standing surveys were in the evidence they provided on the development of a critical approach to TQM. At the time of the first survey, the characteristics of TQM were something to which a company could aspire. By the time of the second survey, respondents had been exposed to QIP for three years and they had received frequent material for the advancement of knowledge of TQM. In the second survey the validity of the characteristics of the upper levels of quality was questioned and criticised rather than held as destination goals. Although the survey showed that many of the pitfalls of TQM implementation had been avoided, there was evidence of strengthened feelings about the inapplicability of TQM to the nature of the business and organisation culture of a PSO.

The following chapters build upon this picture by reporting upon research activities focused upon quantification of improvement (Chapter 8 and 9). Chapter 10 reports on the corroborating cases study at SciTec where lines of investigation followed the themes identified above. Chapter 11 reports upon the development of three models, the basis of which were drawn from the observations reported in this chapter.

CHAPTER 8
BIOFARM CASE STUDY
SURVEY MEASUREMENT RESULTS

Introduction to Chapter

In addition to the observation activity reported in the previous chapter, the participant observational activity at BFL was supplemented and supported by a series of measuring rods. In this Chapter, the impact of those activities are reported and the significance of the outcome considered. This Chapter reports upon the four survey activities cited in box 3 of the figure below. These are the surveys of Quality Indicators, Errors and Accolades, Documented Errors and Hidden Shortcuts

As stated in previous Chapters, the interlinked nature of the elements of this research programme make the practicality of reporting elements in isolation rather difficult. These reports of measurements provide quantification of the progress of the overall programme and draw upon data obtained from interview and observation to provide meaning and context.

Figure 8.1   Conceptual model of action research case study at BioFarm
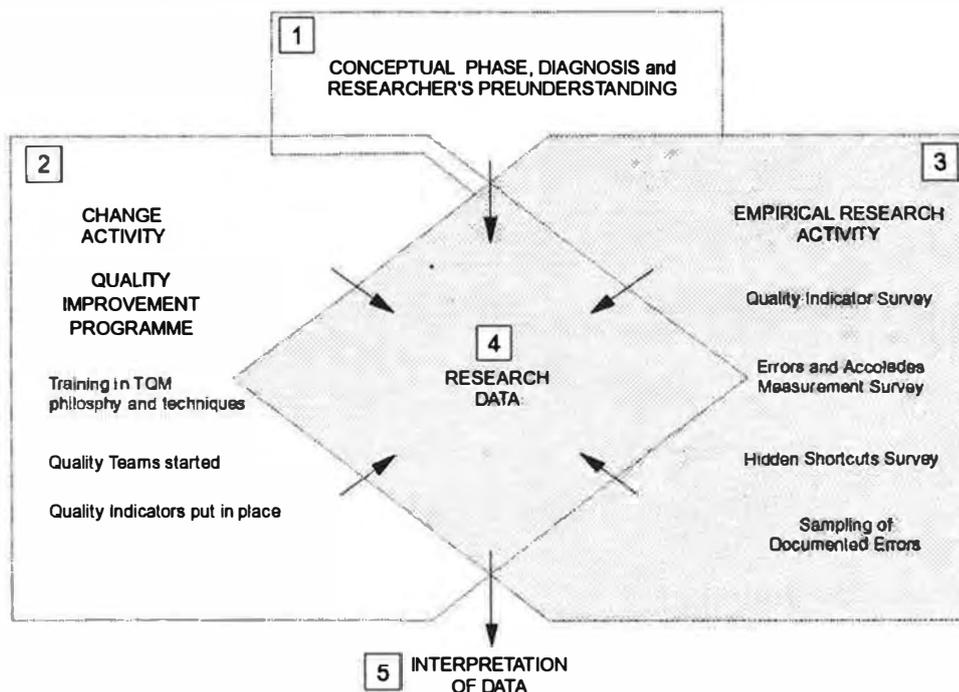
Organisation of the Chapter

The sections in this Chapter are organised as follows

8.1   Overview of survey findings

8.2   Survey of Errors and Accolades (ACE database)

    8.2.1   Overview of survey

    8.2.2   Difficulties in achieving the objective

    8.2.3   Measuring improvement in a changing economic context

    8.2.4   Improvements

8.3   Survey of Quality Indicators

    8.3.1   Purpose and success of the survey

    8.3.2   Background to Quality Indicators and rate of adoption

    8.3.3   Selection of Quality Indicator subjects and reason for selection

    8.3.4   Consultation and announcement of indicators

    8.3.5   Types of Indicator

    8.3.6   Scope of involvement

    8.3.7   Longevity of Indicators

    8.3.8   Measurement frequency and goals

    8.3.9   Improvements

    8.3.10   Changes to procedures

    8.3.11   Change of Indicator

    8.3.12   Feedback

    8.3.13   Enthusiasm and feelings of those involved

8.4   Sampling of Documented Errors

    8.4.1   Overview of survey

    8.4.2   Sampling and findings

8.5   Hidden Shortcuts survey

8.6   Summary of chapter and relevance of findings

8.1 Overview of Survey findings

The surveys reported in this chapter were intended to provide companywide quantification of the improvement of the tangible aspects of performance. From the research design perspective, quantification was intended to provide data to support the broader case study findings irrespective of whether the Quality Improvement Programme achieved its objectives. For the client organisation (BFL) the quantification of aspects of performance provided "payback" for the investment in QIP. They also provided insight and learning tools such that the depth of understanding of quality issues within the company could be better understood and addressed.

However, as the TQM philosophy can be divided into "hard" (finance, productivity) and "soft" (attitudes, culture) elements, the researcher had expected that some improvements, for example, culture change, cooperation and communication, would be difficult to quantify but would nevertheless be influential in improvement of the hard elements. The Quality Indicator Survey and the Survey of Errors and Accolades were intended to provide quantification of tangible improvements in quality in the form of improvement trends measured over a prolonged period of time. The Sampling of Documented Errors and the Hidden Shortcuts survey arose as an extension of the Errors and Accolades measurement whereby it was considered that the measures of errors and accolades represented only a small sector of failures of quality.

None of the measuring rods showed significant improvements in performance at the level that might be considered as a performance breakthrough. Improvements were observed to be small steps rather than giant leaps and were not evident in terms of improved financial performance in the level of operational contribution for the company as a whole. This finding was actually in line with the intent of QIP i.e., to take the approach of steady, continuous improvement (the acorn to oak tree metaphor was used at the QIP launch) and constantly hone and refine quality. However, improvements were made, in particular in the area of the company's major failing of quality - late reports.

258

8.2   Survey of Accolades and Errors - ACE data base

8.2.1   Overview of survey

Documentation providing evidence of failures of quality and accolades for good
performance was gathered between 1989 and 1993. It was summarised and entered
onto a Microsoft Access bespoke database (ACE).

The purpose of this survey was to obtain an extensive picture of the level of error
visible to clients. This was achieved through survey of communications between BFL
and its clients. At the outset the objective of accumulating evidence of errors and their
subsequent categorisation according to type and cause appeared to be a relatively
realistic objective. It was envisaged that the measurement would be used as an
indicator of the achievements of QIP and the quality that the company delivered to its
clients. Through problem identification and recording, it was hoped that improvement
efforts could be focused upon commonly occurring problems such that an improvement
trend would be demonstrated.

Each record entered onto the ACE database was classified using the coding structure
presented in Appendix 6 (6.2). The data were analysed for trends of the error types,
incidence, comparison of error type, and interdepartmental differences. Results can be
found in Appendix 8.

The picture gained from the analysis over five years was interesting if, at first view,
rather unremarkable. The data provided a picture of a limited but demonstrable
reduction in the incidence of communications between the company and clients on
issues of failures of quality. There was evidence of a reducing trend in the incidence of
complaints about the company's major failing of quality (late reports). In this context,
variation in the performance of different departments was evident. However,
complaints about reports (lateness and errors) still constituted around 30 percent of
total ACE entries. Around 5 percent of entries related to the issue of interpretation of
results. This category was considered to be of major significance to the standing of the
company because it included disagreements about interpretation of scientific findings.
These were a matter of professional scientific judgement and keystone of the scientific

service provided by the company. Such disputes had the potential to reflect upon the professional capability of the organisation and often required both scientific and diplomacy skills to resolve. Entries in the area of technical competence accounted for around 15% of the total and represented the most diverse group - there was no real change in the level of entries in this field although the specific type of entry varied at a low level. The remaining entries were accounted for by correspondence and financial errors.

As discussed later in this chapter, any consideration of the nature or extent of improvement requires that the raw data is viewed in the broader context of work volume and business environment if useful conclusions are to be drawn. The survey emphasised the difficulty of attempting to use wide ranging measures in the environment of a professional scientific organisation. Such an environment is characterised by a complexity of variable tasks, some repeated in volume, but many of a unique nature and subject to variables, often of an unknown or uncontrollable nature. Although the cumulative data may suggest that an improvement has been achieved or that one is required, the researcher feels that it is only at the detailed and specific task level that either error or improvement is identifiable.

8.2.2 Difficulties in achieving the objective

As time progressed, a number of difficulties were identified in the implementation of the original objective. These problems were related to:

1. The limited scope and depth of the picture provided by the data - and thus the relevance of the measure as a whole company indicator of quality

2. The variation, unique attributes and complexity of the issues and types of errors with the potential for inclusion : over 190 categorisation codes were applied to around 3800 reported problems. A significant proportion of codes were used less than four times in a year.

3. Difficulties in standardising the coding and assessment of the severity of the problem.

4. Excessive time demand to review communications and maintain the database; over the five year period it is estimated (based upon three sampled occasions) that around 500,000 communications were reviewed.

5. The extent of distribution of reports; dissemination of feedback reports was initially not as wide as desirable.

6. The problems of producing useful measurement in a changing economic climate.

1. Scope

In respect of the limited scope, it is worth considering the nature of an "error" and the characteristics of such that it would qualify as a candidate for inclusion in the ACE database. To qualify:

a. It had to be the subject of a communication between the company and client. The contact could be initiated by either party.

b. It could be any negative comment that had the potential to adversely affect the client's perception of the company or continued relationship with the company. To balance the bad/good picture, it could also be a positive comment

c. It had to be related to the company's scientific service

d. The "error" had to be documented on paper: the contact could be verbal, such as a meeting or telephone conversation, recorded by the company representative.

e. The "written" version had to be routed through the company central mail system.

Given the above qualifiers, it is not too difficult to surmise that errors, mistakes, or failures of quality by any other name, could occur and would have failed to qualify for inclusion or might otherwise have passed through the net of detection.

One paradox arose from the extent that different departments communicated with clients. In a PSO, frequent communication with clients is regarded as

261

desirable. However, in the situation of an outgoing communication explaining a situation such as expectation that an agreed report date would not be met, this would automatically be picked up and included on ACE. Paradoxically, the better the communication, the more likely it was that the issue would be recorded on ACE - this was viewed negatively by those so caught. Review of communications suggested that some departments were far more likely than others to communicate in advance of a problem, thus entering early into damage limitation, and often concomitantly building customer relations. These departments might be seen by others as producing the least optimal performance.

The nationality and business culture of the country and company also has a bearing upon the extent to which communication is formalised. Much of BFL's business was with the Japanese with whom communications are predominately in writing, through a third party (the company's agent) and translated (to and from the Japanese language). This formalisation of contact and language makes evident communications on the matters of failures of quality. By comparison, the less formal business culture and common language of UK and USA clients means that matters are more likely to be discussed and agreed verbally by, for example, a telephone conversation; evidently the latter communications have the potential to go unrecorded or to be reduced to a non-issue not worthy of recording.

Failures of quality that a) occurred during everyday operations, b) were corrected according to the requirements of GLP and c) did not impact upon the scientific integrity of work, were not normally relayed to the client. Such failures might have been as apparently insignificant as a clerical error, to the somewhat more serious problems such as identification of an error in the preparation of the test substance intended to be given to animals. Neither of these matters would have been recorded on ACE even though the latter had the potential to severely damage or write off a study. There was a developing realisation that ACE provided just the tip of the iceberg; there was a danger

that a false confidence could be assumed by those without the insight to understand the complexity of the whole picture.

2. Variation, unique attributes, and complexity

It is well reported that the measurement of failures of quality, and often customer complaints, is a relatively common practice in organisations striving to improve quality. There seems to be some undeniable logic in the statement that to improve, you have to understand the problem - and understanding may be increased as data on the problem is accumulated. A form of analysis such as Pareto, can be utilised to sort the common but numerous problems from the less common, thus allowing quality improvement activities to be focused on removing the most numerous problems. This type of analysis is useful in a production environment or other situations where the activities are sufficient in number and design to make a measure meaningful, and where all problems can be given roughly equivalent severity weighting. But its use reduces where the profile of activities are such as those of a Professional Scientific Organisation. In this context the activities are greatly varied, the frequency of error is low, and the severity weighting can be highly variable, thus making quantification of error and measurement of improvement an activity of debatable value.

3. Coding difficulties

In the early development of the coding, it seemed an excellent idea to develop a four-part code based upon the following classification

a. **The type of problem**: eg. reports, science, protocol, finance, correspondence

b. **Cause of problem**: eg. human error, equipment failure, communication

c. **Severity of problem**: eg. minor, moderate, major.

d. **Consequences**: eg loss of reputation, costs of rework, repayment

These early attempts at coding were beset with difficulties in allocating categories. It was felt that if the categories were too broad, as the original

263

codes suggested above, there would be limited understanding of the nature of the problems, and at best there might evolve a spurious statistical tool which would not be of much value in attaining the original objectives.

Many of the problems fell into more than one category; for example, a report of results might be late because there had been problems with the timing of taking blood samples as a result of misunderstanding of the written instruction (the protocol) being ambiguous. Such an error might be placed in the following categories

a. Type: reports; science; protocol

b. Cause: human failure; communication; technical complexity

c. Severity: It depends upon:

- criticality of report timing
- criticality of blood sample timing,
- level of interference with the animals
- whether this is the first error with this sponsor or
- "the straw that breaks the camel's back" ,
- the attitude and expectation of the sponsor

d. Consequence: dependent upon c. above

It was considered that appropriate allocation of all errors into the above categories suggested the need for a second tier of subcategories. In-depth review of all but the most obvious errors would be required if an understanding of cause and an assessment of severity was to be attributed. It was felt that such a coding exercise would be too complex for the regular dissemination of the outcome to employees; thus it was thought that adoption of an over analytical approach would place the activity into the realm of diminishing returns on effort. Therefore only the "type of problem" classification was developed and applied.

4. Dissemination

The forerunner of the Quality Feedback Report was known as the "Error Report". In this report errors were allocated a score according to perceived

severity; the report was vehemently disliked by those who received it or knew of it. Unfortunately the Quality Feedback Report, which essentially reported on same issues in a similar format, was viewed in a similar negative light. The view of one senior managers was:

> *"When you point out lack of quality it is a kind of stigma. The error reporting thing has been a pain in the arse ever since we started it. It's not looked upon as a positive thing, it's looked at as a negative thing"* (L2)

Some heads of department felt it was "insulting" and "divisive" and did not circulate the report within their areas; discussion with middle managers found that many of them had never seen a copy of it.

On broader dissemination, response to the report was mixed. In one area (toxicology) the original recipient broadened the circulation to include all of the toxicologists. They responded positively, discussing entries, adding additional information and correcting anything which they thought in error; they found the whole-company view of particular value.

By comparison, another middle manager returned her copy to the person who had forwarded it with the following note:

> *"I don't think this was intended for me. I have never seen it before and think it is a disgrace - we are intelligent people who are quite aware of what is right and what is wrong in our departments. I think it is the sort of rubbish that is insulting and undermines managers."*

The above reaction, almost three years into QIP, probably says more about the quality of communication in the manager's department than it does about the value of the report. However, any document received with such disapprobation is unlikely to be used constructively.

5. Measuring improvement in the changing economic climate

The process of measurement and reporting could not, and was not intended to, achieve any improvement in its own right; only changes in other processes could put gains in quality into place. ACE's contribution to quality improvement was that of an information tool, helping people know what to look at and where to look. It also served as a stimulant to keep staff alert to error and, through inclusion of positive comments, aimed to provide some

positive feedback. The overall picture provided one of the indicators of change in the company over the period of this project.

One of the issues of measuring the level of error and rate of improvement was that both were subjected to numerous contextual variables. To suggest that errors reduced by X % over Y months would be a valueless measure unless placed against, for example, work volume. In a PSO, the varied nature of non-standard work makes it difficult to measure activity; there is no common unit of work - production unit - that can be applied throughout the organisation. There is no common selling price - each study is designed and sold on the basis of negotiated price. And there is no baseline of constant activity that will be guaranteed to occur over a prolonged period of time. The foregoing features led to ACE output being measured against the number of employees in the company (errors per head) and the level of earnings (errors per £ million turnover). Figures 8.2, 8.3 and 8.4 show data from 1987 to 1993.

8.2.3 Measuring improvement in a changing economic context

Measuring performance over an extended time period requires consideration of the economic context and overall performance of the company. Keeping in mind the difficulties of common measures enunciated earlier, it was felt that there was value in applying an indicator of work volume such that any improvement could be judged in context. In the absence of a common companywide unit of production the indicators used were (1) Turnover and (2) Rat equivalents/month[1] .

---

[1] **Explanation of the basis of the Rat Equivalent Unit** : Rat equivalents (REs) are units of measurement based on the animal population of the company. The unit is based upon the relative amount of time and effort required to conduct a study on one rat versus another species.

A "rat" is the smallest unit and other animals are given a conversion factor whereby they acquire a "rat-equivalent value". These are:

Species	Conversion Factor
rat or mouse	1
guinea pig	5
rabbit	10
chicken	10
Monkey	20
dog	25
pig	25

Using a monthly census of animals, all populations can be converted into REs whereby month by month comparisons of work volume are then possible.

The majority of activities in the company were directly linked to the live-animal based laboratory activities, thus it is argued that the Rat Equivalent unit provided a good estimate of the revenue earning activity of the company. The unit was not intended as a precision instrument, rather it was a well tested order of magnitude measure; it worked particularly well when applied to large populations where variation of the level of activity applied to individual animals and studies could be averaged. The rat equivalent unit lost reliability when applied to small populations of similar study designs.

Figure 8.2 shows the turnover and work activity of the company from 1987 to 1993. This period was selected because it spans the time of this research project and thereby provides both historic and post QIP context. The span both starts and ends at critical development points in the company history: In 1987 BFL was launched on the USA stock market and in 1993, following a company merger, the company became part of a new division. At this stage Business Process Re-engineering effectively replaced QIP.

Figure 8.2   Annual turnover (£ million) and work volume for period from 1987 to 1993
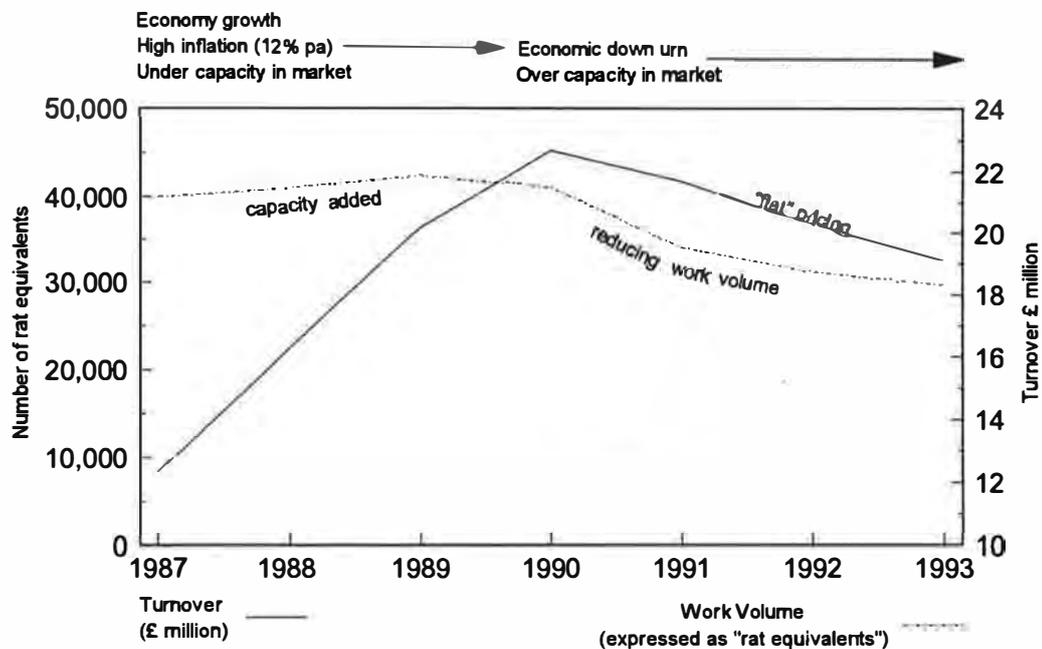
The turnover line on the above chart shows the period from 1987 to be a phase of significant growth for the company. The growth in turnover (64%) was positively

influenced by inflation in the economy and under capacity in the CRO industry. Limiters of growth included the physical capacity of the laboratory and the speed of recruitment and training of staff. By 1990 it was evident that the market was declining (Source: company revenue projections and sales plan) and a gradual decline in work volume was observed.

In terms of quality and the level of errors, the growth of the late 1980s was characterised by major recruitment activity resulting in a high proportion of staff undergoing training. Inexperience of new staff and existing staff in supervision of others appeared to have a negative impact on quality; the need to implement a programme of quality improvement was partly driven by these factors. It was widely felt by managers that there was insufficient trained staff to handle the workload.

> *"We are suffering from growing pains and we are running to keep up with the ball. That affects performance.... "* (L2)

> *"In the present background, with the present level of service, the company can sell all the work it can get....Upgrading quality requires time energy and willpower, and all those things are on ration at the moment because we are so busy"* (L5)

> *If you have a shortage of experienced staff and time dependent work, it is close to inevitable that you are going to have, not necessarily a reduction in quality - but you might find it difficult to improve a lot"*(L8)

By the time of the start of economic downturn, the impact of QIP was becoming noticeable and staff had reached a level of greater comfort in respect of experience and work volume. Peak performance was attained in 1990 followed by decline in revenue considered to be associated with the economic downturn and market behaviour. Selling prices were generally held steady or were cut from 1990, thus the declining turnover line is indicative of a reducing volume of work. Figure 8.3 overpage shows the trend of turnover set against staff numbers and incidence of negative communications. The actual number of negative communications (referred to as ACE entries from 1987) increased much in line with company growth up to 1990, thereafter they gradually declined year on year.

Figure 8.3 **Trend of staff numbers, £ turnover and negative communications for 1989 -1990**

		1987	1988	1989	1990	1991	1992	1993
Staff: average FTE		432.0	522.0	618.0	667.0	659.0	657.0	570.0
Negative communications		482.0	540.0	656.0	699.0	647.0	588.0	542.0
Turnover - £ million		12.3	16.3	20.2	22.7	21.7	20.3	19.1
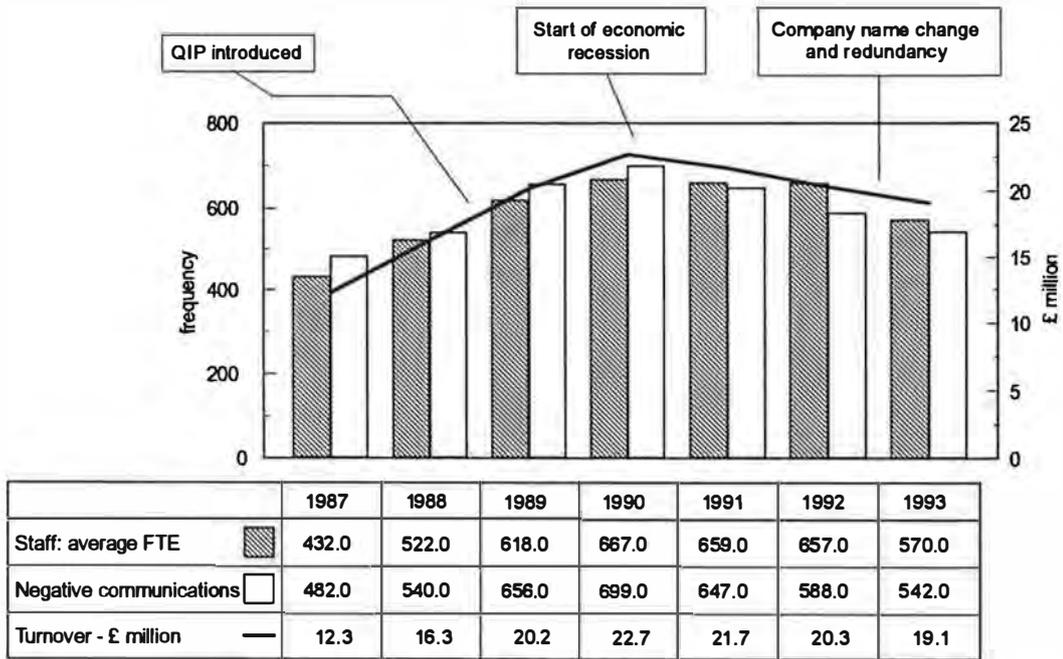
Figure 8.4 **Errors per head and errors per £ million turnover from 1989 to 1990**

		1987	1988	1989	1990	1991	1992	1993
Errors per head per year		1.11	1.03	1.06	1.04	0.98	0.89	0.95
Errors per £m turnover		39.11	33.13	32.47	30.79	29.81	28.96	28.37
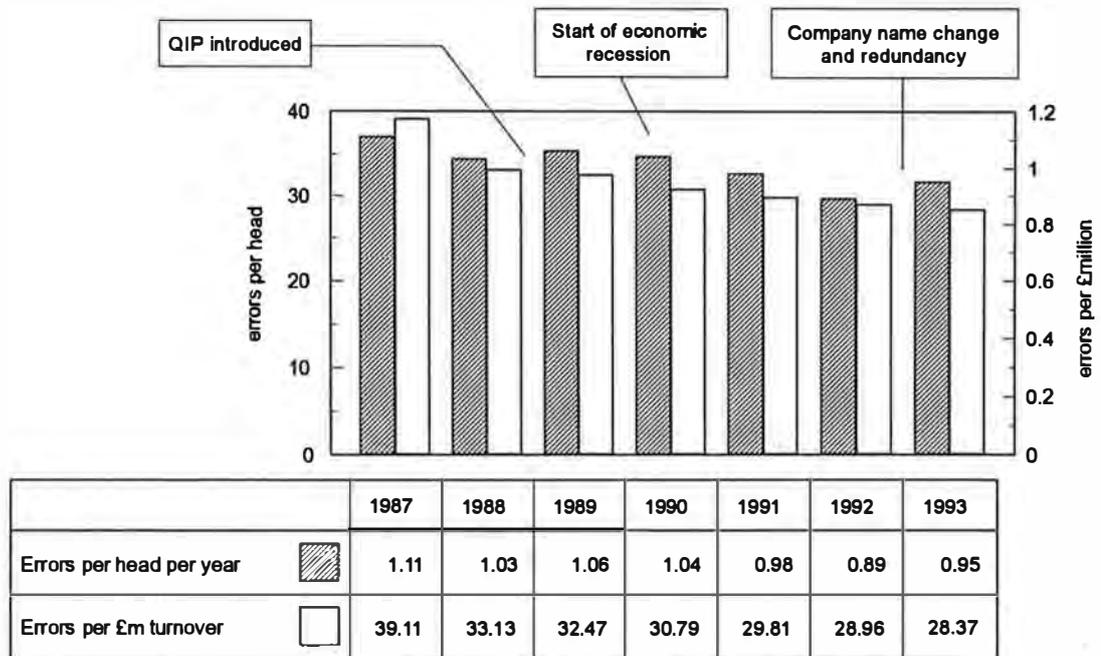
Measured in terms of errors per head of staff per year, Figure 8.4 shows a gradual decline from 1.11 to 0.89 between 1987 and 1992 with a slight upturn in 1993 to 0.95. Errors per £million declined over the same period from 39.11 to 28.37. It could be argued that if turnover increases and the number of errors remains constant, then

269

clearly the errors /£m would reduce. However, as there was actual negligible inflation on turnover, what was actually could realistically be viewed as an improving performance.

The slight increase in errors per head in 1993 was considered to have been influenced by a major reorganisation in the company, including a change of top management, some departmental restructuring, staff redundancy, change of corporate structure and change of company name.

8.2.4 Improvements

ACE data is extensive and it is felt that reporting and analysing over 3,000 entries made during the period in question will not add value to this thesis. However, the key quality issue of late reports is discussed because it provides a window onto a critical area of improvement for BFL and is indicative of differential performance between functions and the complexity of improving this aspect of the work of a PSO. The need to improve reporting performance was widely accepted as a major objective of QIP.

Late reporting could be seen as the culmination of all of the inherent failures of quality in the company. The tendency was to use reporting performance as a measure of adequacy of the leading scientific groups yet the contributory factors to late reports could be attributed to virtually any area of the company. When senior managers were asked during research interviews, what they considered to be the organisation's most important failure of quality, the issue of late reporting was widely mentioned (L2,L3,L5,L6,L8,L9,L10,L11,L16,L22). Examples of responses include

> *"I can only think of a year or two when we have not had a backlog of reports"*[L2]

> *"You go to ABC now, and it's years since we have worked for them seriously and they still say "BFL = late reports""*[L22]

There were ample other data (management reports, quality assurance reports, meeting minutes) that demonstrated that reporting performance had received much management attention and it stood alongside financial monitoring as the only key performance indicator that had been measured in some form for most of the company's history.

270

The reasons why reports were late are many including late or poor quality input from various contributors, labour intensive production processes, lack of standardisation in style and content, bottlenecks and delays in production, editing, review, printing and quality auditing. In addition to the elements of production that could fail, other issues included poor scheduling of work resulting in delayed starts, the need to repeat failed elements of work, shortened time allowance for reporting, clashes in priorities and time availability of appropriately skilled staff for the process. Given that the contributory factors to late reports are so wide ranging, any improvement would need to extend beyond the leading scientific departments and thus it was felt that whilst ACE entries recorded failures of performance against whichever group held project management responsibility, they alone were not in total control of the process.

From the research perspective, what was interesting was the different approaches taken by each leading scientific departments to bring report production under control. The data show that by and large progress was made - but observation suggested that the price of improvement, and the way in which improvement was achieved was inconsistent across departments. The trend of incidence of late reports as recorded on ACE is presented in Figure 8.5 below:

Figure 8.5   Trend of Incidence of ACE entries for Late Reports.
1989-1993 by quarter
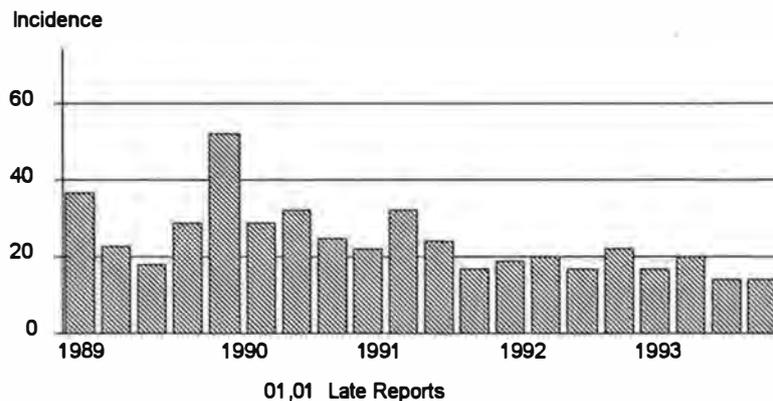
Like all ACE data output, it is necessary to remember that ACE only provides a categorisation of *communications* about failures of quality. It can show if there have been more or less communications in a category, and from this data, an improvement may be assumed but is not proven. The overall picture is complex and subject to many variables. The term "Late" is applied to any report which is not issued at the agreed timeline, i.e. according to the agreed specification. An improvement in respect of meeting this specification could be achieved through application of quality methodology and systems refinement. It could also be improved at extra cost with extra resource, or most easily, it could be achieved by agreeing to extended timelines. Observation suggested that all these approaches were used to varying extents. The issue here is an acknowledgement that the improvement trend suggested by Figure 8.4 required further investigation as a check of its validity.

Using data extracted from the company's centralised Management Information System, it was decided to look at the timing of issue of draft reports against target to establish whether any improvement was evident in respect of meeting timelines. This data would establish

1. The number of reports produced by each department over a fixed time period
2. The issue date of each report against the agreed target date.
3. Whether the picture of the company was consistent across departments
4. Whether the picture supported or refuted the improvement trend shown by the ACE data.

A comparison was made of two years; 1989 before QIP and 1992, when any performance improvement measures had received sufficient time to have an impact. For ease of comparison, the percentage change in reporting performance for the two years was plotted on a bar chart by whole company and then by the three major groups. Chemistry was not included because of the small sample size. As expected the consolidated picture showed improvement. The results are shown in Figures 8.6 and 8.7.

Figure 8.6   **Comparison of report delivery profile for 1989 and 1992 for whole company**
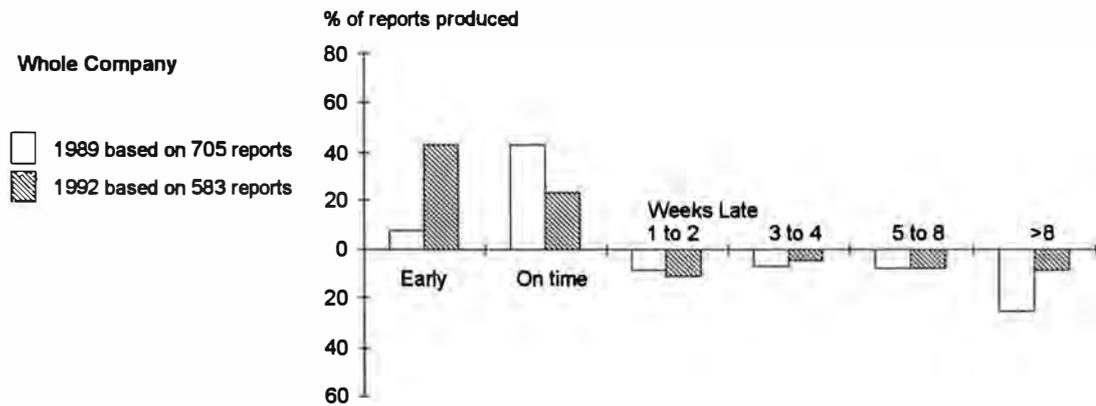
From the above chart it can be seen that for the consolidated company that there was a shift towards earlier reporting with over 40% of reports released early in 1992 and a reduction from 25% to 9% for reports issued more than eight weeks late.

Drilling down into the picture to look at individual department performance, there were marked differences in the number of reports produced and the change in performance level. Both Reproductive studies and Toxicology and Oncology made considerable gains in performance while Short-term Studies showed an increase in the number late reports. Chemistry performance detracted from the improving overall trend. This department was unusual because its relatively youth and inexperience by comparison with the other groups. It was noted that this was the only department that had a higher output in 1992 than in 1989 but, with numbers increasing by only 3 over three years, these figures have minimal influence on the over all picture.

As already suggested, the contribution of each department to the improved performance differs. The comparative performance of Toxicology and Oncology, Reproductive Studies and Short-term Studies is shown in Figure 8.7 overpage.

273

Figure 8.7   Comparison of report delivery profile for 1989 and 1992 for Toxicology and Oncology, Reproductive Studies and Short-term Studies
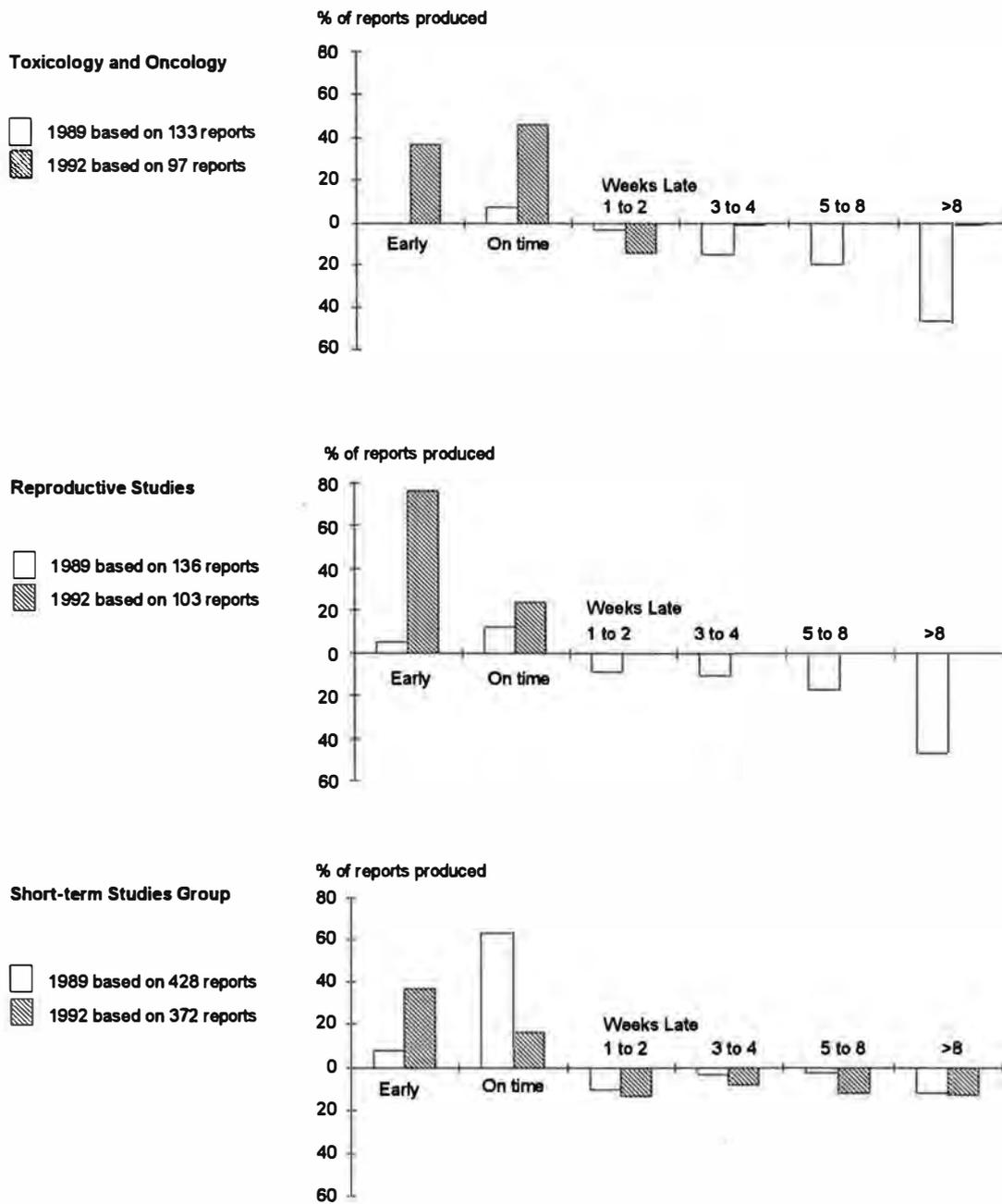
Figure 8.7 above shows that the on-time reporting performance of Toxicology and Oncology (top chart) and Reproductive Studies (middle chart) improved considerably, reducing the number of late reports to 16.5% and 0% respectively. By comparison, Short-term studies showed a deteriorated performance from 28.3% late to 46.5% late. One of the interesting perceptions gained from the ACE data was the number of communications about delayed and late reports, relative to the actual activity. It was

274

noted that Toxicology and Oncology communicated and received far more communications than Reproductive Studies who produced a similar number of reports. The reasons for this were considered to be linked to the departmental style (the desire and authority to communicate) and the critical timing of the report in the product (material under test) development process[2]. The most frequent communicators per report were Chemistry who were more likely than the other groups to discuss technical and scientific problems associated with the work as cause for delay.

Looking at the actual reporting performance alongside ACE data, it is considered that whilst ACE only reflects number of communications on report problems, it is a reasonable indicator of the status of work. However, the reasons why situations arise that might cause a sponsor dissatisfaction are diverse and it is recognised that consolidation of issues to common threads for the purpose of quantification, may have the effect of masking some of the issues.

Figure 8.8 overpage provides a breakdown of late report communications by department. The trends are approximately in line with departmental performance on on-time issue of draft reports.

---

[2] The work conducted by Toxicology and Oncology tends to be at the end of the product development chain therefore the report is often the last inclusion in the dossier of information gathered for submission to appropriate government agencies. Delay in this report may affect the timing of registration of a material for marketing. Any delay at this point may have a marked impact upon the profits that will be made by the sponsor company during the patent life of a product.

Figure 8.8   Departmental trend comparison of incidence of communication about late reports (Code 01,01)
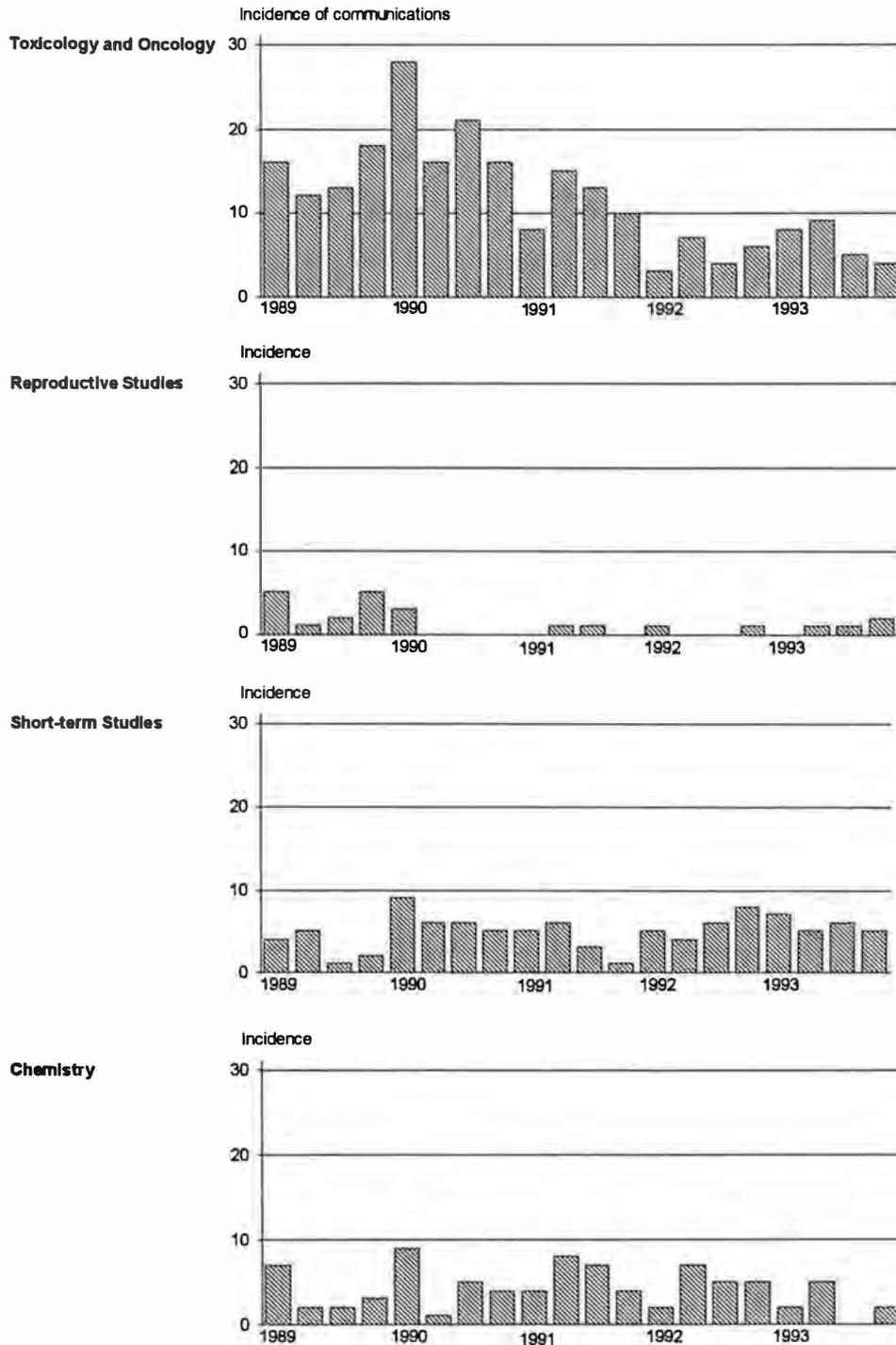
It was observed that the fact of "improved performance" of the reporting of the reproductive studies group was viewed with doubt and scepticism by other departments. It was felt that the improvement had been gained through *"coercion and fear of the "boss" rather than the use of quality methods"* (group interview, Feb. 1992) who was

considered to be *"driving for a target that he had set as a means of satisfying his own ego"*. The Toxicology and Oncology group felt that reporting deadlines for Reproductive studies were, by comparison with their own, relatively generous to the authors; they saw their own as getting increasingly tighter. The data gathered did not provide information to support or refute these accusations. However, it was apparent that the combined measures of reporting performance and ACE were inadequate tools to provide an accurate picture of the nature of improvement or the causes of problems in such a complex and varied process of report production.

It is suggested that the picture presented here is indicative of the problems of single dimension measures for looking at quality improvement. Two measures (ACE and Late Report Analysis), combined with observation and interview were used to look at reporting performance. The measures alone did not provide sufficient depth of understanding of cause and effect to pinpoint necessary change. It is considered to be important that such measures are understood within the broader context from which they originate, not least because of the attraction of apparently simple performance indicators to higher management and the tendency to couch improvement objectives at this higher level without due consideration of the necessity to achieve improvement through attention to the minutiae of contributory factors.

ACE provided analysis of all types of client recognised problems and looked at quality from the perception of the external client. The next survey reported in this thesis (Survey of Quality Indicators) looks at improvement of activities which influence the output of the final product. Like ACE, it also covered an extended period of time. It drilled down to the next level and looked at the implementation, development, attitudes to and success or otherwise of quality improvement activities measured under the label of "Quality Indicators".

8.3   Survey of Quality Indicators

8.3.1   Purpose and success of the survey:

Quality Indicators were the measures that departments were asked to identify and implement as a tool to assist the improvement process and as a means of quantifying progress and providing feedback. For the research process they provided a differentiating measuring rod of the extent of enthusiasm, activity and achievement of the various functions of the company. They also served as evolutionary progress markers in terms of the type and complexity of measures adopted within the company. The survey was conducted in the latter half of 1992 and covered the period from early 1990 to the date of survey.

There were a number of problems with this survey in respect its ability to obtain the desired information. The objective was to gather a comprehensive picture of all of the Quality Indicators that were ongoing or had been used in the company. At this point QIP was more than two years down the line and had progressed to the extent that there was a plethora of information in various forms, generated and distributed around the company. Although information on Quality Indicators had been gathered centrally, it was in a wide range of formats, from single page charts and notes to comprehensive reports.

The survey data was gathered by representatives of a recently formed Quality Forum. These were individuals from each department that had been invited to join a central group to push QIP into a "higher level" of activity. The forum delegates had been selected on evidence of their enthusiasm and active participation in QIP activities. As a group, they were considered to have the best knowledge of activities within their department. It was hoped that participation in the survey would serve to galvanise their efforts.

The information sought was more than just data on the indicators and measurement; from observation and anecdotal sources it seemed that there may be issues of waning enthusiasm and overload in respect of QIs. Also, the varying success rates might provide information on "best practice" for such measures. Thus the process of data

gathering required some work on the part of the forum delegates. Not only did they have to gather information on the indicators per se, but they also had to advance or test opinion - this part was poorly completed. It actually took from August to December 1992 to gather in the information. With the value of hindsight, respondents were being asked to view too great a timespan and this resulted in gathering less comprehensive data than had been desired.

A second problem was that some of these people were in the habit of producing update reports on activity in their departments - they felt that much of the information requested on the survey had already been provided. There was an issue here of the extent to which a researcher can dictate their needs. As much as the information was wanted in a consistent format (to assure the same point was addressed, and for processing), it was felt unjustified to demand that the survey forms were completed and therefore some information had to be extrapolated from their various reports. Few of the survey forms were fully completed - many were returned packaged with all of the memoranda and results tables that had been produced over the course of time.

After several chases, the survey forms that were returned covered 133 Indicators, roughly one Indicator for every four employees. The picture across the company was one of inconsistency with absence or near absence of activity in a number of functions. Some functions experienced considerable problems in identifying subjects for measurement whilst some other area were not convinced of the value of this type of measurement. It was found that effective quality indicators predominantly occurred in the domain of the two major technical departments.

8.3.2 Background to Quality Indicators and rate of adoption

A companywide announcement of BFL's intent to implement a Quality Improvement Programme was made by the Managing Director in April 1989. This was followed in November by a seminar for senior managers of all departments, at which an objective and action was recorded (Notes of meeting, Pearse/Ford 24 November 1989) and agreed as follows:

> *"Each Department is to identify at least one measure of quality for each*
> *operating section, to decide upon a measurement method and have in place*
> *by January 1990. Identification of these indicators should be relayed to Jeff*
> *Finbow*[L21] *by 15 January 1990."*

Departments were advised to "start simple" tackling issues that would be relatively easy to measure and change to effect improvement. It was suggested that Indicators of improvement of activities that crossed departmental boundaries, where the improvement would not be under the control of one group, should be held in reserve until the habit of identification of measurable processes, change, and measurement of improvement had developed.

By late February 1990 the objective had not been met. Only three of twelve departments, Histotechnology, Animal Management and Administration had decided upon their Indicators and put measurement in place. Table 8.9 (overpage) provides the dates, by department, at which the head of department formally advised that quality indicators had been selected.

Table 8.9   Identification and Adoption of Quality Indicators by Department

Department	Earliest QIs in place	Response to Survey	Number of QIs in Survey	Number of other QIs identified
Administration	01/90	y	28	3
Animal Management	01/90	y	51	0
Histotechnology	01/90	y	22	0
Pathology	02/90	y	1	9
Chemistry	02/90	n	0	11
Finance	03/90	n	0	52
Business Development	03/90	n	0	2
Toxicology/Oncology	04/90	n	1	8
Reproductive studies	05/90	y	6	0
Computer Science	08/90	y	8	0
Quality Assurance	08/90	y	8	1
Short Term Studies	01/91*	y	5	11
Pharmacy	02/91*^	n	1	0

*   Dates identified from Survey.

^   Only involvement was in Indicators started by Animal Management

The three departments that made an immediate move to identify indicators, followed soon after by Finance, were the main providers of services to the remainder of the company. Animal Management and Histology were the largest and second largest departments (measured by number of employees) within the company. At that time they had around 150 staff each, the majority of whom were employed on technical activities of a repeated nature; such activities lend themselves relatively easily to measurement. Administration, by comparison, was a department of small and diverse groups; this department found identification of activities that were both measurable and improveable more difficult. Early in the process it was evident that departments that were engaged primarily in project management (Reproductive studies, Toxicology and

Oncology, and Short-term studies), were having difficulty in identifying measures over which they had sole control; they viewed much of their output quality as dependent upon other groups.

A problem encountered in respect of assessing departmental progress was the issue of differentiation between a *Quality Indicator*, and a *Quality Initiative*. Confused with, or separately identified from Quality Indicators, many groups identified aspects of work that they felt would benefit from improvement. In some cases, a Quality Initiative comprised of nothing other than completing an outstanding project or task, or just meeting a basic standard of job performance such as "filing so that documents can be retrieved". Other Quality Initiatives required working groups to invest considerable time in investigating a problem, and developing and implementing a solution; such activities were often observed to sit in the area of Research and Development, for example, development of a procedure or service not previously offered by the company. The researcher frequently experienced blank expressions when asking if a group had any Quality Indicators. But when asking the same group what they were doing about making a contribution to the Quality Improvement Programme, a full description of initiatives would follow. The confusion arises a) when *Initiatives* are seen by the originators as synonymous with *Indicators* and b) from a quirk of language and broadly accepted use of the acronym QIP to mean not only **Quality Improvement Programme**, but also any form of quality improvement initiative. Staff were observed to use the acronym widely; "do you have a QIP?", "Kevin's personal QIP is..... ", "We are displaying our QIPs .....", and so on

Over the period investigated by the survey, companywide there was a steepening adoption curve of QIs up to mid year 1992 when the curve flattened. This can be seen in Figure 8.10 overpage:

Figure 8.10   Adoption of Quality Indicators : 1989 to 1992

Number of Indicators
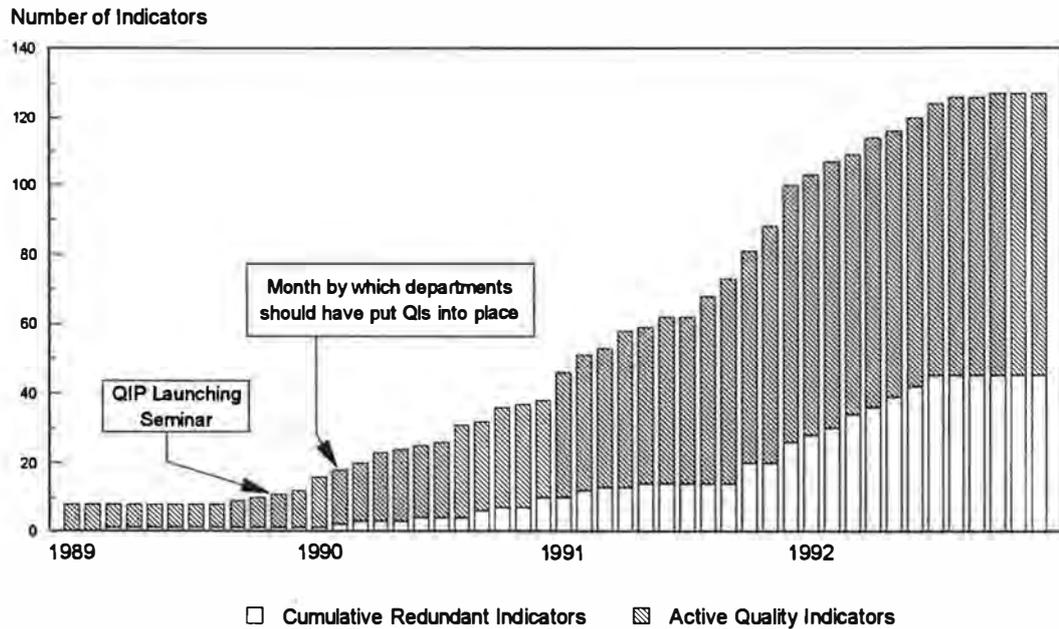
127 out of 133 included. Date of start and finish not supplied for others.

The flattening of the rate of adoption and redundancy was initially thought to be related to the timing and duration of data gathering for this survey. This thought was checked out by questioning respondents and appeared not to be the case.

On a companywide basis some measures of performance predated QIP. Animal Management and Histotechnology had several long-standing measures which easily converted to Indicators: for those two groups, it was a matter of "adjusting" measures they already had, and stepping up a gear. On a cross-company basis the "error report", the predecessor of the ACE Quality Feedback report (section 8.3), had been in place since 1984. The measurement of issue of draft reports against target date was also well established. For the reason that measurement was a familiar activity to much of the company, whether in respect of measuring performance or through the job roles as data producers, processors and interpreters, it was surprising that it took so long for indicators to be established within departments. It took 12 months for all departments to have shown some sign of activity. Two groups, Short-term Studies and Pharmacy failed to provide any evidence of Quality Indicator measurement. Short Term Studies was principally concerned with project management, whilst Pharmacy performed work

283

of a critical and easily measurable nature. The survey and other supporting documentation (memorandum and meeting notes) shows that Pharmacy was eventually party to a joint measurement with Animal Management.

The prediction made at the time of the survey, that the activity of Administration and Study Management would be low, is supported by the data.

1. Administration reported 28 Indicators. Half of these were not considered to be Quality Indicators in the accepted sense; they were outstanding core work activities rather than activities for improvement.

2. The study management groups (Toxicology and Oncology, Reproductive Studies and Short-term Studies) also met the prediction, reporting only nine indicators in total. Chemistry, a department that combined a technical operations and a Project management role did not participate in the survey but had discussed implementation of seven Indicators in September 1991.

The majority of Indicators are attributed to Animal Management (41%) and Histotechnology (21%).

Overall, there was a trailing-off of adoption of new Indicators from March 1992 and a slight increase in the rate of redundancy. It was felt that by the middle of that year, enthusiasm for Indicators was waning and most areas that could be identified for improvement, had been addressed, and it was likely that the ceiling of what people could handle had been reached. The drop off was neither dramatic or worrying. Figure 8.11 shows the number of new indicators and the rate of redundancy by month.

Figure 8.11   Adoption and Redundancy of Quality Indicators from 1989 to 1992

Number of Indicators
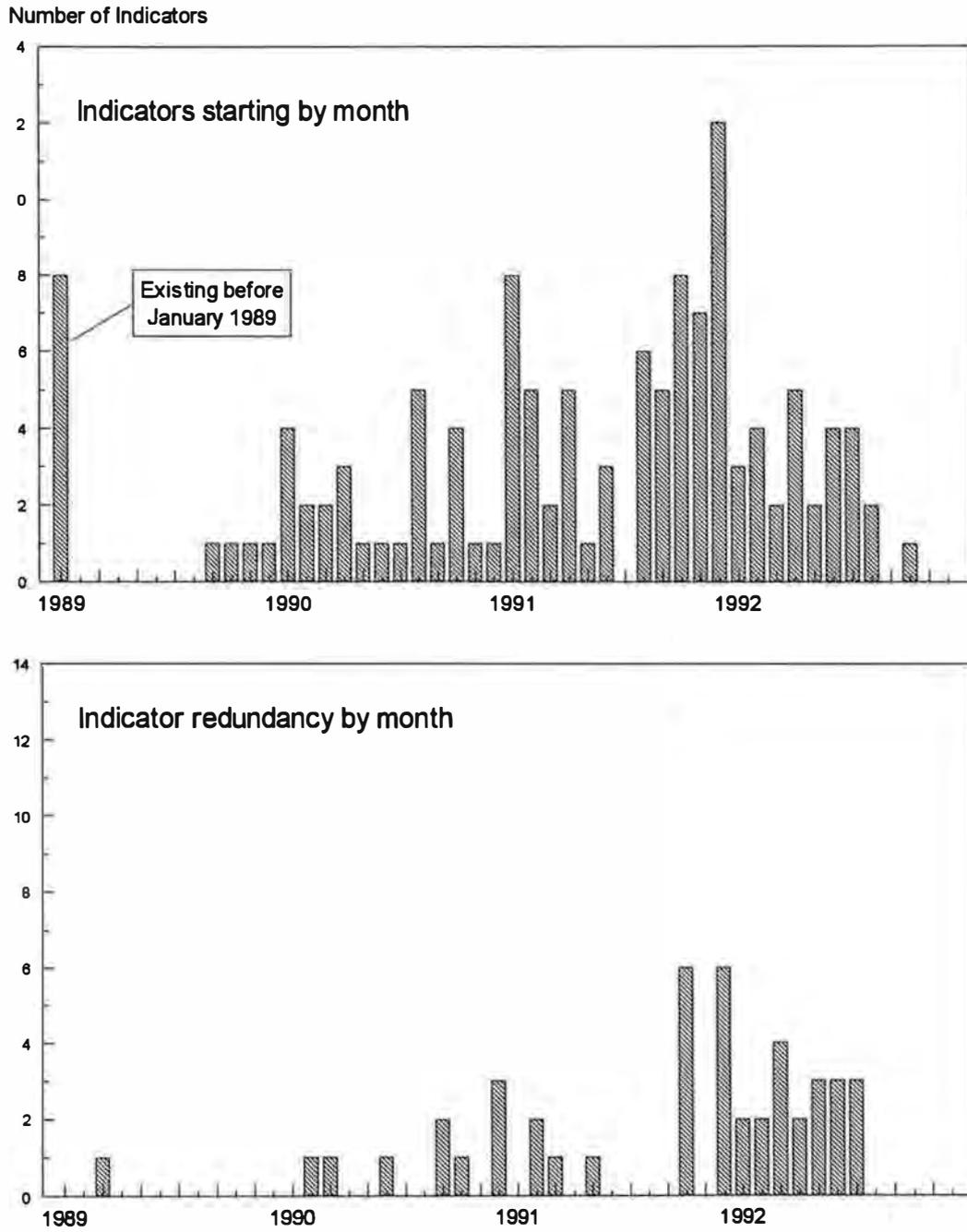
8.3.3   Selection of Quality Indicator subjects and reason for selection

The survey gathered information on the subjects selected for QIs, why that subject was selected, and the source of the data that would be used as the basis for measurement. It was expected that selection of Quality Indicator subjects would be noticeably influenced by the importance of the task or process to the business of the company, the ease with which measurement could be conducted, and the ease with which data used as the basis for assessing improvement could be obtained. The range of indicators suggests that whilst the aforementioned factors might have been considered, they were not key.

It is worth recapping on the reason why departments were adopting QIs; department heads were told that they should put Quality Indicators into place as an aid to improving quality. They and their staff may not have felt that they had any activity within their group that justified such attention, or of which measurement might be useful. In a few cases, there was genuine difficulty in identifying activities with sufficient potential for improvement to make measurement viable. Given the foregoing scenario, it was expected that some areas may have identified a subject for measurement, not because they perceived any value in the exercise, but because it was a "requirement". Of the groups that responded to the survey, this was stated as the reason in only six cases (QI# 83, 104, 125, 38, 69, 91)

Asked "why was a particular topic selected?" many responses referred to the objective of the indicator to *improve something,* eg., *"to reduce errors and ensure corrections are correctly completed"* (QI#9). This type of response suggested that the respondents understood a Quality Indicator to be more than measurement, rather a total activity that included any changes in processes that might be used to make an improvement. Others responded with the *reason or stimulus,* eg., *"Felt under pressure to find something to measure"* (QI#104). In many cases there was a combination of improvement objective and reason. The responses were further analysed using a two dimensional grid. Each response was coded 1 - 6 (motivation axis indicating source of pressure to adopt indicator) and A-F (process improvement axis looking at objective of the indicator).

The responses were then plotted on the grid shown in Figure 8.12. The grid is described below:

Reasons for selection of Indicators

Motivation Axis: *where the pressure comes from to motivate selection:*

1. Regulatory pressure, external to company
2. External pressures (Clients/sponsors of the company, directly demanding improvement)
3. Management Requirement (Includes QIP)
4. Internal customer (another department or group for whom a product or service is provided
5. Supervisors requirement; peer pressure
6. Personal desire to improve

Process Improvement Axis: *the task (process efficiency, effectiveness, conformance to specification of a product) or service (timeliness, presentation, relationships) that provides objective or stimulus for Indicator selection*

A. To measure the impact of actions upon the quality of service

B. In response to complaints and/or deficiencies of service

C. To provide information (finding out about standard achieved in respect of service)

D. To provide information (finding out about standard achieved in respect of task)

E. In response to deficiencies in system/task performance (need to improve)

F. To measure impact of change of process on task (measuring mechanism of improvement)

Figure 8.12   Selection of Indicators - Reasons why particular Indicators were selected
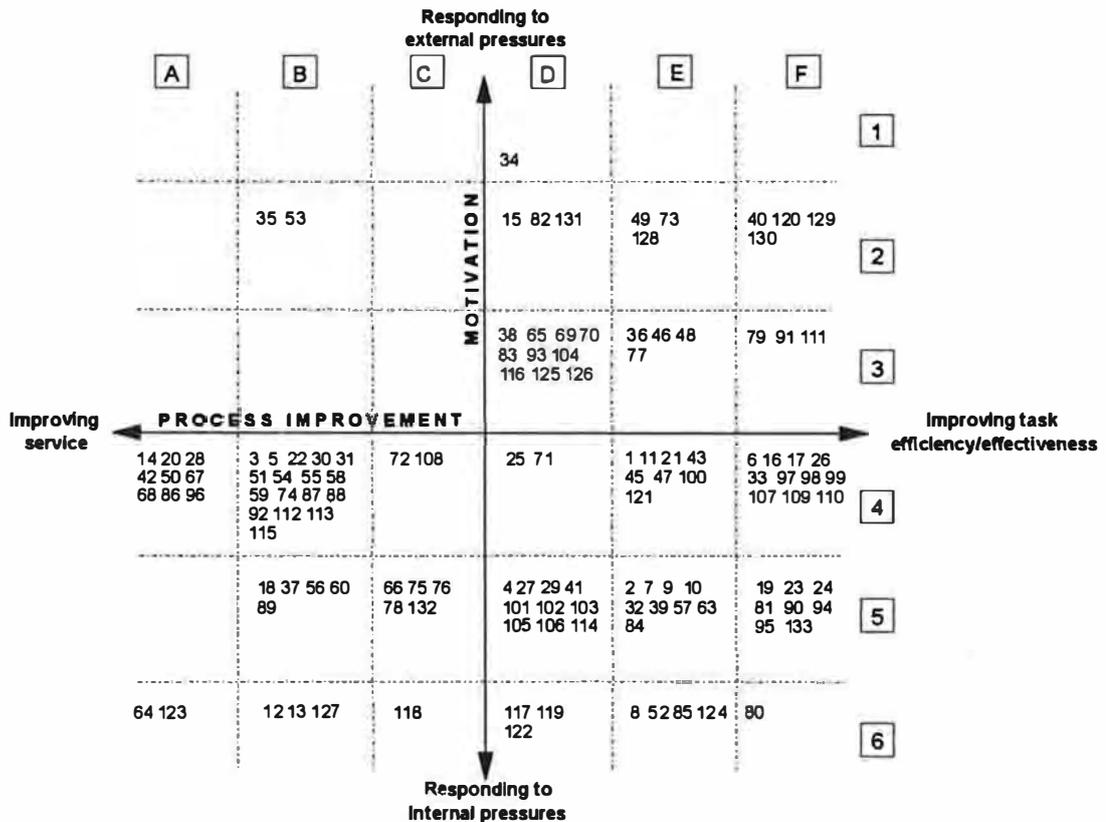
Looking at the grid, it can be seen that there was a slight bias on the Motivation axis to internal pressure, and to task improvement on the Process Improvement axis. There was a paucity of reasons in the upper left quarter. A partial explanation for this distribution may be linked to the functional groups that reported the highest proportion of Indicators. These were predominantly the scientific service providers and administrative groups that had little direct contact with external customers. A secondary line of explanation is linked to the absence of measures of activities (either task or service) that the company considers it does well, and where the use of indicators to measure improvement would be of no practical use; in this area sat the strong service ethos of the company, including the overall responsiveness at the sponsor/company interface, and the generally good relationships that existed with clients.

288

8.3.4 Consultation and announcement of indicators

Information on the means by which Indicators were announced was examined. The researcher was interested in whether or not consultation had occurred in the selection and goal setting process, and the channels adopted to announce each Indicator. This line of enquiry was followed under the assumption that the people affected by the indicator would be more committed to improvement when they had been consulted in the earlier decision making processes.

The survey data, supported by notes from departmental meetings, briefing sessions and memoranda, showed consultation almost always occurred in the selection and goal setting process. Departmental meetings, QIP meetings and departmental briefing sessions provided the preferred discussion forum, often supported by written presentation in the form of explanatory memorandum providing information on the background to and objectives of the indicator. A breakdown of the methods of announcement are presented below

Verbal announcement		*Written announcement*		*Not announced*	
Meeting	59	Memorandum	47	Personal decision	3
Briefing	21	Letter	1	No announcement	5
Discussion	11				
Workshop or presentation	4			More than one vehicle	18

There appeared to be no direct relationship between the way in which an Indicator was an announced and the associated level of consultation, with it's success or otherwise.

8.3.5 Types of Indicator

Reviewing the titles, brief descriptions and focus of measurement, Indicators were classified into seven groups according to what they aimed to improve as listed below:

Code:	*Aiming to improve:*
D	Data accuracy
E	Efficiency, productivity, timeliness
N	Non-conformance level
R	Resource utilisation
S	Service to others; working relationships
T	Technical capability and skills
X	Non Indicators

The classes show the primary function of the Indicator, a number of them falling into more than one group. For example, the histology group put in place a survey questionnaire to measure the satisfaction of their internal customer (the pathologist) with the product they supplied. They used feedback from this questionnaire to improve technical quality. This QI was categorised as "S" - service to others, because the primary intent was to measure the pathologist's satisfaction with the service.

Of 133 indicators described, 15 (code "X") were not considered to be Quality Indicators because they described the conduct of everyday tasks that would be included in the job specification and did not apply any target for improvement. It is not disputed that completion of these activities had value to the company but, for example, such activities as checking references of new employees by the recruitment office, seemed to be a fundamental requirement of the job rather than a distinct initiative targeted at improving quality. Table 8.13 provides further descriptive information on the QI classifications and ranks them in order of incidence:

Table 8.13   Categorisation and Incidence of Quality Indicators

Code	Aims to improve:	By changing and measuring:	Incidence
E	Efficiency, timeliness	Provision of a service or the conduct of an activity to an agreed timeframe	29
T	Technical capability and skills	Technical competence; skills eg dosing, blood sampling; quality of product, eg histological slides; animal welfare	29
D	Data accuracy	Data output for error, edits, losses, legibility etc.	23
R	Resource utilisation	Equipment functioning and utilisation, housekeeping effectiveness	15
S	Service to others; working relationships	Timeliness and effectiveness of within company service. Quality of service provided; communications	13
N	Non-conformance level	Incidence of failure to perform according to requirements	9
X	Non Indicators	Aiming to perform a job rather than improve the performance of task	15
		Total Indicators	133

As an be seen from the above table, 81/133 (61%) of indicators fell more or less evenly into three classes. As expected, departments had focused on those activities most commonly performed by their groups and which they felt had improvement potential. Animal Management dominate the data accuracy category (they spend much of their day recording data), Histotechnology dominate the "technical capability" category (they spend much of their day dissecting animals and preparing histological sections and mounting these on a microscope slide); the "efficiency" category, a feature of work that affects everybody, has contributions from 8 out 13 departments.

Activity level cannot just be taken as directly related to the number of indicators. It is noticeable that the two major technical groups, have in general, selected for measurement activities that are almost constantly ongoing throughout the working week - the core of their activity. By comparison, many of those reported by Administration are the measurement of a periodic activity, and thus require little focus on improvement.

8.3.6   Scope of involvement

The pre survey prediction was that there would be a move from single function (one team or one group) Indicators to multiple or cross-function Indicators. The indicators were categorised according to the extent of people involvement. The four groupings used first were

1. **Intradepartment**: Indicators that were measured within a department by an individual or groups who usually work together. The indicators could be measured as a whole department, by teams, or by individuals or on a cumulative basis.

2. **Cross-group**: These are Indicators that are run between distinct groups within a department, one of which provides the other with a service. The members of the group generally have different skill sets and do not routinely interchange job roles[3]. An example was histology and necropsy measuring the loss of animal tissues, taken from animals by necropsy technicians and received for processing by the histology technicians (QI#111)

3. **Cross-department**: Two or more departments implementing a mutually agreed Indicator. An example was the Quality Assurance Unit and Animal Management measuring Quality Assurance's performance in respect of conducting planned inspections to schedule(QI#86).

4. **Cross-company:** An Indicator that measures whole company or all of the areas in the company that perform an activity. This group included activities that were measured by a single group but to which departments should have been aiming to improve. This is a slightly unusual group in terms of "ownership" of the Indicator and input into improvement. It includes such indicators as the Personnel department's measure of unofficial absence for all departments(QI#64). In this case the measuring group had little influence over any improvement.

---

[3]   At the time of this survey Histology and Necropsy staff functioned as distinct units within one department. Many of the staff have now undergone training in both disciplines and can function in either unit

The breakdown by involvement is shown in the table below

Table 8.14   Involvement scope of Quality Indicators - breakdown by category

Span of involvement	Number in category	%	Measurement of who's performance?	Number in category	%
Intradepartmental	98	73.7	personal	7	7.1
			individual(s)	41	41.8
			team	28	28.6
			teams	17	17.3
			team leaders	5	5.1
Cross-department	21	15.8			
Cross-group	8	6.0			
Cross- company	6	4.5			

As can be seen from the above table, by far the largest number of Indicators were intradepartmental (73.7%). This was expected on account of the original objective for departments to implement indicators locally. From the outset, some Indicators were cross-departmental (Animal Management/Toxicology and Oncology FDC/KIE ratio; QI#129) and cross company (Errors and Accolades; QI#126); it was expected that these would expand more in numbers and scope than they did.

A factor that has to be considered in the implementation of cross-departmental Indicators is the extent of effort that is needed to get them into place, especially where the focus of a proposed Indicator in some way implies that one group has to improve whilst the other group measures its improvement. Before such Indicators are put in place, there often needs to be a bridge building exercise. An example of the problem is provided by the Pharmacy/Animal Management Indicators on delivery of materials to the animal facilities (QI# 31, QI# 28)

Relationship between Pharmacy and Animal Management

There was a long history of animosity between Pharmacy and Animal Management. Pharmacy provides Animal Management with prepared dose forms, which animal technicians then have to administer by prescribed means to the animals undergoing study. All too frequently, in the view of the animal technicians, the pharmacy group would provide a second rate service; they implied that deliveries of prepared doses were late, mislabelled, delivered to the wrong building and so forth. In their frustration, they proved this point by supplying pharmacy with a weekly list of errors. This served to irritate the pharmacy technicians.

> *"My technicians do not appreciate being told they are not doing their job and being supplied with lists of petty things wrong" (L20)*

In their defence the pharmacy technicians said that they were constantly distracted from their work because the animal technicians phoned them perpetually. The following quotations come from a group discussion between the researcher and the Pharmacy Team Leaders

> *"We get disturbed far too much. The animal units are always chasing us to ask where their dose is. The other week Alice was shouting at us because her technicians hadn't got a dose. But they had already had three sets that morning. She was only interested in hers and she failed to realise that other animal units are also wanting their doses"*

> *"Even though Bert and his deputy get together with the AFM's to agree priorities each week, something always changes and it's unusual for things to run smoothly. Every time we get a telephone call, somebody is distracted from their job. That's when errors can happen, they go and check on the progress of something so they can respond to the call and so they interrupt somebody else and they can make a mistake."*

> *"The animal technicians are so rude to us.....* " (Group discussion, Pharmacy 07/91)

The view held in Animal Management was

> *"Animal Management staff cannot do much to upset Pharmacy, other than chase after late or missing products, but Pharmacy can do a lot to upset us"* (tech interview, 07/91)

---

[4] AFMs are Animal Facility Managers, the senior technician responsible for management of the resources and operations of a building dedicated to housing animals used for studies

Both areas were under a misconception of the each other's role and responsibilities. Exchange visits were organised by the team leaders of both areas for staff to observe and discuss the work and problems of the other. Doubts persisted:

> *"Pharmacy staff have visited but they were so distracted by the environment and the animals that I don't think they took much in - they need more time to understand what we do"*[tech interview, 07/92]

After a further couple of months of "sorting out the ground rules", Indicators were agreed between Pharmacy and two animal facilities. What was of interest here was that both indicators, effectively aiming at a common objective, were well thought out, collecting useful information, yet very different in their design. One aimed to provide a balanced picture of the Pharmacy/Animal Management activity interface, whilst the second monitored only the pharmacy performance. These Indicators were announced within a week of each other by comprehensive memoranda addressed to the Pharmacy staff and staff of the relevant animal facility, copied to the heads of department.

The above text is offered as an example of a situation that prevailed at BFL in the early days of the Quality Improvement Programme. The use of Quality Indicators, provided the vehicle for the barrier between these two groups to start the process of erosion. Observation suggested that this scenario was not atypical, rather it was representative of the difficulties encountered in the implementation of cross-departmental measures.

The adoption of cross-departmental indicators appears to be as much influenced by the existence of suitable activities that span departments and have the potential for improvement, as it is by the activity's suitability for measurement and the ease with which they can be quantified. Analysing the output of cross-departmental Indicators, shows that they are mostly based upon repeated activities for which success factors can be identified and quantified.

On a companywide basis there was no clear evolutionary shift to cross-group, cross-departmental and cross-company indicators, although the number of cross departmental and cross group indicators increased both in real terms and as a

percentage of the number of Indicators started during 1991. Figure 8.15 shows the start up numbers, by half year, for the four different groupings according to involvement.

Figure 8.15   Start up of Quality Indicators companywide from 1989 to 1992: Breakdown according to span of involvement

	1989		1990		1991		1992	
cross-company	1	0	0	0	1	2	1	1
cross-group	0	0	0	1	1	4	2	0
cross-departmental	2	1	1	0	4	10	2	1
intradepartmental	5	3	10	4	18	22	15	2
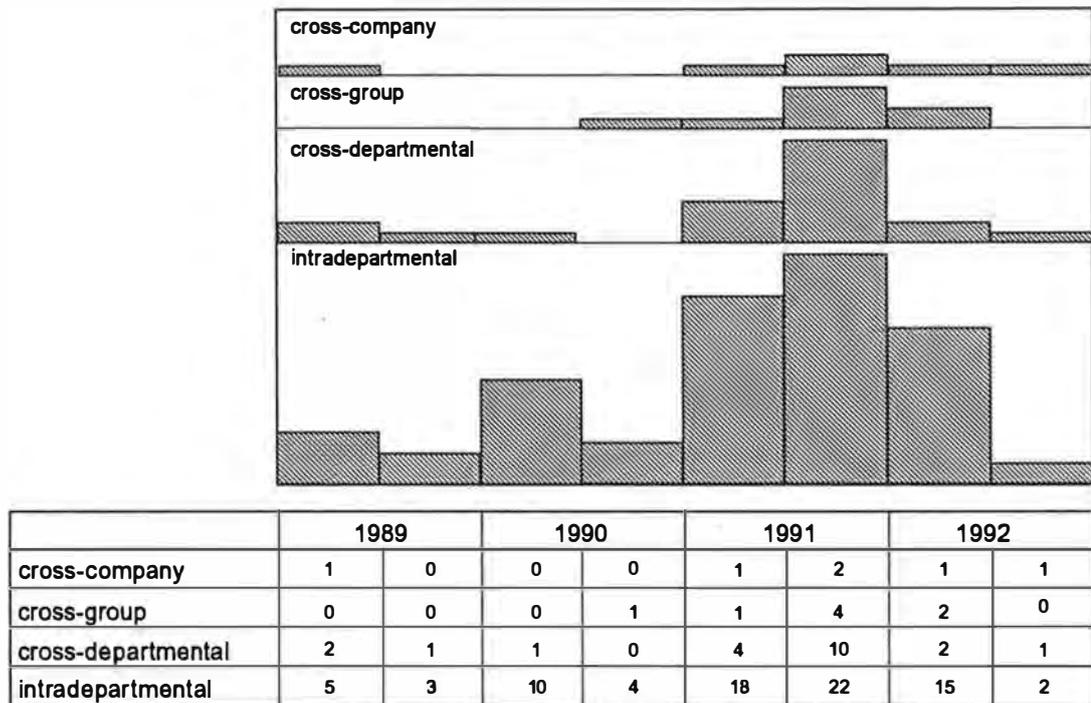
The period of time from 1991 and first half 1992, in which most (60%) of the cross department and cross-group Indicators were introduced, coincides with the peak period for adoption of intradepartmental Indicators. It is thought that this period represents a high point in terms of enthusiasm for measurement and improvement initiatives.

Reviewing the cross-departmental/group/company Indicators adopted in this period, there are no dominant features - the only point thought worthy of comment is that five of the 13 "S" category (service to others and working relationships) commenced in this period.

8.3.7   Longevity of Indicators.

The duration over which Indicators ran varied widely from a one-off occasion lasting just a few days, to more than two years. While the survey was able to establish the duration of indicators that had started and finished, and those that had started but not finished, the absence of redundancy dates for all indicators makes it difficult to draw general conclusions on longevity. Start dates were not given for all Indicators. It is possible that dates were not known for Indicators established in the dim and distant past, and for those that have varied with time, but it is considered likely that Indicators "sans dates" are also indicators "sans measurement", in other words, do not qualify as Indicators under this survey.

Table 8.16 shows the longevity of Indicators for which a starting and redundancy date was provided (lower chart) and for which a start date was given but were ongoing at the time of the survey (upper chart).

Table 8.16   Longevity of Quality Indicators
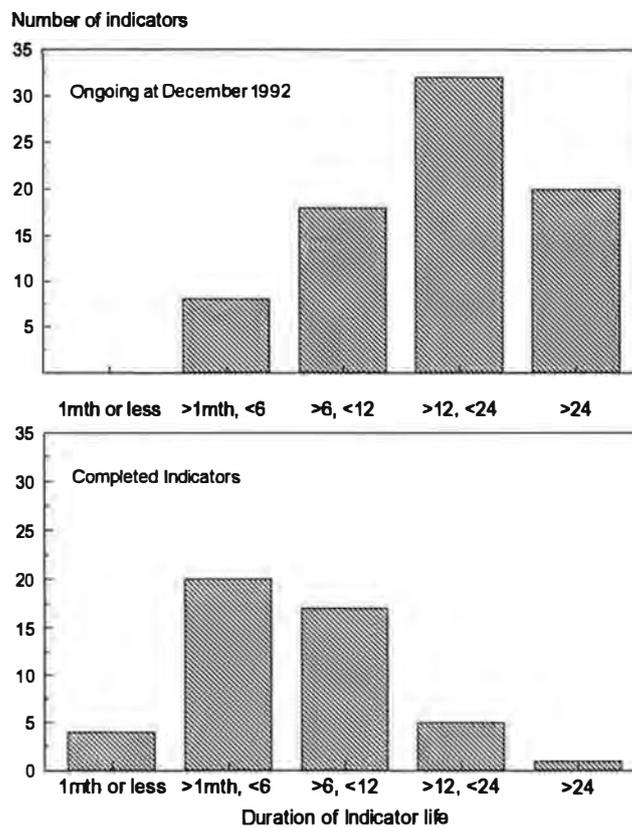
From the data, it appeared that prolonged measurement (12 months and longer) was either preferred or necessary. It is suggested that the reasons for this preference are varied. In the case of some Indicators, where a technical improvement was required, this may have taken many months to achieve. An example would be improvement in the quality of blood sampling (QI#130) where refinement of the technique and measurement of the impact took a matter of months to measure the effect of each progressive change. In some cases the subject of the indicator was an infrequently occurring event, such as performance of a defined assay (QI# 124, ELISA success rate). In such a case an indicator may have an extended life to cover sufficient such events to see any performance trend.

There are other cases where Indicators continue to exist because the habit of frequent measurement is acquired, because of peer or supervisor pressure to be seen to be contributing to quality improvement, or because the targets set have not been met. Peer and supervisor pressure appears to be important. The question that arises is how successful in achieving improvement were the indicators that have finished.

8.3.8 Measurement frequency and goals

From observation and data gathering before the survey, it appeared that the groups that actively measured and provided feedback of their indicators, demonstrated greater awareness of quality concepts, were more open to new ideas, and were well motivated to continue measurement where they felt that it had a positive affect on the process they were measuring, than groups without useful indicators. It was hoped that the survey would provide an insight into the effectiveness of the feedback process, through gathering further information on the frequency of measurement, the means of reporting the measurement and whether or not the measurement was set against goals. Observation had suggested that many Indicators existed because the wisdom of the day was taken as "thou shalt measure" rather than "change and measure the effect of the change"

The "project based" category "X" initiatives provided little opportunity to measure progress so they have been excluded from consideration.

The background upon which people agreed to participate in this survey is explained in Chapter 6. Written lists, based on the input of team members through discussion with their teams were compiled by seven team leaders and given to the researcher. A round-table discussion with five of the team leaders (those willing to participate) took place a week later. During this discussion, care was taken by the researcher to stand by the original agreement that no action would be taken in respect of the shortcuts reported, thus no questions were asked about specific examples of shortcuts; reference was made to them in general terms only.

The results of this survey suggested that within a well regulated, structured and trained group of staff, there were relatively widespread unofficial practices, some of which have the potential to affect the integrity of the science. Some might be regarded as "cheating", a minor form of fraud, whilst others were shortcuts taken in the assumed knowledge that the scientific integrity of work would not be damaged provided that an earlier or contemporaneous task had been completed correctly.

The responses revealed 76 ways in which technicians deviated from the formally defined practices described in Standard Operating Procedures. Virtually all of the deviations were described by more than one team. In what was taken by the researcher to be a desire to protect their personal integrity, the team leaders make it clear that what had been reported were practices that people may have known *others to use* or that they might themselves have been guilty of in the past. Were they to come across such activity now, they would take affirmative action to prevent it continuing. Despite these claims, none of them felt that they could be totally confident that shortcuts were not taken by some staff. However they were quite adamant that nobody would take any action which put animal welfare at risk; they felt that any technician who knowingly took any action which jeopardised the animals should be severely disciplined. These revelations are interesting because they suggest that this group of technicians, as custodians of animals, put the quality of animal welfare above any other activity, including that of the integrity of the scientific data, the bread and butter of the company and the basis upon which they received their salaries.

The shortcuts could be divided into five groups described in Table 8.24. These groups have been called

1. Absence of Action
2. Procedure Modification
3. Error Acceptance
4. Applied Imagination
5. Beat the Clock

Table 8.24   Shortcuts described by technicians

Category	General description	Where applied	Source ref.
1. Absence of Action	Failure to perform an ascribed task.	Routine checking procedures. When the assumption is made that "nothing will have changed" since the task was last performed. Where the requirement for an action is based upon the assumption that the preceding action might be in error.	1,3,6,7,9, 10,14,17, 21,22,27, 28,31,32, 34,45,46, 48,53,54, 55,60,61, 63
2. Procedure Modification	Performing the procedure in a way that differs from the SOP.	Observational procedures, dosing animals with test material. Where the standard procedure is cumbersome and certain actions do not appear to produce useful data. Where the modification is not thought likely to adversely affect the outcome. Where Standard Operating Procedures are over-prescriptive or do not allow for judgement.	4,5,11,13, 16,20,26, 36,37,39, 40,41,44, 49,50,51, 58,62,67, 74
3. Error Acceptance	Failure to correct a mistake made by self or others, usually ignoring it on the basis that the value recorded "could" be correct.	Recording of multiple simple data-points where trends can be adjudged or normal values are known. Updating of animal observation records made during a previous period. Where it is particularly cumbersome or time consuming to make a correction because of the level of explanation required. Where an error is made in the middle of a flow of activity and correction would upset the flow.	23,24,25, 43,47,64, 66,72

321

Category	General description	Where applied	Source ref.
4.			
Applied Imagination	Finding original ways to perform a task.	Animal husbandry procedures such as feeding, changing cages.	1,8,12,15, 18,19,29, 30,33,42,
	Finding original ways to make it appear that a task has been adequately completed.	Where it will be difficult to detect that any deviation from the accepted procedure has taken place.	56,57,59, 65,68,73, 75,76
	Inventing data.	Where a data-point has been accidentally missed.	
	Claiming actions that have not happened.	Where a daybook entry is required to confirm that an action has been taken place (but it had not).	
5.			
Beat the Clock	Providing a personal challenge by completing a task in a lesser time than previous "record holders".	Simple repeated tasks such as weighing 600 animals where uncomplex data is required.	52,69,71
	Finding timesaving shortcuts by performance of multiple tasks simultaneously.	Simple tasks of a repeated nature where no data is generated such as filling water bottles, measuring food residues.	
		Tasks where the repeated nature presents no other intellectual challenge.	

Category	*General description*	*Where applied*	*Source ref.*
4.			
Applied Imagination	Finding original ways to perform a task.	Animal husbandry procedures such as feeding, changing cages.	1,8,12,15, 18,19,29, 30,33,42, 56,57,59, 65,68,73, 75,76
	Finding original ways to make it appear that a task has been adequately completed.	Where it will be difficult to detect that any deviation from the accepted procedure has taken place.	
	Inventing data.	Where a data-point has been accidentally missed.	
	Claiming actions that have not happened.	Where a daybook entry is required to confirm that an action has been taken place (but it had not).	
5.			
Beat the Clock	Providing a personal challenge by completing a task in a lesser time than previous "record holders".	Simple repeated tasks such as weighing 600 animals where uncomplex data is required.	52,69,71
	Finding timesaving shortcuts by performance of multiple tasks simultaneously.	Simple tasks of a repeated nature where no data is generated such as filling water bottles, measuring food residues.	
		Tasks where the repeated nature presents no other intellectual challenge.	

The reasons why shortcuts were taken and in what circumstances throws some light on the importance of job design and feedback in achieving best levels of performance. There were a number of factors mentioned that influence the probability of shortcuts being applied; these factors can be viewed as a number of continua. Figure 8.25 diagrammatically shows the factors:

Figure 8.25   Continua of factors that influence the use of shortcuts
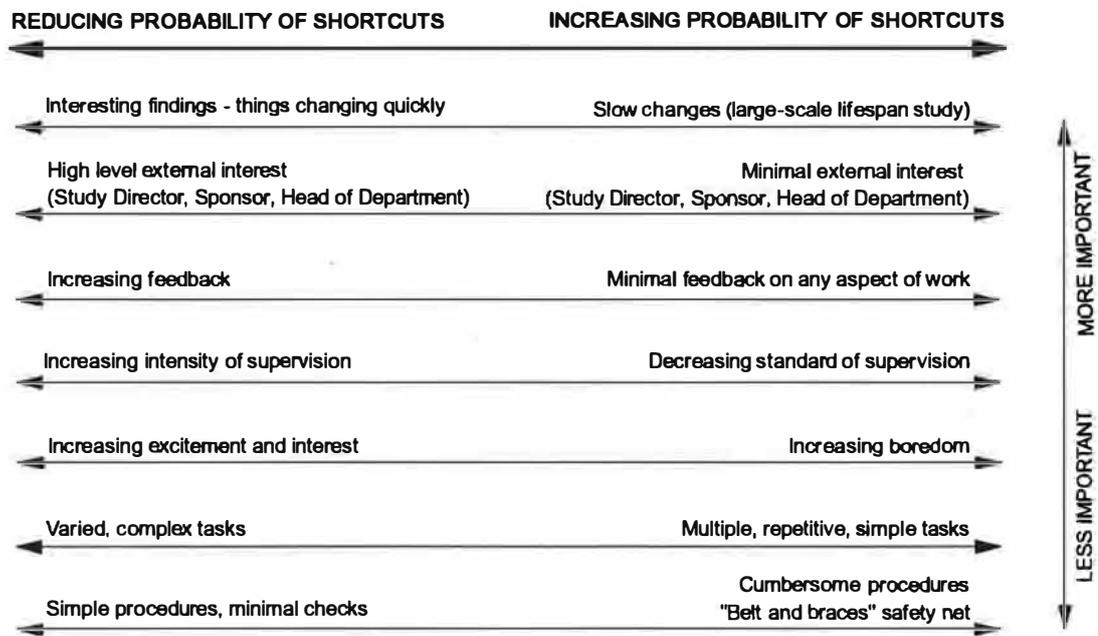
The above figure shows factors that the team leaders felt were most likely to influence whether or not shortcuts were adopted. It is surmised that the position on the continuum that short cuts are applied will vary depending upon the attitude of the individual. It should be stressed that the above figure represents what the *Team Leaders* thought were the factors - and their perspective may be different from their staff.

The continuum were ranked from those thought to have greatest influence (more important) to those of lesser influence (less important). The ordering of the continuum from top to bottom in the figure should be viewed as non-linear and flexible. The order in which they are placed is based on the relative weighting suggested by the team leaders suggested. One team Leader, Henry Strong[LT3] was particularly vocal in his views and the others tended to concur.

The team leaders felt that the level of personal challenge in the job had a great deal to do with the commitment to performing tasks correctly. They felt that many of the tasks required of the technicians were mundane and did not need staff of their qualification/intelligence level. Conversely, a lot of these tasks were related to the ability to handle and observe animals to notice the unusual; an observation missed could be critical - they felt that this element of work couldn't be performed adequately by a "*lesser quality person*".

The way in which many technician's provided themself with the challenge they needed to keep them alert was to work against the clock, but performing procedures as prescribed in the Standard Operating Procedures rather than taking shortcuts. It was suggested that efficiency and high productivity generally gained approval so there would be little censure for working faster albeit that it was recognised that fast working increased the probability of unintentional error. They also felt that the tight staffing levels forced the pace of work, sometimes to an extent that standards were inadvertently compromised. Interestingly, they did not rate time shortage, other than their own time for supervision, as one of the factors that made the use of shortcuts likely.

> "*It is actually quite a nice feeling to have a heavy workload, feel rushed off your feet and finish everything, without problems, to the right standard....*
> *this is fine when it happens once a week or so, but when you are rushed every day, I think that is where the short cuts start to creep in*"[(LT 3)]

The high work volume and the need for team leaders to be almost constantly involved with practical work was seen to negatively influence the quality of supervision, and consequently the interest that junior staff might have had in their jobs. The group said that one new member of staff have complained vehemently about his treatment and said that he took shortcuts because "*nobody would know or care*"

> "*As team leaders we should be spending far more time with our junior staff. We give them easy stuff to do at first because they have to learn the systems and how the studies work. If we don't have time to talk to them and train them how to do the more interesting tasks, then they don't move on. I suppose it must be pretty disheartening to leave school with your 'O' levels or 'A' levels, and come here to start your career, to get some basic training and then get thrown in a room filling water bottles and cleaning out*".[(LT2)]

There were some scenarios that would ensure that all work was performed by the book and to the highest standards. The group quoted an example of an ongoing project; this study was of complex design with "*things happening all the time*". The design of the study had changed and there were a high number of interesting clinical findings. The Study Director was a frequent visitor to the animal facility, updating himself on progress through data review and discussion with the technicians. The sponsor of the study had visited and spoken to the technicians - he was complementary about the way the study was being managed despite difficulties related to the material under test. The extent of interest in the study prompted frequent review by the Animal Facility Manager who, acting as a communication channel, assured that the technicians were kept informed of all other communications relating to the study. In situations like this, when the work is interesting, the technicians feel involved, and there is plenty of feedback "*no one would dream of taking any shortcuts*". Conversely, they cited a two year mouse[5] study where "*the poor old study technician*" has to follow the same routine week after week, and practically nothing changes.

> "*If somebody can stick with the same study for that long, they either have to be brain dead or find something to keep their interest*"[LT3]

In the particular example cited, the study technician took great pride in producing meticulous data and in the cleanliness of the animal room.

> "*His sink shines so you can see your face in it and you could eat your dinner of the floor .... but it is a very unusual technician who would be happy working on the same boring study for so long...*"[LT3]

The consensus view was that it was working with studies of this design that failed to provide sufficient interest to the technicians and, because of the lack of activity

---

[5] The study to which they referred was a lifespan carcinogenicity mouse study (104 weeks long with 480 mice). It is designed to investigate the cancer causing potential of the material under test. The mice are given the test material in their food for the duration of the study. The animals are weighed weekly and their food intake is measured. They are examined weekly to identify any tumour development. When this occurs, the tumours are measured each week to assess speed of development. Blood samples are taken from a small group of animals at the beginning and end of the study. Basically the weekly routine involves weighing and observing animals, weighing out food for each cage (twice a week), changing the animal's bedding material, filling up water bottles, changing their cages for washing at defined intervals, and generally keeping their physical environment clean and ordered. Essentially the group of animals have to be cared for and observed from 4 weeks of age to senility. Such studies are regarded by the technicians as "dull"

variation, or unexpected findings, such studies were rarely the focus of external interest. If shortcuts were taken, it was on this type of study.

> *"We record so many negative observations and make so many measurements that are not included in the report, that sometimes it feels as if we are wasting our time"*[(LT5)].

> *"There are so many checks that are simply there because somebody got something wrong in the past. It's a pain to have to do something just to prove you got the earlier job right"*[(LT1)]

> *"Most people will follow an SOP to the letter even if they think it goes over the top in terms of what it requires....... I don't think people who take short cuts ever think anything will go wrong. They often don't know why a check was installed in the first place so it doesn't always make sense for it to be there"*[(LT4)]

> *"if it was easier to correct mistakes, you wouldn't get people pretending nothing is wrong"*[(LT4)]

Consideration was given to the potential impact of cutting corners. The team leaders said that sometimes junior staff took a shortcut not realising that they could affect the study through, for example, cross-contamination of the material under test. They perceived that if any problem resulted from taking shortcuts, it was often not evident. If animals had remained healthy, then the theoretical knowledge about microbial or test material cross-contamination had no relevance. If some food intake data was not *"exactly correct"*, but it only represented a small percentage of one week's data out of two years, and the values were within the expected range, then it would probably go unnoticed. They felt that there were some staff who could not be trusted and required close supervision - they were not necessarily junior staff

> *"There are some technicians who have been here years, and have not changed from the way they did things in the past. I would not put a trainee with Fred Able, for example because although he knows exactly what he <u>should</u> do, I don't think he'd always sets the right example. Because he has been working here so long, junior staff think that what he says is right"* [(TL2)].

At this level, there did not appear to be any way of quantifying the extent of bad practice. It was assumed that the lists produced by the team leaders were not complete in that it was considered unlikely that any technician would admit to any deviation which they knew to be serious. Even with the "amnesty" on affirmative action, it was considered reasonable to assume that the depth of the investigation would be unlikely

to secure "confessions" if a party felt particularly guilty about a practice that they had applied. The contributors had nothing to gain from providing information, although it was felt that they welcomed the opportunity to participate in the research and to contribute an insight that might be useful for improving practice.

What was revealed were practices that managers might have preferred not to know about. The company environment and regulated nature of work dictates that such practices are highly unacceptable. Good Laboratory Practice was, after all, developed in response to extreme versions of a similar behaviour. Investigation of errors often flounders at the level of a failure to understand how such a mistake or result came to be. The identification of this covert activity could provide some of the missing explanations.

8.6   Summary of chapter and relevance of findings

What was reported in this chapter was

1. A companywide measure of errors as they would be perceived by clients (ACE)

2. A survey of internal measures of improvements in practices (Quality Indicators)

3. A measure of errors that had been adequately corrected in such a way that they would not be picked up in (1) above

4. An insight into covert, unacceptable non-quality activity

These activities were attempts to quantify the frequency and type of failure of quality at BFL to look at the impact of QIP on the improvement trend of quality. The intention was to look at the company from a number of different perspectives, using different approaches with the objective of addressing differing dimensions of the effectiveness of the quality improvement effort.

The survey of Accolades and Errors (ACE) provided a measure of the overall quality level of BFL in absolute terms as seen by the clients of the company. It was a companywide indicator of the incidence and nature of failures of quality that provided trends of categories of error. Looking at ACE output in absolute terms, the results showed only a minimal reduction in the number of errors per head and the number of errors per £ of revenue despite the presence of quality improvement activity. However, the level of error reported was predicated upon the volume of written communication between the company and clients and was influenced by a growing awareness of the recognition of problems, tightening deadlines and an increasing expectation of some clients that all problems were immediately communicated. To this picture can be added the view that over the period measured, the nature of work became increasingly complex and the clients expectation of quality increased.

ACE is an example of the potential of measurement to provide an unreliable and misleading picture of the impact of quality improvement. It is suggested that whilst a great deal of evidence was collected, without an in-depth understanding of context of that measurement and the variables which have influenced the output, useful conclusions cannot be drawn. Overall, the researcher concluded that gains in quality *were* made in respect of the conduct of work but paradoxically, increased communication with clients, a quality objective, masked the improvement picture.

It had been considered that most performance improvement would be invisible to the client thus ACE would not provide a useful picture of effort or achievement. The survey of quality indicators looked at the improvement of activities (eg tasks, systems, techniques, relationships) that contributed to the final product. This level of measure had been focused upon activities that were felt to be candidates for improvement; most were techniques or procedures repeated in volume. Improvements were found to occur as a direct result of focus upon the task, as an outcome of changes in techniques or procedures, or because of extended operator experience and effective training.

Quality Indicators can be considered a failure as a means of motivating and monitoring quality in the scientific groups. Other than measures of the time taken to produce scientific reports against the target time, these groups did not adopt measures of improvement. A key improvement target for these groups was better communication between company and client and improved status of scientific advice. Neither of these activities were easily quantifiable in terms of frequency or acceptability.

Although improvements were demonstrated through measurement, the main value of Quality Indicators was found to be their contribution to improving relationships and removing barriers between departments. This occurred because activities which were often most in need of improvement had been those at the interface of groups. The requirement of QIP to have Quality Indicators in place encouraged staff to work across boundaries with their internal customers or suppliers in other departments. Effective communication, the lack of which was originally identified as a potential barrier to improvement and a contributory cause to many errors, was thereby increased.

Following on from the findings of ACE, the sampling of documented errors looked deeper into the organisation and provided quantification of the minor errors. These errors were such as those resulting from data transcription, which were corrected but not communicated directly to the clients; they nevertheless impinged upon the appearance and credibility of scientific data. The reason that this sampling activity had been conducted was because it was felt that the output of ACE alone provided an unjustified confidence about the actual quality of work; the need was identified to take a closer look at errors in data records. These were the type of errors that Quality

Indicators were intended to eliminate and were felt to be representative of the sort of problem that had economic significance because of the level of rework generated and the potential negative effects on client confidence. The number of such errors identified was in the order of ten-twenty fold greater than those recorded by ACE.

Finally, investigation of the cause of failures of quality had led the researcher to assume that sometimes errors were covered up. It was considered that a combination of ACE, the Quality Indicators and documented errors still did not give a full picture of failures of quality; the survey of hidden shortcuts confirmed that original premise.

The survey of hidden shortcuts provided an interesting and disturbing insight into the causes of error and the attitudes of technicians to complying with formal procedures. The respondents of the survey provided information that suggested that technicians failed to conduct required procedures, modified formal procedures, failed to correct their own errors, made up values for missed data and provided themselves with a challenge by conducting procedures against the clock. Apart from the risks to the science that shortcuts presented, the shortcuts themselves had the potential to cause or perpetuate error.

What this survey told the researcher was that even in an environment that apparently exudes quality and where efforts are in place to reduce the incidence of identifiable error, a destructive level of activity exists that undermines the intent of organised quality programmes. The situation uncovered was paradoxical in that the procedures designed under GLP consider and attempt to eliminate all potential for error. In achieving that objective, procedures had become burdensome, reducing the mental stimulation of the technicians, thus leading to boredom. In this situation, the taking of shortcuts becomes attractive. What this suggested was that the elimination of such practices requires consideration of procedure and job design and accountability. It is felt that the notional concept of culture change espoused by the advocates of TQM would be inadequate to deal with this situation. Elimination is more likely to occur through procedure and job redesign and the allocation of personal responsibility.

These findings contributed to the development of the Dimensional perspectives metaphor reported in Chapter 11.

The frequency and form of measurement varied widely according to the focus of the Indicator. The frequency of measurement and frequency of reporting were not always coincidental. This was particularly the case when the measure reports on a cumulative of individual performances as exampled by many of the Histotechnology and Animal Management Indicators measuring data quality. The following list provides examples of frequency of measurement reported in the survey, organised by broad categories

1. By activity: A record was made every time an activity was performed (every test, every animal, each sampling, each audit etc.).
2. By study
3. Number of occurrences
4. Time period (day, week, month, twice/month, 3/week, every 8 days etc.)
5. Sampling (every 10th job)
6. One off surveys
7. By document - every protocol, per report
8. Continuously monitored, measured by occurrence
9. On a random basis (spot checks, as required, as appropriate, infrequently, on use
10. By batch

Of the 133 Indicators, 102 were said to be set against some form of improvement goal. The goals that had been applied to Indicators were as varied as the measurement frequency. Although in general, the goals were not very clearly defined, where numeric goals were stated (49/102) more than half of these were looking for a "perfect" performance. Phrases and values like "100% on target" "right first time", "zero defects" and "error free" were used widely. The point at interest here is that these expressions had become part of the language of Indicators at BFL yet they are the same expressions of which senior managers were suspicious - they did not care for slogans and had little belief in concepts like "Zero Defects" - and which were contributory to the desire to utilise a home grown quality improvement programme.

However, the majority of the indicators sit at lower levels in the company and measure the performance of technicians and support staff. Histology managers, in particular,

had always wanted a high visibility programme to which staff could easily relate, with targets that could be easily remembered. In this discipline there had been a change of senior management - the new head of department had not been involved in the original discussions on TQM and frequently advocated a high profile, "flag waving" approach.

Whether an absolute value becomes the target seems to be linked to the subject of the indicator. In cases were original data is being recorded there is no acceptable level of error - by nature of the task and purpose, the data has to be right. In situations where delivery of a product by a service group to the right destination is measured, there is no reason why a target should be other than 100% correct - it is a relatively easy task to perform in error free mode.

In a work society where the majority of staff are working in day to day compliance with formal rules (Standard Operating Procedures) the notion of targeting 100% freedom from error is within their mindset. However, the objective of QIP to establish Quality Indicators across the whole company meant that staff less familiar with measurement techniques, and who worked outside the scientific core, had been asked to identify relevant measurable indicators. These areas appear to have been less adept at identifying improvement goals.

Of the goals reported there appeared to be five different types shown in the Table 8.17 overpage:

Table 8.17   Five types of goals applied to Quality Indicators

Category	Examples	QI# in category
1 Absolutes	• Eliminate all non-conformance (QI#7) • The target is "zero defects" (QI#21), • 100% success target (QI#4)	2, 4, 7, 9, 14, 15, 18, 19, 21, 22, 28, 30, 32, 34, 36, 42, 65, 75 ,78, 86, 91, 100, 111, 113, 116, 122, 128, 132
2 Progressives	• Background rate was 2-3%. Less than 1% seemed a reasonable aim. (QI#102) • Hit rate for pituitaries had to be above 70%. (QI#109) • Continuous reduction in % performance based on historic information (QI#130)	8, 26, 29, 39, 43, 66,79, 80, 81, 87, 98, 102, 103,105, 109,121, 123, 129, 130, 131
3 Unfocused	• To improve (QI#1), • Self obvious (QI#114), • Assumed" (QI#126)	1, 2, 3, 6, 10, 12, 13,16, 17, 24, 31, 33, 37, 38, 46, 48, 68, 82, 90, 92, 94, 95, 120, 124, 126,
4 Preventatives	• To prevent need for amendment of protocols (QI#71) • To improve the response to answering calls to such a high rate that nobody complains (QI#113) • Escape is unacceptable and must be prevented (QI#6)	6, 47, 49, 71, 88, 89, 114, 133,
5 Monitors	• Monitor amount of repeat work (QI#106) • To aid monitoring of recut levels (QI#110) • To bring the extent of a problem to the attention of the necropsy staff (QI#97)	5, 27, 35, 40, 41, 67, 70, 72, 73, 76, 77, 83, 84, 85, 96, 97, 101, 104, 106, 108, 110,125

301

8.3.9 Improvements

The assumption had been made that the most successful indicators were likely to be those with agreed goals but, that the absence of goals did not necessarily preclude success.

Success can take on a broader definition than simply an improvement of the target of the indicator. One of the interesting findings that arose was that Indicators sometimes improved an underlying problem, such as poor communication, even when the measurement of the Indicator was directed to the improvement of another problem. An example of this is found in QI#14, "Despatch of animals to necropsy".

> This cross-department indicator was set up to measure the effectiveness of the despatch of animals to the necropsy laboratory. Over the years this apparently simple process had been plagued by problems, whereby one group blamed the other for not conducting their part of the procedure adequately. Standards were set with a target of 100% compliance. Starting from a compliance level of 60%, the 100% level was reached after 13 weeks. Measurement continued to see if the performance was sustainable. Compliance dropped back to an average of 85-90% with 100% not being reached a second time until another 13 weeks had elapsed. Whilst the focus was upon meeting the Standard, the actual benefit of the Indicator was an improvement in co-operation and communication between the two groups. This had a positive knock-on effect to other activities at this interface (Monthly Indicator Updates; Quality Circle minutes - Necropsy/AnMan, March 1992).

Thus it can be seen that the above Indicator has several facets to "success". The achievement of 100% compliance with a standard benefited the contributing parties and the overall quality of the company product. The improved communications and co-operation led to the setting up of a cross-departmental Quality Circle which then addressed all activities at the interface between the two groups. In this particular case, the people involved were consulted before the indicator was adopted. The goals were clearly defined and communicated. There was regular monitoring and easily

302

assimilated feedback. All Indicators were not subject to this level of organisation and some (31/133) did not have goals to work towards.

To look at whether the presence of agreed goals had an influence on the success of indicators in progress (active) and those that had terminated, the survey responses were plotted on a grid to see how many indicators fell into which group. The outcome is presented in Table 8.18

Table 8.18   Quality Indicators: Breakdown of numbers of QIs in respect of Improvement and Goals

	Improvement?	*Goals?*	*Active?*	*Number of QIs in combination*	*Percentage of total*
1	yes	yes	yes	38	28.6
2	yes	yes	no	30	22.5
3	yes	no	yes	9	6.8
4	yes	no	no	4	3.0
5	no	yes	yes	5	3.7
6	no	no	yes	2	1.5
7	no	yes	no	6	4.5
8	no	no	no	5	3.7
9	QIs for which three categories were not completed			34	25.6
	Total QIs in survey			133	100.0

The above table shows that 61% of Indicators (Lines 1-4) showed improvement in some form. Of these, the majority (68/81) were set against goals. Of the 18 indicators for which no improvement was Indicated (Lines 5-8), 11 were set against goals. The reasons for failure are varied in scope and significance such that it adds no value to attempt categorisation of such small numbers. Of these eleven:

• One ceased to exist because of internal reorganisation(QI#49)

- The "computerised recruitment system" (QI#52) was a category "X" non Indicator (see earlier) for which the hopeful recipient of the system was entirely dependent upon another department to prioritise and deliver. Given the circumstances and Computer priorities in the company at the time (Operations committee minutes, Computer Science meeting notes) this Indicator was probably doomed to failure.

- Paperwork anomalies (QI#102) had only been in place for two months and no improvement trend had been noted but "participants remain enthusiastic and helpful"

- Some useful information emerged about a potential link between keying ability and age (QI#8 "Foetal Pathology revalidation Index"). Those involved considered that they might have been at their physical limit and thus, despite all efforts, could not improve their computer keyboard skills.

- One had been an "enforced Indicator" to which there had been considerable resistance. "It was disliked to the extent that it was abandoned" (QI#93)

- In three cases (QI#21, "Rejection of Equipment provided by services", QI#70 "Maintenance customer satisfaction questionnaire" and QI#105 "Whole body autoradiography recut rates", the groups involved considered that they were starting to measure from a high quality baseline and found improvement difficult to measure. In the first two cases, neither group enjoyed the level of scrutiny of their work afforded by the Indicator.

- The Quality Assurance Report review questionnaires (QI#84) were "seem as a waste of time since (results) not yet collated". However, there had been some benefit as disagreements between QA and the report producing departments had been investigated.

- In the case of the final two, the assumption of "no improvement" is placed against a goal requiring 100% compliance. In the case of Security Staff checks of Identity tags, they regarded success as 100% staff compliance. Various measures had been taken to ensure better compliance (reporting offenders etc.) but compliance did not rise to 100%. In this case, the security group were measuring the wrong thing - they should have looked at the effectiveness of their various attempts to increase compliance with the requirement for each person to wear an identity tag. Similarly,

the reprographics staff had set a target of "all in-trays to be cleared by the end of the day".

Of the 7 Indicators that did not have goals and showed no improvement (line 5 and 6), as with the above group, there is no consistent picture for the reasons that no improvement was gained. As reported:

- only one Indicator (QI#69) "Engineer call-outs", was considered a "waste of time".

- In three cases (QI#82, 83 and 104), measurement demonstrated that there was no real scope for improvement.

- QI#44, "Holidays and Sickness" was withdrawn as an Indicator but the respondent acknowledged that people involved were now more aware of the impact of sickness on other staff.

- One Indicator (QI#107, "Paperwork errors in Histology") had only been in place for one month, and it was considered too early to establish an improvement.

8.3.10 Changes to procedures

Respondents were asked whether any steps had been taken to improve the system or process being measured, and if so, what those changes were. It was felt that in a few cases, it would not be necessary to change a procedure to bring about improvement; the fact that a procedure was under the spotlight could provide the motivation for an improvement. However, it was assumed that, more often than not, there would be some change to the system to facilitate improvement. This assumption had failed to take into account the very varied and focused nature of the target activities of QIs reported in the survey. Many of them were focused upon a single activity where it was difficult to imagine a change to the process that would result in improvement.

The survey data showed that 75/133 (56.4%) of activities associated with measurement of an Indicator had been changed in some way. Of the 75 there were 61 that had shown improvement (6 x no improvement, 8 x no response).

- In some cases, the use of the Indicator *was* the change in procedure; it provided a vehicle to introduce previously absent monitors of quality eg QI#32 "Animal Room Hygiene, QI#90 "Tissues Missing at Necropsy".

- Where Indicators were measuring technical capability eg., QI#130 "Blood Sampling", and QI#98 "Missing Tissues", the procedures were frequently refined to achieve better results.

- Training /skills development and experience was reported as a change in process in four cases (QI#106, 43, 130, 131)

- None of the changes described were in any way radical or extensive. They tended to be procedural refinements.

- Where there had been no change in the procedure (58/133) Improvement occurred in 24 cases (22 x no response given for improvement)

8.3.11 Change in the Indicator

Review of Indicator updates and general observation suggested that as staff became more experienced in the use of Indicators as a vehicle for improvement, they would gradually become more progressive, tackling more complex issues and eventually activities which crossed departmental boundaries. It was expected that the survey would show this trend through identification of Indicators that had evolved and, as already covered, a demonstrable move from intradepartmental to cross-functional Indicators.

There were 17 Indicators that were stated to have changed since introduction. The nature of these changes were:

- Change of emphasis in measurement from "good" to "bad" (QI# 93, 126)

- Simplification of measurement and/or recording of measure (QI# 92, 97, 111)

- Expansion or refinement of scope (QI#91, 99,101, 109, 110,129, 130)

- Change in format or expression of feedback (QI#8, 80, 98, 131)

- The Indicator has become the "Standard Operating Procedure (QI#106)

8.3.12 Feedback

Feedback and publicity were considered to be an essential features of successful Quality Indicators and thus it was assumed that some form of feedback would be used for all indicators. General observation (Meeting notes, Quality Indicator Updates, Visual displays, Quality reports) suggested that while many Indicators were expansively communicated, communication of others was not at all evident. The survey aimed to obtain data on the form and frequency of feedback.

Many respondents provide examples of feedback that had been used at some stage or were still in use. By far the most common form of feedback (66 out of 98) was a visual tool such as an updateable barchart, line graph, or similar that could demonstrate an improvement trend. These were frequently accompanied by explanatory notes/memoranda. The breakdown of communication forms is given in the table below:

Table 8.19   Breakdown of communication forms for Quality Indicators

Means of reporting and communicating results	*Frequency*
1. Updateable Charts	66
2. Tables or dedicated record	22
3. Report	7
4. Verbal feedback	2
5. Memorandum alone	1
6. Others not reported	35

Respondents were asked the results of Indicators were communicated to those involved and /or others. The survey provides the following insight:

Table 8.20   Communication of Results of Quality Indicators

To whom results are communicated	*Number of responses*
1. Communicated to those involved and others	73
2. Communicated to just those involved	34
3. Not communicated	5
4. No response	21

As is evident in the above table, there was some inconsistency between responses that claimed to have communicated results to those involved versus the forms of communication or presentation used. Reviewing comments made on feelings about Indicators, it was noted that failure to make use of or communicate results reduced enthusiasm for an Indicator. Examples are this were QI#100 "damaged Pituitaries" where concern was expresses about display of results because they might be seen by sponsors who would then be aware of the magnitude of the problem. A similar issue arose with QI#8 "Data Accuracy". In the case of QI#109, "Tissue Hit rates" there was a feeling that results that were available not always communicated. This is interesting because one of the benefits perceived of this indicator was the provision of more feedback on performance.

It was noted that the information provided in the survey was relatively incomplete by comparison with the tangible evidence of feedback observed around the company. For example, notice board displays and report contents provided wider evidence of the use of more than one presentation form than the survey data suggests. It is thought that the survey question *"In what form have results been presented?"* may have been narrowly interpreted to refer only to such tools as tables, charts and reports.

8.3.13 Enthusiasm and feelings of those involved

Quality indicators, alongside training, were a dominant instrument of QIP intended to motivate involvement in the improvement process. Although the concept was introduced to senior managers as "It will be" there was a great deal of latitude in respect of time span of implementation, selection of QI topics, ratio of QIs to staff and so on. The programme relied on creating enthusiasm and drive through involvement and feedback. The survey aimed to obtain data on people's feelings about the Indicators with which they were involved. They were asked closed "Yes/No" questions in respect of phrases that might be used to describe feelings about Indicators. The responses are given in Table 8.21 below.

Table 8.21   **Survey responses on how people felt about Indicators (yes/no options)**

Was the indicator:	Predicted "yes" response level	Number of responses	Actual Response			Prediction met?
			yes	no	% yes	
1. A useful exercise	>90%	102	98	4	96.1	y
2. Valuable to process	>70%	101	84	17	83.2	y
3. Informative	>50%	92	69	23	75.0	y
4. A challenge	>50%	90	68	22	75.5	y
5. Competitive	<10%	94	18	76	19.1	n
6. Divisive	<10%	91	9	82	9.9	y
7. A waste of time	<10%	130	2	128	1.5	y

The responses presented in the table confirm the pre-survey predictions with the exception of Competitiveness where twice as many Indicators were regard as competitive than predicted (less than 10% predicted, actual was 20.2%). Overall the number of indicators so described is low (13%) and the underprediction is not thought significant.

Looking at the prediction of the number of Indicators about which people involved would feel enthusiastic, this too was slightly inaccurate. Pre-survey, it was anticipated that there would be enthusiasm for more than 70% of Indicators. The actual percentage was 60.5 (69 Indicators/114 responses). This result was disappointing when considered against the purpose of Indicators and the desire for widespread acceptance and use. To look at feeling in greater depth, they were viewed in four groups:

1. Positive
2. Neutral
3. Reservations and mixed feelings
4. Negative.

The descriptions of the groups and examples of the Indicators in each is presented in Table 8.22 below:

Table 8.22   Feelings on Quality Indicators: Break down by group

Feeling group	*Description*	*Examples*
Positive	Use words and phrases like "enthusiastic", "keen", "generally liked", "approval", "beneficial", "achieve", "effective".	Felt by all to be beneficial (86)
		General approval - vital to department strategy (79)
	Value seen in the measurement and people enjoy participation. Evidence that feedback is valued.	Regard Indicator as a positive thing because they are influencing activity which has an influence on customer satisfaction (71)
		Generally liked. People found it useful to receive feedback on mistakes (107)
		Enthusiastic - more so as improvements occur (120)
Neutral	Take it or leave it attitude. No evidence of real or sustained enthusiasm. Words and phrases like "indifferent", "interest waned"	No depth of feeling either way - the indicator just happens. (3)
		Individuals indifferent, partly because of other commitments (50).
		Indifferent - all part of the job (74)
		Keen (ish) (39)

Feeling group	Description	Examples
Reservations and mixed feelings	It's alright but...... Often enthusiastic but with a caveat. Feelings may have changed from positive to negative or vice versa	Enthusiastic - Some reservation by Pharmacy who think that animal management are trying to catch them out (28) Generally a good idea but not always practical. It was a nuisance to break off other jobs but worth it to reduce hassle. (87) Rewarded when results show the value of measurement. Frustrated when anything happens to damage the standard (130) Initially enthusiastic to assess the quality of sectioning. However, the results did not produce data that could be used effectively, hence became indifferent (105)
Negative	Evidence of dislike. Words used like "dislike" "blame" "enforced" "reluctance"	Statisticians blamed the Study Directors and vice versa (112) Initially keen. After a while honesty was questioned, then general disliked (24) Some participants have felt they are under scrutiny for bad performance. They don't like that. (30) Loathed vehemently.... (116) Considerable resistance to adopt an "enforced Indicator"

8.4   Sampling of documented errors

8.4.1   Overview of survey

The ACE survey had looked at failures of quality from the perspective of the external client and the Quality Indicator survey had looked at activity intended to improve performance such that the levels of entries on ACE were reduced. However, it was felt that there was a need to further investigate the extent of error to confirm a hunch that errors captured by ACE represented the tip of the iceberg. The researcher's observation and involvement in correcting errors, review of raw data and data audits suggested that significant time was consumed through repeating actions out of which data was generated, correcting clerical errors or investigation to facilitate understanding and correction of unwanted occurrences. This activity occurred outside the scope of ACE.

As indicated earlier in the Chapter, ACE was not expected to identify all errors that occurred at BFL. Errors which were not formally communicated to a client were not captured on ACE; there was no requirement for errors which were corrected "at the bench", and which did not cause damage to the system, to be systematically logged. However, the presence of such errors was thought to be indicative of factors such as inattention to detail, carelessness, poor data capture systems and/or inadequacies in standard setting, training or ability. The importance of this observation was that whilst the communication of an error to a client was generally regarded as an major failing in need of remedy, it was observed that a significant proportion of managers continued to accept minor error without comment on the basis of "we all make mistakes". The level of minor error perceived by the researcher suggested that the mindset of "get things right first time", whilst widely quoted, was not so widely applied.

By sampling the level of fully documented errors of around 80 staff of Animal Management and 20 of Pharmacy for a period of one month on two occasions, three months apart, the hunch that problems captured by ACE represented a minority of the total fully documented problems was confirmed. Of the two groups combined, it was found that approximately 25 percent of all problems would have been captured by ACE and conveyed directly to the client. The remaining 75 percent would have by-passed

313

ACE and been documented in the study data; they may have been referenced in the final study report. These errors were either subject to reporting by a formal file note or by correction and explanation within the original data.

8.4.2   Sampling and findings

Animal Management and Pharmacy were selected for this survey as two groups that produced copious volumes of hand written data. The question of the status of clerical error arose at the time of the first sampling. Managers of both areas asked whether this category of error should be documented as part of the survey. Some considered that the extent of minor mistakes was such that any count might be inaccurate and counting might be a waste of their time.

> *"There are hundreds of crossings-out and corrections that we could not guarantee to recognise them all"*[L.20]

Also, there was a reluctance by some managers to accept that clerical error, even though it required rework to correct, should be regarded as an error at all. The logic they used was quite simply that such a mistake was only viewed negatively because of the context in which it was recorded. By comparison, if a person was entering data on a computer or writing a report and they mis-entered a number or misspelled a word, the extent of failure of concentration was probably much the same as with a mistake in the hand-written data, yet because correction would be done simultaneously it would go unnoticed. They perceived this situation as unfair.

Ultimately it was agreed that provided all major errors were to be included in the survey, an estimate of the number of corrected clerical errors could be provided and included in the estimate would be values that had to be taken a second time (eg. animal bodyweights), recalculations, erroneous transcription and straightforward clerical error such as transposed numbers. The findings (excluding the estimated errors) were as shown in Table 8.23 over the page:

Table 8.23   **Documented Errors in Pharmacy and Animal Management**

	Problems recorded on ACE		*Problems documented but not recorded on ACE*		*% problems not picked up by ACE*
	Department	*#*	*Department*	*#*	
Sample 1	Animal Management	4	Animal Management	15	73.1
March 1992	Pharmacy	3	Pharmacy	4	
	Total	7	**Total**	19	

Sample 2	Animal Management	3	Animal Management	18	
June 1992	Pharmacy	3	Pharmacy	3	77.8
	Total	6	**Total**	21	

The above table provides data from both sampling occasions. It can be seen that 73.1% and 77% of errors were not captured by ACE. The number of errors that fell through the ACE net in the first sampling was greater than expected, but these values are supported by the findings of values in the in the same order of magnitude in the second sampling. It was noted that the total number of documented errors was higher in Animal Management. This was assumed to be indicative of the larger sample size. The proportion of Pharmacy errors reported be captured by ACE was far higher than Animal Management (46% vs. 17.5%). It was suggested that the difference was linked to the relative criticality of the activities performed by the two groups. The wider variety of tasks in Animal Management meant that problems of a less critical nature arose than in Pharmacy, where most of the work was directly linked to the preparation of test materials into dose forms for animals. Most errors in this area, such as formulating a mix at an incorrect concentration, or failure to select the correct material or vehicle, were likely to affect the scientific integrity of work and are thus were likely to be communicated to the client.

The errors were categorised using the ACE coding; it was noted that the errors did not fall neatly into the categories - this was not surprising in view of the fact that the ACE categories had been developed to cover errors that were reported to clients. All errors reported in the survey fell into the same major category (06 - technical competence) but many recorded by Animal Management were unique and sufficiently "unusual" that further classification was of little value. An example of a somewhat obscure "error" occurred when a technician dosing a group of dogs by capsule; the capsules are made of gelatine and are quite palatable to dogs. The technician placed one capsule on a wall between two dog pens whilst she administered the first of two. The second capsule "disappeared" assumed "stolen", by the dog in the adjacent pen.

8.4.3 Estimated errors

The information provided on reweighs (where a second weight is taken because the first is not valid) and clerical errors was more comprehensive than expected and, in four cases, supplied with additional notes providing context for the count. The significance of the extra notes was that it was indicative of the desire of two managers to understand what they were measuring and eradicate minor error. These two managers were actually measuring this type of error as a Quality Indicator.

Overall 965 errors were reported for March and 1268 in June. To put this into context, the number of data points captured by one animal unit, running twenty rat studies would be in the order of 100,000 to 300,000 per week depending upon mix of work, thus for the three units involved it is estimated that the volume of data-points recorded would have been in the order of 2.5 million. Where values were high, respondents pointed out the reasons. For example, where data collection forms are manually prepared and predated, a single misdating at the beginning has a knock on effect, requiring a number of changes for the original single point of error; where a balance has not been calibrated correctly, all animals weighed on it may have to be reweighed - again, a single error with a knock on impact.

316

It seemed that managers wanted to demonstrate that "things are not as bad as they look". In an attempt to throw light on the *actual* standard of performance, one manager had calculated the number of occasions that a task (animals weighed per week) was completed, the number of reweighs required, the number and percentage that were eventually changed due to technician error and the amount of time taken for the process.

The unusual nature of some of the more significant errors led to discussion with the researcher about the causes of such problems. In several cases it appeared that short cuts had been taken and there had been a failure of compliance with Standard Operating Procedure. This finding suggested that there might be a level of "invisible" unacceptable activity at the level of data recording. This prompted the need for a further survey, the Hidden Shortcuts Survey into undisclosed and unofficial practices.

8.5   Hidden Shortcuts Survey

This survey added a third dimension to the data gathered on failures of quality. At the top level were the problems visible to all; those that were communicated to clients and reported widely in the company via the Quality Feedback Report based on the ACE database. Next came the documented problems, specific to studies, which tended to be viewed in their immediate context and often without reference to the broader picture. Finally, there were the types of problems identified in the survey of Hidden Shortcuts. It is this third category that are considered to have major implications for those attempting to move an organisation to a higher quality level.

Contributing to this survey were seven teams of five animal technicians (average) with a wide spectrum of experience and personalities. Responses were team based and thus it is not possible to judge the actual level of individual contribution.

The technicians had been asked to comment upon two issues: They were asked :

1. To reveal shortcuts that they took in the course of their work

2. To consider why and in what circumstances they might take shortcuts

Before discussing the findings it is worth consider the profile and reputation of the source of the data:

> Contributing individuals were animal technicians, mostly of the third and lower upper-quartile of school leaving academic attainment. Most had completed or were continuing their education with their professional institute up NVQ level 4 equivalent. They were the staff with responsibility for the care and well being of laboratory animals and for the conduct of laboratory techniques under the authority of personal licences issued by the Home Office. The majority of their duties were either organising and supervising or conducting the live animal based procedures of which are required as part of the safety testing protocol. They had fully documented records of training and had demonstrated competence in procedures performed without supervision. As a group they were well respected for their professionalism, high standards and positive outlook. They are a group that have been particularly enthusiastic about the Quality Improvement Programme.

318