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SUSTAINING COMPETITIVE ADVANTAGE IN THE MEDICAL TECHNOLOGY SECTOR IN THE WEST OF IRELAND THROUGH WORKPLACE INNOVATION

A DISSERTATION IN ONE VOLUME

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Dedicated to Frank & Maura, my Parents.

Statement of Confidentiality

The work carried out in this project is a contribution to the Sustaining compeTitive advantage in the mEdical techNology secTor (STENT) project.

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LIST OF RELATED PUBLICATIONS

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Declaration

I hereby declare that the work presented in this thesis is my own and that it has not been previously used to obtain a degree in this institution or elsewhere.

Kevin Fitzgerald
2007

ABSTRACT

This research examines the impact of workplace innovation on competitiveness in the medical technology sector in Ireland. Workplace innovation is the adoption of new work systems in organisations, including process or administrative changes, which lead to positive outcomes.

The research methodology consists of a broad pilot study of five companies, and an in-depth case study of a large multinational company, resulting in the development of a number of key findings.

Lean Manufacturing and Six Sigma are currently the means by which the studied companies are innovating in their workplace. A Workplace Innovation Life Cycle has been developed, which provides a means for companies to benchmark their Lean and Six Sigma efforts based on the Product Life Cycle model.

An approach to workplace innovation is described. The case company utilises a work system encompassing a bundle of Lean and Six Sigma practices. An innovation 'gear train' model is developed, which describes the drivers of workplace innovation. A Champion is required to drive improvement teams, management and operators towards workplace improvement.

Outcomes from workplace innovation implementation include increased throughput and reduced inventories, increased productivity, while yield levels remain relatively unchanged.

Workplace innovation has allowed these companies to become more flexible and thus in a position to respond to market changes. However, innovation in the medical technology sector can be characterised primarily as 'low road', resulting in marginal but continuous improvements, through cost reduction and sales increases. High road approaches aim to develop and expand the business through innovation and higher value premium products. There is a need to develop high road innovation, to ensure continuing competitiveness, prosperity and growth for the sector.

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LIST OF ACRONYMS

ATC	Atlantic Technology Corridor
BMW	Border, Midland and West
cf	Latin for confer – see other texts
CRM	Cardiovascular and Cardio-Rhythm Management
DFLS	Designing for Lean Sigma
DMAIC	Define, Measure, Analyse, Improve, Control
DoHHS	Department of health and Senior Services
DTI	Department for Trade and Industry
EEC	European Economic Community
EI	Enterprise Ireland
EU	European Union
FDI	Foreign Direct Investment
FMEA	Failure mode and Effect Analysis
Gage R&R	Gage Repeatability and Reproducibility
GMIT	Galway-Mayo Institute of Technology
HPWO	High Performance Work Organisation
HPWP	High Performance Work Practice

HPWS	High Performance Work System
HR	Human Resources
IBEC	Irish Business and Employers Confederation
ICT	Information Communication Technology
IDA	Industrial Development Agency
IE	Industrial Engineer
ILO	International Labor Organization
IMB	Irish Medicines Board
IMDA	Irish Medical Device Association
JIT	Just In Time
LEI	Lean Enterprise Institute
MNC	Multinational Corporation
NCPP	National Centre for Partnership and Performance
NUIG	National University of Ireland, Galway
Nvivo	Software for analysis of qualitative data was used to process data
OECD	Organisation for Economic Coordination and Development
PCTA	Percutaneous Transluminal Coronary Angioplasty
POBA	Plain Old Balloon Angioplasty

PLC	Product Life Cycle
QFD	Quality Function Deployment
R & D	Research and Development
SMED	Single Minute Exchange of Dies
STENT	Sustaining competitive advantage in the mEdical techNology secTor
STS	SocioTechnical Systems
TPM	Total Productive Maintenance
TQM	Total Quality Management
WILC	Workplace Innovation Life Cycle
WIP	Work In Progress
93/42/EEC	European Union Medical Devices Directive

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

The medical technology sector in Ireland is important to the Irish economy. It is significant in terms of employment and exports. Over twenty-two thousand people are employed in the sector, making up about one tenth of the manufacturing workforce in Ireland. Exports are over six billion Euro and growing year on year (IMDA, 2006). According to the Industrial Development Agency (IDA) in Ireland, fifteen of the world's top twenty-five medical technology companies are based in the country. Ireland is a proven location for medical technology multinationals, as a base for research and development, manufacturing and marketing of products (IDA, 2006a).

Clusters have developed since the mid-1990s in both the west and the east. Galway is a major manufacturing centre for multinationals. Dublin has moved towards innovation-led companies (Enterprise Ireland, 2006). The Border, Midland and West (BMW) assembly noted this 'interesting focus' of medical technology companies in Galway and surrounding counties (BMW, 2004).

The sector has grown over decades of development. In order to ensure continuing growth, the sector will need to overcome challenges, for example rising costs and changes in the scale of globalisation. Forfás, a national policy and advisory board for enterprise, trade, science, technology and innovation in Ireland cites innovation and the role of knowledge as main drivers for future economic development in Ireland (Forfás, 2004).

This chapter further describes the sector and threats to its future, and introduces research focusing on workplace innovation.

Section 1.2 describes medical technology products and the sector as a whole in Ireland, and its cluster in the west.

The motivation for the research is outlined in section 1.3 leading on to a description of the research in section 1.4.

Section 1.5 introduces the methodology to carry out the research in this area, while section 1.6 summarises the structure for the rest of the thesis.

1.2 MEDICAL TECHNOLOGY

Medical technology is a term used to describe medical devices and instrumentation, rather than the larger healthcare and pharmaceutical manufacturing industries (Harvey, 2001). Medical devices are defined by European Union Medical Devices Directive (93/42/EEC) as:

> "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
>
> - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - Diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap,
> - Investigation, replacement or modification of the anatomy or of a physiological process,
> - Control of conception
>
> And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" (EEC, 1993).

Of all employees involved in the manufacture of medical devices in Europe, Ireland has 6.3% of the total workforce. This gives it the highest share of employees involved in the medical technology sector (Pammolli *et al*, 2005). It is worthwhile to manufacture medical devices, as the value added created from their production value is higher than in pharmaceuticals or manufacture of electrical machinery (45.8% versus 37.4% or 32.4% respectively) (Eucomed, 2004b).

The medical technology industry has been a cornerstone of the Irish economy, and continues to grow. According to the Irish Medical Devices Association (a representative body within the Irish Business and Employers Confederation / IBEC for the medical devices and diagnostics sector in Ireland), more than 130 companies are involved in the sector, exporting in excess of six billion Euro and growing by about ten percent yearly (IMDA, 2006). Over twenty-two thousand (or 10%) of the manufacturing workforce are employed directly in the sector, with a further fourteen thousand employed indirectly. Two fifths of employees have third level qualifications, while over half of the companies are involved in research and development (IMDA, 2006). This sector has a size similar to the largest medical technology clusters in Minnesota and Massachusetts in the US (IMB, 2004).

The origins of the sector can be traced back to the 1970's where multinational or overseas companies including Becton Dickinson and Abbott Laboratories began to establish in Ireland (Stommen, 2005). With their knowledge of the industry and regulatory requirements this Foreign Direct Investment (FDI) allowed the sector to grow throughout the 1980's and 1990's, where a supply chain developed encompassing both multinational and indigenous or Irish-owned companies (Stommen, 2005; Enterprise Ireland, 2006).

The sector has developed rapidly since; multinational companies gained more autonomy and responsibility to develop and manufacture certain products and product families. Some management buyout activity has increased the share of Irish investors. Indigenous companies have focused mainly on high-value products, for instance catheters and stents, minimally invasive surgery, ventilation and respiratory care equipment, and have seen success with these (EI, 2006).

The IDA (Industrial Development Agency) provides reasons why the medical technology sector has grown over the years (IDA, 2006b). Firstly Ireland provides technical and managerial talent. As mentioned earlier, when multinational companies arrived in Ireland from the 1970's, they brought the knowledge to produce the technology with them. As the sector developed, Ireland retained this knowledge. Galway, as an example, contributes to this knowledge through the local National University of Ireland, Galway (NUIG) and Galway-Mayo Institute of Technology (GMIT). Both institutions have research centres specialising in medical technology, providing graduate and postgraduate talent. Secondly and importantly, Ireland provides a competitive corporate tax rate of 12.5% on all trading activities (Forfás, 2004). It also provides other tax advantages such as patent royalty tax exemptions and Research & Development tax credits. Additionally it encourages an R & D environment in industry; providing Irish Government grant assistance and help through Science Foundation Ireland.

The sector has developed to an extent that it must be categorised into sub-sectors (IDA, 2006c):

- Cardiovascular and Cardio-Rhythm Management (CRM). These active and non-active implantable devices deal with heart conditions in differing ways and range from stents and catheters to pacemakers (Eucomed, 2004).

- Orthopaedics. These implants range from knee prosthesis to orthopaedic shoes to spinal corsets (Eucomed, 2004). Key players are located in Ireland, including Stryker and Johnson & Johnson DePuy (IDA, 2006c).

- Diagnostics. Six of the top seven global diagnostics manufacturing operations companies are based in the country (IDA, 2006c). These in-vitro testing products can include devices for clinical chemistry, microbiology, immunology and genetic testing (Eucomed, 2004).

- Ophthalmic. These products encompass for example contact lenses, eye glasses, optical lenses, and ophthalmoscopes (Eucomed, 2004). Firms located in Ireland include Alcon, Bausch & Lomb, Essilor and Vistakon (IDA, 2006c).
- Other key medical device sub-sectors. The IDA includes contract manufacturing, medical equipment, filtration and hospital products into this sub-sector (IDA, 2006c).

Of these sub sectors, Forfás identified Cardiovascular, Cardio-Rhythm Management and Diagnostics as the most important high-value manufacturing areas, offering opportunity for further development and growth in Ireland (Forfás, 2004). Ireland already has a large market share of the Cardiovascular and Cardio-Rhythm Management market. Top global cardiovascular companies such as Abbott, Boston Scientific and Medtronic are clustered in the west of Ireland. These companies alone have a combined manufacturing workforce of about eight thousand personnel or more than a third of the medical technology manufacturing workforce (IDA, 2006c; IMDA, 2006). They are involved in minimally invasive cardiovascular techniques forming the centre of a medical device cluster, based in Galway (Enterprise Ireland, 2006).

This cluster is interdependent and interlinked, and supports smaller firms, allowing them to 'both feed off the larger ones but also provide much needed flexibility for large firms to grow' (Harvey, 2001). These companies main customers are hospitals, cardiologists, consultants and physicians, and its products are used in Angioplasty procedures.

Angioplasty is the mechanical widening of a narrowed or totally obstructed blood vessel. Balloons are inserted into these vessels by means of a long tubular catheter inflate to widen these narrow vessels and clear blocked vessels. The first coronary angioplasty was carried out more than twenty-five years ago, and has since been an alternative to open heart surgery (Angioplasty.org, 2006a).

However, this procedure has not been without problems. Sometimes the plaque that causes these obstructions in the first place returns, requiring repeat procedures. This 'restinosis' or re-blocking was observed during the first decade of using angioplasty balloons, and in a minority of cases, the artery would collapse after the balloon was re-inflated at the same location, requiring the need for emergency open heart surgery (Angioplasty.org, 2006b).

This led to the development of the stent, a metal tube or scaffold that is inserted after balloon angioplasty. Stents reduced the restinosis in the vessels, but about a quarter of these stents needed repeat procedures. On the other hand it prevented abrupt artery collapse. Up until the 1990's stents were bare metal, but since the turn of the century companies have begun to coat them with anti-restinosis drugs, which have been quite successful in drastically reducing the plaque growing back post angioplasty. The market for these drug coated or 'eluting' stents is $5 billion globally (Angioplasty.org, 2006b), and is an important product for all the major device manufacturers. Drug eluting stents too have had problems. More recently complications in the form of blood clots (or stent thrombosis) have been documented, but investigations into these reports are ongoing (Angioplasty.org, 2006c).

The west of Ireland can mean the Midlands, West and Northwest area with a population of over a million people (IDA, 2006d). The West region itself comprises the counties of Galway and Mayo, making up just under a third of this population (IDA, 2006e). When this thesis refers to the west, the primary focus is on Galway, and on these clustered interdependent and interlinked companies in the medical technology sector.

In short, the sector has given a significant boost to Ireland's economy, particularly over the last decade. The cluster in Galway continues to develop and grow here. In order for this prosperity to continue, the sector must continue to adapt to a changing competitive environment. This adaptation is described in more detail in the next section and provides the motivation to carry out research in this area.

1.3 MOTIVATION

The factors which facilitated the growth of the medical technology sector have changed in recent years. Forfás (2004) outlined some key factors that have made it more challenging for the industry in Ireland to remain competitive globally, including:

- Rising costs. The cost to do business in Ireland has become significantly higher in recent years, eroding relative competitiveness and reducing attractiveness for foreign direct investment.
- Globalisation. Competition has become international and intense. Rather than increased trade links between countries, direct investment by foreign firms has increased (Clark & Guy, 1998).
- A global shift towards services. Internationally traded services are becoming increasingly important in the economies of more developed countries, as they are a source of highly skilled, knowledge intensive jobs.
- Changes in demographics. Economic growth in Ireland in the 1990's was facilitated by a significant increase in employment. At the moment, indigenous sources of labour are reducing, so there is a need for increased immigration of highly skilled workers.
- A growing importance of knowledge. A knowledge intensive Ireland needs to continuously build expertise, ensuring continuing competitiveness. This in part is driven by universities and institutes of technology.

- Changes in EU policies. The EU can set limits on state aid to enterprise. As the EU becomes larger, these grant aid limits may be higher for accession states while becoming tighter for the EU-15 states such as Ireland.

While recognising these factors, Forfás acknowledged that Ireland's growth and success during the 1990's was in part thanks to the 'engine' of foreign direct investment. This was a driving force for production activities, whereby they manufactured and shipped products under supervision of the parent company. This in turn built up Ireland's expertise in process development and manufacturing (Forfás, 2004).

With the above competitive factors challenging the future of Irish manufacturing growth, Ireland now needs to become more innovative, market-led and knowledge-based to remain competitive on a global level. Being market-led means Irish enterprises must take control and learn their markets and customers needs, in order to provide the best solutions. Becoming more knowledge-based means that they develop more homegrown designs and ideas, rather than having multinational parent companies provide the expertise.

According to the Oxford Handbook of Innovation, the term 'innovation' is the 'first attempt to carry … out … an idea for a new product or process … into practice' (Fagerberg *et al*, 2005, pp4). Forfás suggests the need to develop new ideas, and market them in the best way to meet customer requirements; essentially the need for Ireland to innovate in order to remain competitive in the medium to long-term.

There is also a need to innovate in the medical technology sector. It is critical that the sector remains cost competitive and retains manufacturing jobs in Ireland. Innovation comes in many forms, but this research focuses on innovation in workplace practices, rather than focusing specifically on product or process innovation. In order to address this need for ongoing prosperity in this sector, the thesis explores key research questions, outlined in the next section.

1.4 RESEARCH

This research explores the medical technology sector in the west of Ireland, focusing on workplace innovation in companies in Galway. The research questions are carried out in the form of an industrial engineering socio-technical analysis of the medical technology sector and are as follows:

1. What is the nature of innovation in this sector, particularly at the level of the workplace?

   The level of workplace innovation in the medical technology sector from the shop floor perspective is explored from a number of companies.

2. What kind of workplace innovation is in these companies and how is it optimised?

   This question asks what workplace innovation actually is, and how companies in the sector implement it.

3. How effective are these workplace innovations? What is the impact on production and innovation measures?

   Technical metrics are described here. The effectiveness of these innovations are determined, particularly how they measurably improve the workplace.

4. Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?

   An ideal combination of workplace innovations may or may not lead to overall external benefits for the organisation. This research determines the extent to which workplace innovation and competitive advantage are linked.

5. Where is the emphasis? Is it on costs, new ideas, new product introduction, etc?

   If there is a link, the most effective measures of innovation are highlighted, in order to determine the importance of innovation to the sector.

In short, the research is a study of the relationship between innovative work practices and competitiveness within this sector, and whether or not the right mix leads to better overall company outputs.

1.5 METHODOLOGY

Briefly, the research is approached by a researcher with a background in Industrial Engineering (IE). Industrial engineers design processes and systems that improve quality and productivity (IIE, 2007). They draw from specialised knowledge and skills across disciplines – from mathematical, physical, physiological, electronic communications and social sciences – and use methods of engineering analysis and design to specify, predict and evaluate systems (METU, 2007A). IE is geared towards promoting continuous improvement and best manufacturing practices within a company (METU, 2007B). It is suited for research in this area, from determining, describing and measuring workplace innovation, to evaluating its effectiveness within the medical technology sector, from both socio / people and technical perspectives.

The research is qualitative and is conducted in two phases, illustrated in the figure below.

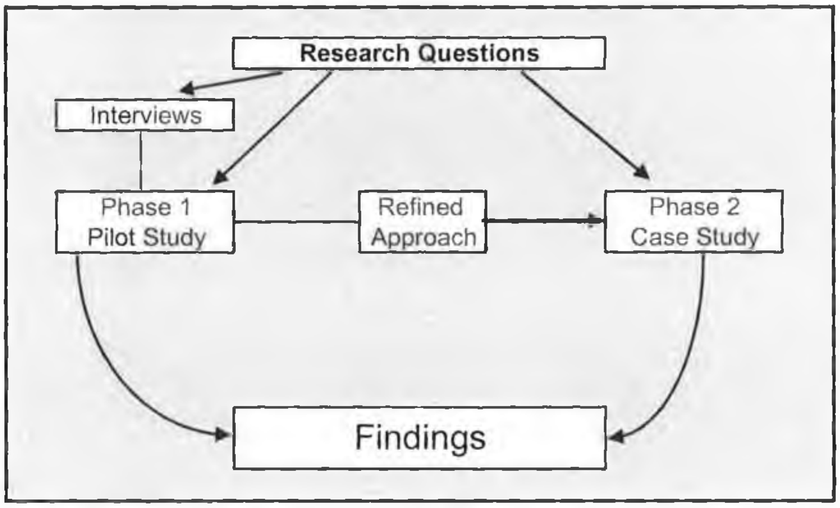


Figure 1: Research Phase 1 and 2

Phase one involves a pilot study examining the medical technology cluster in Galway. A selection of five representative companies are analysed and findings give a broad overview of the cluster and its approach to workplace innovation. The pilot study further defines the direction of the research, while refining interview questions.

Phase two involves a follow-on in-depth case study exploring a high performance case company. The study describes workplace innovation in the sector in a more in-depth and comprehensive way, in order to answer the key research questions. The findings of these studies, outlined in chapter six, determine the extent of the link between innovation in the workplace and company competitiveness.

1.6 LAYOUT OF THESIS

The thesis has been divided into seven chapters. Chapter two begins with a literature review of the need for competitiveness in the medical technology sector, and of innovation as one way for companies to remain competitive. The chapter analyses innovation in general and workplace innovation in greater depth.

Chapter three describes a methodology for the thesis.

Chapter four describes the pilot study. Both chapter five and six examines the case study and subsequent findings.

Finally chapter seven concludes the thesis, describing findings and recommendations for future research.

1.7 SUMMARY

Among other things, the medical technology sector in Ireland is vital in providing high-skilled well-paid employment with increasing levels of exports. In order to stay competitive in a global market, it has been identified as a sector that must innovate to maintain long-term prosperity.

This thesis has an industrial engineering focus on both socio / people and technical aspects of workplace innovation and its effects on competitiveness. A research methodology has been introduced consisting of a brief pilot study and a case study, the first to get a broad appreciation of the sector, and the second to study a company in greater detail. Before describing the studies, the literature is analysed in the next chapter, and the methodology is described thereafter.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

As noted in chapter one, this is a study of workplace innovation in the medical technology sector. There is a critical need to explore this area, and determine how it impacts on company outcomes.

This chapter examines the key literature surrounding workplace innovation and competitiveness, drawing conclusions, and setting the direction of the research work in the subsequent chapters.

2.2 ORGANISATIONAL INNOVATION FOR COMPETITIVENESS

Major reviews of competitiveness by Porter (1990), the international Organisation for Economic Coordination and Development (OECD) (1996) and Teece (1987) generally agree on a similar definition of competitiveness: 'the ability of a firm to increase in size, market share and profitability' (Clark & Guy, 1998). This thesis uses the same definition of competitiveness. Innovating for competitiveness is particularly relevant in Ireland; some Irish institutions such as Forfás and the National Centre for Partnership and Performance (NCPP) have highlighted the need for innovation in the medical technology and Information Communication Technology (ICT) sectors, in particular over the coming decade to remain competitive in manufacturing (Forfás, 2004; NCPP, 2003).

Since the late 1990's, the competitive environment for organisations has changed drastically, due to globalisation. Companies now, more than ever, search for strategies to continually differentiate and improve their products and services. These strategies, in some cases, provide sustainable competitive advantage, while others differentiate to remain in business (Damanpour & Schneider, 2006; Popadiuk & Choo, 2006;

Damanpour & Wischnevsky, 2006). Drucker (1994) concurs with this analysis suggesting that in 'a period of rapid change, the best – perhaps the only way a business can hope to prosper, if not survive, is to innovate'. In short, in a time of increasing global pressures, innovation can be a source of sustained competitive advantage for a firm (Clark & Guy, 1998). Geroski *et al* (1993) give an instance of how one organisation can gain a competitive advantage over another by major innovations that are difficult to imitate.

Tidd *et al* (2005, p5) note that for organisations, 'success derives in large measure from innovation'. Even Joseph Schumpeter, considered an 'initiator and stimulator of innovation research' theorised that these 'new combinations' of existing knowledge and resources (or innovations) open up the potential for new opportunities in business, continually changing the organisation (Laestadius, 2003, p4; Fagerberg *et al*, 2005, p18).

The term 'innovation' is broad and has many definitions. The Oxford Handbook of Innovation introduces the term by contrasting it with invention. While invention is the first occurrence of a new product or process, innovation is really the first effort to carry it into practice (Fagerberg *et al*, 2005). In other words it is 'the successful exploitation of new ideas' (DTI, 1994) or 'the means by which the entrepreneur either creates new wealth-producing resources or endows existing resources with enhanced potential for creating wealth' (Drucker, 1998, p149).

In recent times, innovation in organisations rather than innovation by autonomous individuals has become a popular area of research (Van de Ven & Rogers, 1988). Slappendel (1996) traced the earliest interest in organisational innovation as far back as the late 1950's. Damanpour and Wischnevsky (2006) reflect this trend in the research by defining innovation as something that can be considered 'new to the individual adopter (of the innovation), to most people in the unit of adoption, to the organization as a whole, to most organizations in an organizational population, or to the entire world'.

A less encompassing definition of organisational innovation is 'the adoption of an idea or behaviour that is new to the organization adopting it' (Daft, 1978: p197). 'The idea can be new or old in comparison to other organizations as long as the idea has not been previously used by the adopting organization' (Daft, 1982: p131). Adoption of innovation means that it is new to the organisation, while at the same time having positive outcomes from changes carried out within the organisation (Angle & Van de Ven, 2000; West & Anderson, 1996). Rogers (1998, p4) redefined innovation as 'the process of introducing new ideas to the firm which result in firm performance', reflecting the direction of innovation research.

Nurturing innovation in organisations in any respect is difficult, but academic research can make valuable contributions (Damanpour & Wischnevsky, 2006). The field of innovation is very broad, with many different dimensions (Damanpour, 1991; Gopalakrishnan & Damanpour, 1997). Examples of these dimensions include 'Open versus Closed innovation' and the 'theory of diffusion of innovations', to name a few, but these are outside the scope of this research (*c.f.* Chesbrough, 2003a, 2003b; Rogers, 2003, respectively).

Past contribution to the research has involved a categorisation of innovation into 'contingency theories' or types of innovation (Gopalakrishnan & Damanpour, 1997; Damanpour & Wischnevsky, 2006). Three ways to categorise organisational innovation have emerged and gained more attention in the literature in the recent past (Damanpour, 1991; Gopalakrishnan & Damanpour, 1997).

The first of these areas of research is the study of product versus process innovations. Product innovations are new products or services introduced to meet an external or market need, while process innovations are new elements introduced to produce a product or render a service (Damanpour, 1991).

A second area of study is the categorisation of innovations into radical versus incremental innovations – establishing the level of change associated with the innovation (Gopalakrishnan & Damanpour, 1997). Radical innovations are fundamental changes that embody radical changes in technology (Popadiuk & Choo, 2006). Incremental or evolutionary innovations on the other hand are 'insignificant' or minor changes to products or processes that do not involve a high degree of novelty (OECD, 2005; Damanpour, 1991).

The third area of research emerging in the literature is the separation of innovation into technical versus administrative innovation (Sanidas, 2004). Technical innovations encompass the knowledge of the process and components in the product or service. Administrative innovations are innovations in organisational structure or administrative processes; in other words changes in the way the firm organises work (Gopalakrishnan & Damanpour, 1997). These two components are likely to co-develop, but are less effective when treated separately (Mazzanti *et al,* 2006). These three directions of research are illustrated in the following diagram:

Dimensions of Organisational Innovation

Product	⟷	Process
Radical	⟷	Incremental
Technical	⟷	Administrative

Figure 2: Dimensions of research into Organisational Innovation

There are instances in the literature of 'overlaps' within these three areas of research. For example Harrison and Samson (2002) suggest that product versus process innovation is a sub component of technical innovations. The Oslo manual, a benchmarking report for innovation surveys and research for OECD members also splits technical innovations into

Technological Product Innovations and Technological Process Innovations (OECD, 2005).

Similar approaches of sub-dividing innovation, describing innovation as new knowledge incorporated into products, processes and services, classifying them according to technological, market and administrative / organisational characteristics are described by Afuah (1998) and Popadiuk & Choo (2006). This definition considered an additional external category of Market innovation, referring to new knowledge outside of the organisation, for example with distribution channels or with stakeholders. This consideration is nothing new – as far back as 1934, Schumpeter split innovation into five components: new products, new processes, new markets, sourcing new suppliers, and reorganising an industry. This definition focused on technical innovations while taking the external market into account. Schumpeter's classification was decades ahead of the others, as very few studies concentrated on this categorisation of innovation before the 1970's (Godin, …).

These examples highlight that it is difficult to place specific types of innovation into one category – they can 'overlap' in the three areas of innovation research, focusing on certain aspects of organisational innovation within the workplace. The term 'Workplace innovation', used in this thesis, also demonstrates an overlap. It can be categorised as process or administration innovation, and can be radical or incremental. It is described in greater detail in the next section.

2.3 WORKPLACE INNOVATION

The term 'workplace innovation' is used by Irish authors to describe the right 'bundle' or diffusion of innovative or High Performance Work Practices (HPWP) that lead to improved economic performance in firms (McCartney & Teague, 1997). HPWP are new ways of organising work, rewarding performance and involving employees in the decision-making process in the workplace (ILO, 2005). These 'bundles' have a synergistic performance-raising effect on the organisation (ILO, 2000; MacDuffie, 1995). Synergies can be among practices, as well as between systems of practices and the firms overall competitive strategy (Huselid & Rau, 1996). Essentially they must be brought together in a manner that optimises the 'fit' between them, in order to produce high performance and competitiveness for the firm (Nadler *et al*, 1992). The identification of the best synergy or complementing bundle is difficult, as some bundles of HPWP will work better than others. The analysis of these synergies is a weak one in research (Cappelli & Neumark, 2001). Osterman argued against this weakness by noting that 'the market has become far too differentiated and complex for there to be one 'right' way to organise and manage employees' (Richman, 1994). However, Osterman focused on specific innovative methods (job rotation, quality circles, total quality management and team-working) rather than focusing on the somewhat broad variety of synergistic HPWP in the manufacturing sector (Huselid & Rau, 1996). Geary (1999) refers to this bundle of practices as workplace innovation. Some sources adopted this 'fairly loose definition' in their study of workplace innovation in Ireland (McCartney and Teague, 1997).

There is considerable evidence to indicate that innovative work practices and performance are linked: systems of innovative work practices with employee involvement will see improvements in productivity and overall outputs (Kling, 1994; Huselid, 1995; Osterman, 1995). Furthermore, Flood & Guthrie (2005) found in their study of 165 Irish firms that greater use of workplace innovation reduced employee turnover and increased firm productivity. Others agreed with this, strongly linking business innovation to improved business performance in Ireland (Roper & Hewitt-Dundas, 1998; Black & Lynch, 1997; 2003; McCartney & Teague, 1997; NCPP, 2003).

Some authors have described innovation as having two potential strategies based on performance outcomes: a 'high road' or a 'low road' strategy of innovation (Brödner & Latniak, 2003; Di Martino, 2001; Totterdill, 2000). High road looks to develop and expand the business through innovation (Brödner & Latniak, 2003). In a sense its aim is to make the firm a high performing work system through achieving a dynamic balance between product and process innovations (Totterdill, 2000). On the other hand low road innovations solely aim to cut costs, allowing the business to become more efficient and flexible. One could describe workplace innovation based on these 'high road' or 'low road' outcomes. These are broadly categorised depending on the type of outcomes from the innovative work systems. An innovative work system that broadly maps on to 'low road' innovation is Lean Manufacturing, while High Performance Work Systems could be considered 'high road' workplace innovation.

2.3.1 Low road Workplace Innovation: Lean manufacturing

A popular example of a method of workplace change that broadly maps on to low road innovation is Lean Manufacturing. This is a means to continually strive to reduce waste and improve flow (Womack *et al*, 2003). At the same time some see it as reducing operator's autonomy while working towards low road targets (Niepce & Molleman, 1998).

Lean Manufacturing, sometimes referred to as Lean Production, was introduced to the western world in the early 1990's through the publication of the book 'The machine that changed the world' (Womack *et al*, 1990). It described the best practice application of Just In Time (JIT) manufacturing and the Toyota Production System, work systems that originate back as far as post-World War 2 Japan. The term 'Lean' was originally coined by John Krafick, a research assistant at MIT with the International Motor Vehicle Programme in the late 1980's (LEI, 2004). This research programme formed the basis of the work by Womack *et al.*

A few years later, Womack and Jones (1996) published 'Lean Thinking', describing concepts of converting a mass production firm into a Lean organisation. According to Womack and Jones (2003), Lean "provides a way to do more and more with less and less – less human effort, less equipment, less time, and less space – while coming closer and closer to providing customers exactly what they want" (p14). Taiichi Ohno, the founder of the Toyota Production System, describes Lean more succinctly: "All we are doing is looking at the time line from the moment the customer gives us an order to the point when we collect the cash. And we are reducing that time line by removing the non-value-added wastes" (Ohno, 1988; Liker, 2004, p7). So the key concept of this work system is to improve flow to the customer and eliminate the waste in manufacturing activities. Womack & Jones (2003) describes five steps to achieve this:

1. Specify value in the eyes of the customer. Production activities are classified into value-added and non-value added activities, depending on their impact to the customer. I.e. the customer will not see (or care) about activities that have no effect on the end item. The implementing organisation should aim to eliminate these non-value or 'wasteful' activities.

2. Identify the value stream: once all non-value activities are removed, a value stream map is drawn up. This exercise is similar to a flow chart, but contains more information including inventory levels, lead-times, breakdown times and yield levels. This map helps organise all activities per product family into one sheet and generate overall metrics for the line.

3. Make value flow without interruption: activities are reorganised to allow the product or service to flow without interruption. In shop floor activities, this would mean aligning manufacturing activities as close together as possible. Batch sizes and inventory levels should be reduced, and problems associated with reduced inventories are eliminated.

4. Allow the customer to pull value: this step requires the organisation to become flexible and responsive to customers needs. The notion of 'pulling' value goes against traditional 'pushing' of product. Rather than the organisation building to forecasts, they are in a position to build for the customer as they demand it. The order starts with the customer rather than at the start of the line.

5. Pursue perfection / Kaizen: Kaizen is Japanese for continuous improvement (LEI, 2004). Once flow is in place, and all wastes are eliminated, the organisation should aim to continuously improve. This involves re-specifying value and drawing up a new value stream map, continuously aiming to reduce waste and improving flow in the process.

Proper application of Lean can lead to the following positive improvements in the manufacturing environment:

Productivity	Increased between 10-100%
Throughput times	Decreased between 40-90%
Inventories	Decreased between 40-90%
Scrap	Reduced between 10-50%
Space savings	Between 30-60%
Overtime	Decreased up to 90%
Safety-related injuries	Decreased up to 50%
Product development time	Decreased up to 30%

Figure 3: Lean Savings (Sources: Liker, 1998 & Berger, 2002)

Although Lean offers these savings, authors are quick to point out that based on the last two decades of Lean application in companies, only a few cases have been truly successful with real changes (Bicheno, 2000).

There are many tools used when implementing Lean in an organisation. They are grouped into waste minimisation, flow improvement tools and new layouts. These can range from basic work step improvements to entire line reengineering. Tools used to achieve this can include the following:

Lean Tools	**Description**
Waste minimisation tools	Many forms. E.g. inventory, waiting, over processing.
Value Stream Mapping	A map of the entire value chain, identifying all the activities involved in the product from start to finish.
Value-added analysis	Identify value in the eyes of the customer. Categorise into value added, non-value added, and non-value but necessary.
5S house keeping	Tool to organise a workplace, establish standardised conditions, and maintain the discipline that is needed to do the job.
Flow improvement tools	Allowing customer to pull value when needed.
One-piece flow	WIP eliminated, allowing flow through the value chain.
Kanbans	Signal to internal processes to provide a product. Used with pull systems.
Pull production	Manufacture of product as customer wants it.
Total Productive Maintenance	Machinery performing with zero breakdowns and high quality.
Poka-yoke (error proofing)	A mistake-proofing procedure or device designed to prevent or detect errors.
Single Minute Exchange of Dies (SMED)	A series of techniques to allow for rapid changeovers of production machinery.
Just In Time principles	Producing and delivering the right items in the right time in the right amounts
Layout improvements	Can range from basic work step improvements to entire line reengineering
Flow charts	Graphical representation of sequences in a process.
Line balancing	Alignment of work steps to minimise process delays and fluctuations with production levels.

Figure 4: Lean tools

Over the last few years, new implementation options have emerged for practitioners of Lean. Some follow Womack and Jones' direction (Womack & Jones, 2005). Others have started to implement Lean with Six Sigma methodologies (George *et al*, 2004).

The first option follows Womack and Jones (2005) re-focus on the customer in their most contemporary work. They describe a Lean Consumption versus Lean Provision scenario. Customers consume while firms provide. Consumption is described as 'hassle for the customer'. It involves 'searching for, obtaining, installing, maintaining, repairing, upgrading, and, eventually, disposing of many goods and services' (p9). Provision is described as supplying the value desired by consumers easily or even effortlessly. Where customer choice is continuously increasing, this approach attempts to identify and solve customer's needs – effectively providing a Lean solution.

While Lean solutions is more theory-based and a long-term solution to customer needs, a second and more common approach for companies to implement a work system based on Lean Manufacturing and Six Sigma methodologies. Six Sigma originated in Motorola and General Electric in the 1980's (Pande *et al*, 2000). Many credit Motorola in their development of Six Sigma as a key business initiative in 1987 (Harry, 1998). Six Sigma can be described as "a business improvement approach that seeks to find and eliminate causes of mistakes or defects in business processes by focusing on outputs that are of critical importance to customers" (Snee, 1999). In terms of statistics, a sigma refers to the standard deviation of the process about its mean (Quality Council of Indiana, 2006). For a six sigma process, more than 99.9999998% of products made are within specification, or in other words 0.0000002% are out of spec. This equates to 0.002 defects per million opportunities. The average American company is at a four sigma level, producing an average of 6,210 defects per million (Harry, 1998). The aim for these companies is to move as close to six sigma as possible, using a range of statistical and quality tools. Most of these statistical and quality tools have been around since post-war Japan, but Motorola grouped them into a methodology described as DMAIC, which is commonly used by Six Sigma practitioners since (Hahn *et al*, 1999; General Electric, 2001). Other tools include the use of Total Quality Management (TQM) and Statistical Process Control (SPC) tools. These tools are summarised in the following tables (Quality Council of Indiana, 2006; General Electric, 2001):

Six Sigma Tools	**Description**
DMAIC	
Define	Define the problem area and project to address the problem. Key elements: • Define the customer • Define customer requirements and expectations • Define project boundaries / scope • Map the process flow
Measure	Identify key measures, collect data, measure process variation and baseline performance Key elements: • Develop plan to collect data for process • Determine current status by collecting data from multiple sources • Collect customer survey results
Analyse	Identify root causes of defects, defectives or significant deviations out of process specification, quantify the improvement outcomes Key elements: • Identify gaps between current status and goal performance • Prioritise opportunities to improve • Identify excessive sources of variation • Determine confidence limits and statistical procedures
Improve	Reduce variability or eliminate the cause Key elements: • Create innovative solutions • Develop and implement improvement plans
Control	Monitor the improvements and sustain the process Key elements: • Prevent reverting back to old system • Develop a monitoring control plan • Institutionalise the improvements by modifying the overall system

Figure 5: Six Sigma tools

The following TQM and SPC tools are used throughout the implementation of a DMAIC project:

Total Quality Management (TQM) tools	
Fishbone diagrams	Tool to graphically display cause and effect relationships between variables.
Brainstorming	Uninhibited technique for generating ideas when the best solution is not obvious.
Failure Mode and Effect Analysis (FMEA)	Tool to assess and prioritise risks and effects of failures.
Quality Function Deployment (QFD)	Process to ensure customers needs and wants are heard and translated into technical characteristics.
Statistical Process Control (SPC) tools	
Control charts	Tool to analyse variation in a process.
Statistical tools	Other tools using statistical methods (e.g. Binomial, Poisson, etc).
Gage R&R	Tool to indicate the consistency and stability of measuring equipment.
Process capability indices	Method to compare actual variability of a process to the process specification.

Figure 6: TQM and SPC tools

This grouping or integration of a number of statistical and quality tools has led Six Sigma to be sometimes referred to as 'Total Quality Management on steroids' (Quality Council of Indiana, 2006).

Where Lean focuses on eliminating waste, Six Sigma tries to reduce variation. In more recent times, organisations are beginning to implement both work systems in parallel. This 'Lean Six Sigma' or 'Lean Sigma' methodology symbiotically provides benefits of variation and waste reduction in processes (George *et al*, 2004). Some organisations implement Lean with the DMAIC structure, while others use Six Sigma tools using Lean thinking principles.

In summary, lean success is difficult to achieve. It takes innovative approaches to achieve successful, but perhaps low road, outcomes. For example, Lean and Six Sigma, whether they are used individually or together both aim for the same – increase low road company outcomes. Lean consumption and provision initiatives mark a move towards high road innovation, focusing more on the customer, and considering more than just bottom line outcomes for the organisation. However the implementation of High Performance Work Systems could be considered as a means to truly achieve high road innovation. These are described in the next section.

2.3.2 Towards High road Workplace Innovation: High Performance Work Systems

The terms High Performance Work Systems (HPWS) or High Performance Work Organisation (HPWO) have been used to describe the collection of the right bundles of HPWP (Huselid & Rau, 1996). Writers since the late 1990's, particularly in the US, have gravitated towards the term 'High Performance Work System' (HPWS) to describe innovative work organisations (Wood, 1999).

A considerable bulk of the research into HPWS has originated in the US, and it seemed that European researchers were less concerned during the early 1990's with this area. Galang (2004) noted that much interest into the HPWS paradigm has grown outside of the US since, particularly in Canada, the UK, New Zealand, Singapore, South Korea and Ireland (through work of the NCPP, 2005). It has origins in Socio-Technical Systems, an optimisation of social and technical work system elements within an organisation (Nadler *et al*, 1992).

A notable study of HPWS in an Irish context was carried out in the food / drink / tobacco, electronics, and banking and finance sectors (McCartney & Teague, 1997). In an international context, similar studies were carried out, within the steel, apparel and medical electronic instruments and imaging industries (Appelbaum *et al*, 2000). These studies have been carried out across multiple sectors, providing evidence that HPWS is apparently prevalent in Ireland, but with limitations (*c.f.* O'Donnell & Teague, 2000).

The key concept of HPWS is that work is organised to allow front-line workers (e.g. operators in a medical technology organisation) to participate in decisions that alter organisational routine (Appelbaum *et al*, 2000). Practices in a HPWS require these workers to gather information, process it and act on it. HPWS differs from traditional work organisation in the way employees participate in important decisions, require further upskilling and benefit from incentive systems (Katz *et al*, 1985; MacDuffie, 1995; Ichniowski *et al*, 1997; Rubinstein, 2000). Nadler *et al* (1992) describe HPWS as a system which optimises the congruence or 'fit' between work, people, technology and information in order to produce high performance in terms of responsiveness to customer, market demands and opportunities.

The difference between this and Lean or Six Sigma methodologies is that HPWS encompass Human Resource practices. These HR practices can include hiring, training, performance management, compensation, among others, intended to enhance employee skills, knowledge, motivation and flexibility (Gephart & Van Buren, 1996).

The application of HPWS differs by company, but key outcomes remain the same. In manufacturing, the introduction of HPWSs lead to higher plant performance, which mean more to management. Opportunity to participate in decision-making leads to increased trust and basic rewards for the workers. It does not increase worker's stress, and wages associated with participation are significantly improved as it increases (Appelbaum *et al*, 2000).

In an Irish context, it seems that HPWS is advanced in only a minority of Irish workplaces, while at the same time the recent success of the Irish economy has been achieved without it (Geary, 1999). HPWS are not widely adopted for a variety of reasons (ILO, 2005):

1. Other business strategies can deliver enhanced profits and productivity in the short term. Lean manufacturing and Six Sigma methodologies are good examples of these strategies.

2. HPWS may be more suitable for some product markets than for others. Studies have been most thoroughly carried out in the steel, automobile and components manufacturing industries (U.S. Department of Labor, 1993). Fewer studies have been carried out in the medical technology sector.

3. System inertia. The organisation may focus on an existing system, and the application of a new workplace innovation like HPWS may be difficult.

4. Mistrust between management and employees. This is a HR issue. It may be that trust prevents the front line worker from participating in decision making due to mistrust from both sides.

5. Role of unions. The implementation of HPWS may be seen as a way to sideline unions, developing direct lines of communication with the employee.

Definitions of HPWS vary depending on the organisation and the industry. Whitfield and Poole (1997) summarise this ambiguity as being "therefore evident that the construction of rigorous definitions of high-performance systems that can be used for empirical analysis needs to be undertaken with extreme circumspection. Moreover, the comparison of differing studies of such systems must be mindful of the variations in definition which are implicitly or explicitly adopted." In other words, there is not an agreement in the literature of a definition of HPWS – it varies with context. No two HPWS are exactly alike (Bassi & Van Buren, 1997). In the context of high road innovation in the medical technology sector, HPWS is used in this thesis to describe work system which encompasses HR metrics. It can be considered a bundle of practices used to synergistically improve the organisation. In a sense, it is a means for organisations to move towards becoming high road workplace innovators.

2.3.3 Choosing between 'high road' and 'low road systems'

'Low road' systems may lead to 'low road' outcomes, such as productivity increases and cost reductions. 'High road' systems, on the other hand may contribute to 'high road' outcomes, such as a continuously developing workforce, new product introduction, new innovations, and gains in market share.

Workplace innovation can be viewed in terms of 'high road' and 'low road' outcomes. From the previous section, it may be that HPWS encapsulates the definition and characteristics of true workplace innovation. In other words HPWS may be an ideal state – with organisations constantly striving to become 'the high performance work system'. However Lean Manufacturing incorporates a number of 'High Performance Work Practices' or HPWPs. It is widely accepted that an effective HPWS is made up of the 'right bundle' of HPWP, but HPWS varies by company. Therefore, Lean Manufacturing could be just a small element of a HPWS, and with other HPWPs (e.g. Six Sigma) it makes up a truly innovative work system. Lean Manufacturing can be considered a toolkit for innovation, while HPWS is an environment for it.

For the medical technology sector, cost competitiveness is important, and Lean Manufacturing or Six Sigma methodologies are means to continually keep costs low. In other sectors, low road innovation has been seen to be easier to achieve than high road innovation: 'cutting the buck is much easier than expanding the bang' (Hamel & Prahalad in Brödner & Latniak, 2003). HPWS may be an example of 'best practice' workplace innovation, but these authors suggest that industry practitioners tend to focus on easier low road improvements, using tools such as Lean and Six Sigma. As a consequence, these short-term low road approaches to productivity and investment have been found to slow the pace of high road innovation (Totterdill, 2000).

In considering this, the next section develops a number of research questions in order to explore workplace innovation in the medical technology sector.

2.4 RESEARCH QUESTIONS

Drawing from definitions of innovation in the literature, the term 'workplace innovation' is used in this thesis to describe the adoption of new work systems in the organisation, which lead to positive outcomes. In other words, new ways of doing work that are implemented for the first time, which have positive results for an organisation, can be considered workplace innovations. In the literature review, workplace innovation was categorised in terms of process or administration innovation; by changing processes or ways of doing work. Changes can be radical (made over a short period of time) or incremental (implemented as part of a new work system), but must have positive low road or high road outcomes.

These positive outcomes are needed for job retention, manufacturing in Ireland, and the Irish economy as a whole. This leads to the need for an examination of best practices of workplace innovation in industry, particularly within the medical technology sector. Five key research questions are described, linking these research areas of workplace innovation and overall company competitiveness.

2.4.1 RESEARCH QUESTION 1: WHAT IS THE NATURE OF INNOVATION IN THIS SECTOR, PARTICULARLY AT THE LEVEL OF THE WORKPLACE?

Workplace innovation is happening in the medical technology sector in the west of Ireland, but its extent is not widely known. In focusing the research, the extent of workplace innovation is determined in the workplace itself – on the shop floor.

2.4.2 Research Question 2: What kind of workplace innovation happens in a medical technology organisation? How is it optimised?

The type of workplace innovation being adopted is examined in the entire sector, and specifically in one case company. The way in which it is implemented in the organisation is then studied.

2.4.3 Research Question 3: How effective are these workplace innovations? What is the impact on production and innovation measures?

The research needs to determine the measures used to gauge workplace innovation, and in turn their effectiveness must be investigated.

2.4.4 Research Question 4: Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?

In using the 'right bundle' of workplace practices and innovations, the impact of workplace innovation on company outcomes is determined.

2.4.5 Research Question 5: Where is the emphasis? Is it on costs, new ideas, new product introduction etc?

The final research question determines where the importance of workplace innovation lies in terms of the overall company. The extent of high or low road innovation within the organisation can be examined through describing workplace innovation on the shop floor.

Many multi-sector studies of workplace innovation have been carried out in the past, both in Ireland and internationally. Few have focused solely on a single sector, much fewer on workplace innovation in the medical technology sector. This research explores this gap (described earlier in section 2.3), through debating the research questions, using a pilot study and case study approach. This methodology is explored in depth in the next chapter.

2.5 SUMMARY

There are many dimensions of innovation addressed in the literature, ranging from product to process innovation, radical to incremental innovation, and technical to administrative innovation. Workplace innovation is focused on in this thesis, which overlaps many of these dimensions of innovation. It is the application of a new work system in an organisation for the first time, which leads to positive outputs for the firm. A key idea coming through the literature is that workplace innovation and competitiveness are inextricably linked: good application of workplace innovation in a firm positively affects its competitiveness.

A review of the literature led to the categorisation of workplace innovation. It has either 'high road' outcomes (such as a continuously developing workforce, new product introduction, new innovations, gains in market share) or 'low road' outcomes (such as productivity increases and cost reductions).

'Low road' or 'Lean' workplace innovation responds to short-term competitive challenges (for example the threat of increasing costs in Ireland's case). It can be argued that implementing a 'high road' or 'High Performance Work System' approach to workplace innovation can ensure longer-term success for organisations.

This research analyses the level and type of workplace innovation in the medical technology sector. Few studies have been carried out on this sector in the past, much fewer in the area of workplace innovation. Five key research questions have been highlighted in this chapter, linking research areas of workplace innovation and overall company competitiveness. The next chapter develops the methodology in which these research questions will be addressed.

CHAPTER 3: METHODOLOGY

3.1 INTRODUCTION

This chapter describes the methodology used in studying the impact of workplace innovation on the medical technology sector in the west of Ireland. A two phase approach is used. A pilot study provides a general top-level analysis of the sector, while a following case study provides an in-depth examination of workplace innovation within a large medical technology organisation in the west of Ireland.

The chapter first describes a research approach. Types of research methodologies are then described, and the methodology for this thesis is outlined.

3.2 RESEARCH METHODOLOGY

There are many sources of literature describing research methodologies, and many guides available on how to do research. This research approach is based on a simple framework offered by Maylor & Blackmon (2005). The figure below illustrates the framework, while mapping onto the thesis chapters.

3.2.3 Do research

Actual research is carried out by collecting and processing data. This thesis used interviews, surveys and a case study to collect data. NVivo, a software package for analysis of qualitative data was used to process data (Seale, 2002; Tappe, 2002). This section of the research framework is completed before describing the research.

3.2.4 Describe research

The rest of the thesis is dedicated to describing the research, describing the pilot and case studies and findings from each. Conclusions were drawn from processing the information gathered from the NVivo software package. The results are then disseminated through presentations, papers, conferences etc.

3.3 DESIGNING A RESEARCH METHODOLOGY

This chapter explores the 'design research' segment of Maylor & Blackmon's (2005) framework in section 3.2. Kumar (1996) divides this approach into four steps:

- Conceptualise a research design
- Construct an instrument for data collection
- Select a sample
- Write a research proposal

3.3.1 Conceptualise a research design

A review of the literature developed a number of research questions:

1. What is the nature of innovation in this sector, particularly at the level of the workplace?

2a. What kind of workplace innovation happens in a medical technology organisation? 2b. How is it optimised?

3. How effective are these workplace innovations? What is the impact on production and innovation measures?
4. Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?
5. Where is the emphasis? Is it costs, new ideas, new product introduction etc?

The research design involved two phases. Phase one would address the type and the level of workplace innovation in the medical technology sector in the west of Ireland. In order to do this it would need to be a broad reaching research instrument. Phase two would be more in-depth, exploring workplace innovations, its effectiveness, linkages to competitiveness, and its effectiveness. It was clear that a more detailed study would be required to describe the phase two aspects.

3.3.2 Construct an instrument for data collection

There are two key philosophies or approaches to collecting data. Some use the terms 'Scientific' versus 'Ethnographic' approaches (Maylor & Blackmon, 2005). Others use the terms 'Positivistic' versus 'Phenomenological (or Interpretivist)' in approaching social sciences (Collis & Hussey, 2003). The terms 'Quantitative' and 'Qualitative' are more commonly used to describe overall research approaches.

A quantitative (Scientific / Positivistic) approach is used 'if you want to quantify the variation in a phenomenon, situation, problem or issue, if information is gathered using predominantly quantitative variables, and if the analysis is geared to ascertain the magnitude of the variation' (Kumar, 1997, p10). In other words this is the collection of data that is best expressed as numbers (Maylor & Blackmon, 2005).

Qualitative (Ethnographic / Phenomenological / Interpretivist) data collection should be used 'if the purpose of the study is primarily to describe a situation, phenomenon, problem or event... and if the analysis is done to establish the variation... without quantifying it' (Kumar, 1997, p10). This on the other hand is an approach to the collection of data that is difficult to reduce to numbers (Maylor & Blackmon, 2005).

These two approaches are at two ends of a continuum, and the research design determines the type of approach that should be used to collect data. There are many types of instruments available for each approach. Qualitative and quantitative approaches at times overlap and blur, and it is not unusual for quantitative approaches to produce qualitative results, and vice versa (Collis & Hussey, 2003).

In defining the research questions it became apparent that this research tends to be more qualitative in nature, or more towards the qualitative end of the research continuum, because innovation is difficult to quantify (see figure below).

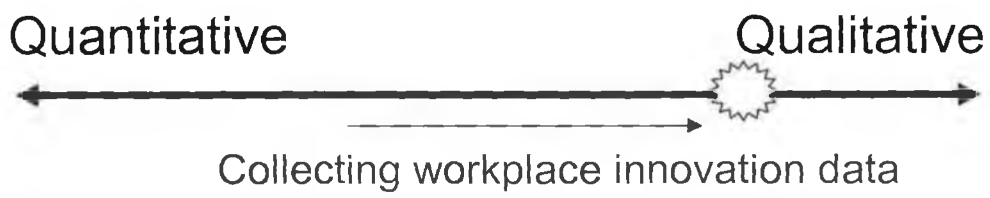


Figure 8: Research 'continuum' (adapted from Morgan & Smircich, 1980)

A qualitative approach is also taken to extract meaning from and develop an understanding of the research. There are many qualitative data collection tools such as observations, focus groups, interviews, document studies, key informants, alternative assessments, to name a few. A case study approach was selected, as it best suited for type of research. A case study is a 'phenomenon in its natural setting, employing multiple methods of data collection to gather information from one or a few entities (people, groups or organisations)' (Benbasat *et al*, 1987).

A case study approach was best suited for the following reasons (Winegardner, 2001; Yin, 1984):

- The primary instrument for data collection and analysis is the researcher. Through mediation, gathering and interpretation of information, the thesis will evolve, clarify and be summarised. This can only be achieved through fieldwork.
- Focusing on gaining the insider's perspective, through interviews, surveys, etc. is central to qualitative research and is achieved by communication with workers within the sector. This can be achieved through interviewing as part of the study.
- There is an 'inductive approach' to knowledge generation in case studies. This means through building abstractions, concepts, hypotheses, or theories from these firms, (rather than testing existing theory) findings from the research questions can be hypothesised.
- The medical technology sector in the west of Ireland provides an ideal opportunity to study workplace innovation. A case study like this has not been carried out in the sector in the area of workplace innovation. Galway is seen as a 'capital' area for this sector, particularly by IBEC, Forfás, BMW and the Atlantic Technology Corridor (ATC). The interest in the research lies in understanding the meaning people have constructed, of workplace innovation.
- It represents a critical case for testing the research questions – a longitudinal study will determine if the case company grew and stayed competitive and innovative, despite competitive pressures such as rising costs and globalisation.
- Finally, the end product is descriptive. The design continuously evolves as a flexible response to changing conditions of the study. Considerable time is spent in the natural setting of the study, and the sample selection itself is non-random, purposeful and small. By selecting a case study, all this can be achieved.

Case studies can be categorised into three types of qualitative research: application descriptions, action research and case study research. Case study research is the preferred approach and has a clear objective in the conduct of research. The other two categories focus on practical implementation of a system, and a hindsight approach (Benbasat *et al*, 1987). The instrument constructed for this research consists of two parts.

1. Phase one: a study of a number of firms in the medical technology sector. Data gathered here is based on interviews with senior managers and engineers in a number of medical technology companies. This study is further described in chapter four.

2. Phase two: an in-depth case study of a best practice organisation. The data collected for this study is gathered through questionnaires, recording, transcribing, and analysis of interviews, follow-up questions, meetings, and through analysis of company records and reports. This study is described in chapters five and six.

3.3.3 Select a sample

The third step in the design of a research methodology is to determine the sources to apply the research instrument. Sampling theory is guided by two theories. Firstly, bias in the selection should be avoided. Secondly, maximum precision in the study must be attained for a given outlay of resources (Kumar, 1996).

A two-phase approach was taken in carrying out the case study. Firstly a multiple case study, referred to here as a pilot study would be carried out. The pilot study would examine companies from large and small, indigenous and multinational organisations in the west of Ireland area. Selection is based on accessibility rather on it being a representative sample of the sector. Secondly, a further in-depth case study of a multinational organisation would be selected. This would consist of an in-depth longitudinal analysis of an innovative area within a leading medical technology organisation in the west of Ireland. Reasons for selection of these companies are included in respective chapters.

3.3.4 Write a research proposal

Finally, this step in designing the research finalises preparatory work, describing the research problem and plan. This proposal provided the basis for chapter one in the thesis. A plan was developed to first carry out a pilot study, then concentrate on an in-depth case study. The pilot study examines the first two broad research questions, while the in-depth case study investigates the remaining deeper questions. This approach can be summarised with the diagram below:

Research Questions		Study
1	What is the nature of innovation in this sector, particularly at the level of the workplace?	Pilot
2	A. What kind of workplace innovation happens in a medical technology organisation? B. How is it optimised?	
3	How effective are these workplace innovations? What is the impact on production and innovation measures?	Case
4	Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?	
5	Where is the emphasis? Is it on costs, new ideas, new product introduction etc?	

Figure 9: Summarising research methodology

This model forms the basis for carrying out the research in the rest of this thesis.

3.4 SUMMARY

The research methodology is developed to investigate the problem area. In this thesis a two-phase approach has been designed. Firstly a multiple case study or pilot study investigates a small number of companies in the West of Ireland, selected by opportunity of access. Secondly an in-depth case study of a multinational will provide deeper investigation and answers to the research questions.

In the next chapter, the pilot study of a number of large and small, multinational and indigenous medical technology organisations, to determine how these companies innovate in their workplace, is described. In chapters five and six, an in-depth case study investigates this prevalence deeper, exploring workplace innovation effectiveness and emphasis, and its relationship with competitiveness. Chapter seven includes findings from both.

CHAPTER 4: PILOT STUDY

4.1 INTRODUCTION

This chapter examines the first two research questions through findings from the pilot study.

Research	Questions	Study
1	What is the nature of innovation in this sector, particularly at the level of the workplace?	Pilot
2	A. What kind of workplace innovation happens in a medical technology organisation? B. How is it optimised?	
3	How effective are these workplace innovations? What is the impact on production and innovation measures?	
4	Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?	
5	Where is the emphasis? Is it on costs, new ideas, new product introduction etc?	

Figure 10: Pilot Study research questions

The pilot study involved studying large and small indigenous and multinational organisations that have remained competitive through workplace innovation. The research in each firm followed a standard pattern of interviewing using a combination of semi-structured and structured interviews.

The interviewed companies were selected for a number of reasons:

- Ease of access – the research team had access to these companies through supervision of undergraduate projects.
- Type – companies range in type from small to large indigenous and multinational companies.
- Location – all companies were located relatively close to the researching institution.

Interviewees from five differing companies were selected, details of which are summarised in the figure below[1]:

Interviewee	Position in company	Number of Employees	Product type	Approx. years in Ireland
Small Indigenous A	Senior Manufacturing Engineer	<50	Medical devices	>5
Small Indigenous B	Senior manager	<50[2]	High precision medical devices	>5[3]
Small Multinational	Manufacturing Engineer	<250[2]	Cardiovascular accessories	>10
Large Indigenous	Manufacturing Engineer	<500	Medical devices / metal fabrication	>5[3]
Large Multinational	Senior Manufacturing Engineer	>500[4]	Vascular devices	>10

Figure 11: Details of Interviewees

[1] General source unless indicated otherwise: IDA Ireland website (multinationals) and Enterprise Ireland website (indigenous)
[2] Subsidiary of larger indigenous company
[3] Established in the west of Ireland for over 20 years, ventured into medical technology in the last 5-10 years
[4] Source: Interviewees

The interviewees were in management or manufacturing engineering positions, but would see themselves as being directly involved with the product lines. The interviews themselves were designed to be a half-hour in length each, broken up into a number of sections, to reflect the research questions. All interviews were recorded and then fully 'definition of workplace innovation'. Cross checking between interviews and comparison with the literature were used to ensure validity (Silverman, 2000; Miles and Huberman, 1994). The interviews were explored in order to provide answers to the first two research questions:

- Research Question 1: What is the nature of innovation in this sector, particularly at the level of the workplace?
- Research Question 2: What kind of workplace innovation happens in a medical technology organisation? How is it optimised?

4.2 RESEARCH QUESTION 1: WHAT IS THE NATURE OF INNOVATION IN THIS SECTOR, PARTICULARLY AT THE LEVEL OF THE WORKPLACE?

Workplace innovation seems to be happening in all companies to some extent. Two key needs emerged from the interviews. Firstly medical technology companies need to continuously innovate to keep competitive. Secondly within these organisations there is a need to continuously drive down costs. Lean Manufacturing is the means by which these firms achieve both.

4.2.1 NEED 1: INNOVATE TO COMPETE

Competition is high in the medical technology sector and acts as an external driver for companies to innovate. For example, many cardiovascular companies concentrating on many different aspects of the same product, for example – peripherals, ancillary pieces, custom kits, guide wires, stents, balloons, catheters, inflation devices. "*In general there's not a lot to distinguish between (one company's') products and the other products out there*". In order to stay competitive, companies need to keep "*improving layout, doubling work stations... it's a competitive world out there*". From the interviews it was evident that these companies must be flexible yet specialised in what they do, while being responsive to demand. With this flexibility and speed, quality of product is still most important. If the product is made poorly, a rival competitor will be waiting to replace it. These factors encourage innovation within these companies.

4.2.2 Need 2: Reduce costs

Organisations want 'bottom line' benefits or cost reductions from innovation. It was evident from the interviews that successful improvement programmes produced improved process yields, drastically reduced lead-times and increased throughput: "*the end game is what you're trying to get; in terms of lower throughput times, better productivity, higher quality, and a safer product, because you got higher yields, so you got less rework happening et cetera…*". Scrap reduction was mentioned most frequently as the biggest direct cost savings from these initiatives. Manufacturing costs were indirectly reduced for some through eliminating waste and significantly reduce cycle times or process times. In any event, costs were reduced by "*making more for less*". Positive effects were seen on sales in some cases.

4.2.3 Response: Lean Manufacturing

Most interviewees regarded the use of Lean Manufacturing (with some incorporating six sigma quality initiatives) as the most important ways their companies innovated in the workplace. Key Lean tools included value stream mapping, improving flow and waste elimination. Other manufacturing-problem solving tools in use in these companies included design of experiments, root cause analysis, Failure Modes and Effects Analysis, cellular manufacturing, and overall equipment effectiveness.

The majority of the companies interviewed saw a correlation between workplace innovation and their Lean "*enterprise umbrella*" or within "*the whole Lean Manufacturing / business idea*". One interviewee added to this, by describing workplace innovation as a way to "*think outside the box*", or "*trying to think and do things creatively*". It was also mentioned that true innovation with Lean means implementing it "*outside the (traditional) manufacturing area*", for instance "*into the area of (support) services, and being at the cutting edge of this*" or implementing Lean at line ramp up.

Of all the companies interviewed, Lean was being investigated or implemented in some form – some had their initiatives implemented company-wide, some were at roll out stages, and others saw failed initiatives. Others were considering starting Lean programmes. In whatever stage of implementation, Lean Manufacturing for these companies is the means by which workplace innovation is happening.

Some were planning to start Lean Manufacturing, some were implementing it and seeing savings, some had failed attempts, while others were extending it by introducing Six Sigma methodologies. Based on this, a model based on the Product Life Cycle (Levitt, 1965; Day, 1981) has been developed which broadly maps the pilot companies to each of these stages:

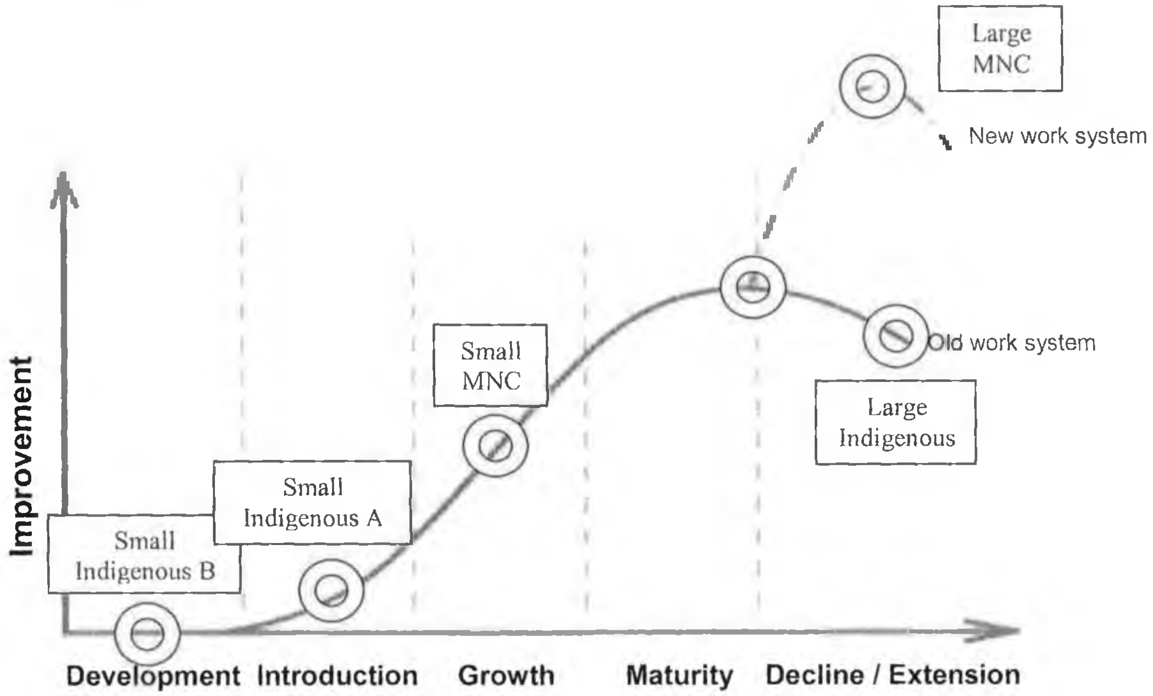


Figure 13: Workplace Innovation Life Cycle (WILC)

Like the product, the workplace innovation follows from a birth to death cycle, only to be superseded (or extended in Product Life Cycle terms). The x-axis still represents time as the curve develops. On the other axis, sales can be exchanged for 'improvement'. Improvements can be expressed in terms of any shop floor metric that the workplace innovation aims to improve, be it WIP, quality, sales, costs, time, absenteeism levels, morale, etc. The individual stages within the Workplace Innovation Life Cycle (WILC) are described next, mapping the pilot companies respectively.

- Development Stage: During the birth or development stage, the workplace innovation team is formed. The project 'champion' is identified at this stage, along with the key stakeholders and representatives throughout the organisation. The system itself is planned and developed, using even the most basic of project management techniques, for example timescales, milestones, responsible parties, and most importantly closing out dates.

  The Small Indigenous B was considering implementing Lean for the first time. This company is a subsidiary of a larger company located in Galway for more than 20 years. The subsidiary itself is also relatively new and small, and had not yet started to implement Lean techniques. This company could be considered in the development stage of the WILC.

- Introduction Stage: Once ready for launch, the system is introduced company-wide. Operators on shop floor level are introduced to the concept through briefings, meetings and presentations. Areas for improvement are identified and projects commence. The most effective workplace innovation initiatives target 'low lying fruit' first: quick win projects that see massive improvements in a short time. This helps establish buy-in with both management and operators alike, while keeping the momentum of the initiative.

The Small Indigenous A had started introducing Lean company-wide. It is a relatively new company, so was focusing on trying to improve flow rather than reducing waste. It carried out layout improvements at the time of the interviews, and had seen limited savings.

- Growth Stage: When quick-win projects are successful, and the initiative begins to formalise, the system enters its growth stage. Projects optimise systematically throughout the organisation. Improvements are greatest at this stage. The workplace innovation system becomes 'engrained' in the organisation.

  The Small Multinational had started Lean and seen some quick wins and improvements on its lines. It mapped its processes and seen savings and improvements through it's Kaizen (continual improvement) and housekeeping efforts.

- Maturity to Decline Stages: In the maturity stage, the system has improved every assembly line on the shop floor. Improvements become more and more difficult to make using this systems' rules. At this stage, management needs to be looking at the next generation improvement model, or to effectively innovate with the existing system. Inevitably the system will approach one of two stages: decline or extension.

  In the decline stage, the last of the improvements with the existing system is achieved. At this point, old habits begin to creep back, improvements are lost or decline, support for the initiative itself decreases, and overall things tend to revert back to the 'old ways'.

  An example of this was observed in the Large Indigenous company. It had seen a failed Lean programme over the two years prior to the interviews. Improvements had been made, but not enough in the eyes of the interviewee.

- Maturity to Extension Stages: A more positive outcome is to build on current success and extend the life cycle. This can be achieved by either 'innovating' the current innovative life cycle, or adapting a new system altogether. An example of this extension would be to use Six Sigma methodologies with Lean for the first time, or to move to a Lean Solutions scenario (as described by Womack & Jones, 2005; and George *et al*, 2004, in the literature review). Other ways to innovate with the work system would be to use it in situations where it was not originally designed for, e.g. implementing a manufacturing focused system in a services focused area, or innovating across value chains rather than single links in the chain. Through doing this, the workplace innovation reverts back to the growth stage, but will eventually mature and decline, unless the cycle repeats.

  Lean had been implemented company-wide in the Large Multinational. Savings had been seen on its manufacturing lines. The company had started to carry out Six Sigma programmes and moved its Lean efforts into the back office. This company maps onto the extension stage, by the way it has developed its Lean system innovatively.

- Next stage: Planning the next new system must be underway once the existing system is seen to decline. Bringing through this new system starts the next phase in the workplace innovation, the birth or preparation stage, hence repeating the cycle. Adoption of a High Performance Work System or similar new system is an example of this.

4.3 RESEARCH QUESTION 2: WHAT KIND OF WORKPLACE INNOVATION HAPPENS IN A MEDICAL TECHNOLOGY ORGANISATION? HOW IS IT OPTIMISED?

All five companies interviewed described themselves as being innovative in some form. Five key enablers to workplace innovation were developed from interviews and experiences of the interviewees.

- Drive innovation from the top down
- Support innovation with 'Champions'
- Support the human element
- Have an innovation team in place
- Innovate daily

4.3.1 Drive innovation from the top down

Within an organisation, innovation should typically be driven from the top down, filtering from top management. In some companies, management challenged the employee to 'think outside the box'. Others encouraged innovation while ensuring they aligned to company goals. These drivers must be supported by visible metrics and set goals, encouraging communication and competition. Some examples of driving metrics included lead-time reduction, increased flexibility, and quality over quantity. *"If you don't know how you're doing, you don't set further goals for yourself. You just keep going along and you don't know have things had an immediate impact*". "*Making sure that people are understanding of what's expected of them and that they're getting feedback... that's number one*".

Poor focus from top-down or "*innovation for innovation's sake*" is a negative approach to workplace innovation. Management moving on to other new projects can be detrimental to innovation efforts: "*you might have an engineer you hired to do Lean, a Lean project, but then a business project will come up, new business opportunities, then you get dragged into that*".

Furthermore, top-down support means ensuring resources are in place to support innovation. Resource issues can hinder innovation, be they staffing issues, time or demand constraints. Without the right resources in place, workplace innovation can be difficult to undertake and drive.

4.3.2 Support innovation with 'champions'

Innovation 'Champions' and incentives support these goals. 'Champions' can come in the form of consultants, internal innovators, or letting a new engineer "*loose on (the problem) and see if (they) can actually fix it*".

4.3.3 Support the human element

Rather than adopting new technologies and machinery, it was clear from the interviews that the people element was the most important enabler of workplace innovation. Human Resource practices such as regular meetings, updates, regular feedback on performance, personal development plans, and employee coaching / mentoring and training "*must be in place first, as a background, a mindset*". Another interviewee backed this up saying that prior to any workplace innovation initiative "*related HR practices must already be in place*".

Through HR practices, new innovations can be rewarded through, for example, incentives to meet targets, rewards for implemented suggestions, or in response to positive management reviews. In short, a system in place to allow innovation and encourage innovation to come from the bottom-up is paramount.

4.3.4 Have an innovation team in place

A team must be established; one interviewee quoted that "*every company more or less has the same, they call them different things, but they involve the supervisor, manufacturing engineer, quality engineer and a planner*". Another commented "*for every line there would be a team, a quality engineer responsible, a manufacturing engineer responsible, a supervisor and a planner... responsible for the day-to-day issues, continuously improving the line and dealing with problems with manufacturing, with non-conformances, whatever is wrong*". Others agreed with this, adding "*teams are a major part of how (they) operate*".

4.3.5 Innovate daily

The interviewees saw themselves as innovating through initiatives such as day-to-day process improvement and projects, meeting performance targets, rather than once-off big improvements. Some saw this as 'fire-fighting'; dealing with problems as they came up. Quality issues in the form of process variability or line instabilities were mentioned as barriers to innovation. If the line or process is unstable, the main focus will be tackling these issues first before considering improving on them.

4.4 SUMMARY

This chapter described phase one of the research: a pilot study of five companies ranging from small to large, and indigenous to multinational. The pilot study addressed two broad research questions.

Firstly the level of workplace innovation in the medical technology sector was determined. It seems that all medical technology companies innovate in their workplace in some form, as there is a continuing need to compete and reduce costs to survive in the sector. Lean Manufacturing was described as a form of workplace innovation by the interviewees. All companies interviewed were in the process of implementing Lean at some level. This level of implementation was broadly mapped onto a Workplace Innovation Life Cycle based on the Product Life Cycle Model.

Secondly the ways in which workplace innovation happens in these companies were addressed. Five key enablers were identified: drive innovation from the top down, support innovation with 'Champions', support the workforce, use teams to innovate and finally innovate daily.

The interview questionnaire for the pilot study was refined and changed for the case study, as this required a deeper analysis of workplace innovation in the medical technology sector. The next chapter introduces the case study company and leads into the second phase of the research.

CHAPTER 5: INTRODUCTION TO THE CASE STUDY

5.1 INTRODUCTION

The Pilot Study examined the medical technology sector in Galway from a broad perspective, sampling a small number of companies in order to address the broader research questions. This chapter describes the case study, with refined questionnaires, and a focused approach, in order to carry out an in-depth analysis of workplace innovation within a leading medical technology organisation in the west of Ireland.

Reasons for selecting a specific case company are highlighted first. The company background and case line is then described. Case study access and sources of information are outlined, leading into the research questions in the next chapter.

5.2 CASE STUDY SELECTION

A large multinational company was selected to carry out the case study. It was selected as it met Yin (1984) and Winegardner (2001) criteria outlined earlier in chapter three. Further to this, an area was identified by management and the researcher as a good case study for a number of reasons:

1. It was an opportunity to examine the research area in industry, from a local and leading cardiovascular organisation.

2. It would explore the research questions, and improve understanding of the research area.

3. The chosen line was a pilot line for its Lean and Six Sigma initiatives.

4. The product was nearing the end of its life in Galway. This was an ideal opportunity to study the life of a line from start to eventual transfer.

5.3 COMPANY BACKGROUND

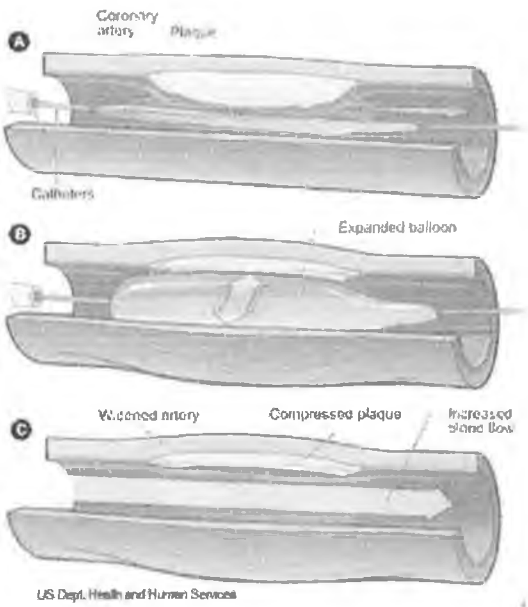
The case company is based on the east side of Galway city. It employs more than 500 people. Its business division in Galway predominantly focuses on the manufacture of cardiovascular products. It has been operating in Galway for more than five years, and has both Manufacturing and Research and Development operations. A large proportion of products manufactured at the site resulted from R & D carried out at the facility (IDA, 2006f).

This cardiovascular business forms part of a large variety of businesses in the overall organisation, ranging from other implantable devices to diagnostic equipment. Global net sales are more than ten billion dollars annually, yet the company's vascular business contributes to a small share of that (less than ten percent).

The organisation globally has over 25,000 employees, and operates in over a hundred countries worldwide. Its main headquarters is located in a large medical technology cluster in central North America. Much of its growth has been driven by acquisitions (Pharma Licensing intelligence report, 2006). The Galway plant itself was part of an acquisition by the company in the late 1990's. It has since become one of the top 100 most profitable companies in Ireland (Sunday Business Post, 2005).

The case company builds a variety of cardiovascular products: 'dry' or uncoated coronary stents, angioplasty balloons, guiding catheters, and ancillary products to treat heart related illnesses. The product the customer uses can be an angioplasty balloon by itself, or combined with a dry stent or drug eluting stent. Angioplasty balloons that are not combined with stents are sometimes referred to as POBA (or Plain Old Balloon Angioplasty) catheters. The procedure to place these catheters and stents in the artery of a patient is known as a Percutaneous Transluminal Coronary Angioplasty (PCTA) or more commonly referred to as an angioplasty.

Both catheters and stents combined with catheters have similar operation. See diagrams below:



A) Catheter is threaded through the femoral artery and directed to the site of the blockage in the Coronary artery. Marker bands on the Catheter align it to the plaque build-up.

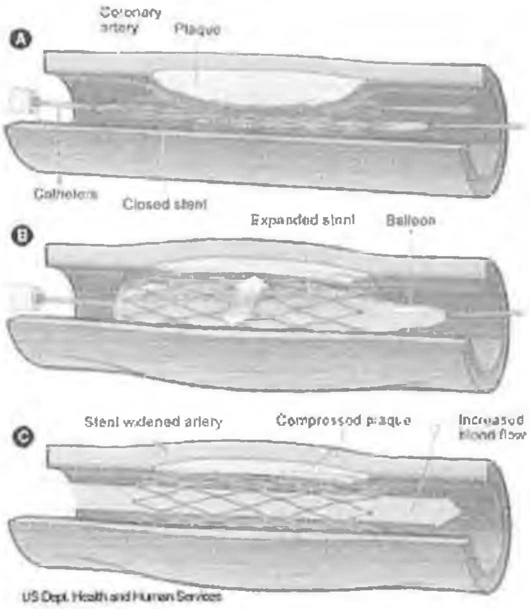
B) Compressed air is pumped through the catheter. Balloon is inflated, expanding and compressing the plaque build-up.

C) The balloon is in turn deflated and removed. Blood flow is increased

Figure 14: Catheter operation (Source: US DoHHS, 2007)

The catheter is used to increase blood flow in narrowing arteries. As mentioned in chapter one, Catheters are sometimes sold with stents crimped on the balloons. The stent is placed at the site of the blockage, acting as a scaffold preventing the artery re-narrowing.

The following diagram is similar to the previous angioplasty diagram, but in this case, the stent is left in place:



A) A stent is crimped on the Catheter.
As before, the Catheter is directed to the blockage.

B) The Catheter balloon is inflated and the stent expands into place.

C) The balloon is in turn deflated and removed. The stent remains in place. Blood flow is increased

Figure 15: Stent operation. (Source: US DoHHS, 2007)

This thesis uses the term 'POBA line' to describe the catheter product manufactured by the case company. For confidentiality reasons the case line is referred to as POBA line, rather than by the product name. POBA product is one of five distinct product families being manufactured in the facility. The line itself has three main variations, but manufacturing differences are relatively minor.

The next section describes the case line. The section itself is divided into product, process and people.

5.4 CASE LINE

5.4.1 PRODUCTS

The POBA catheter is illustrated in the following diagram:

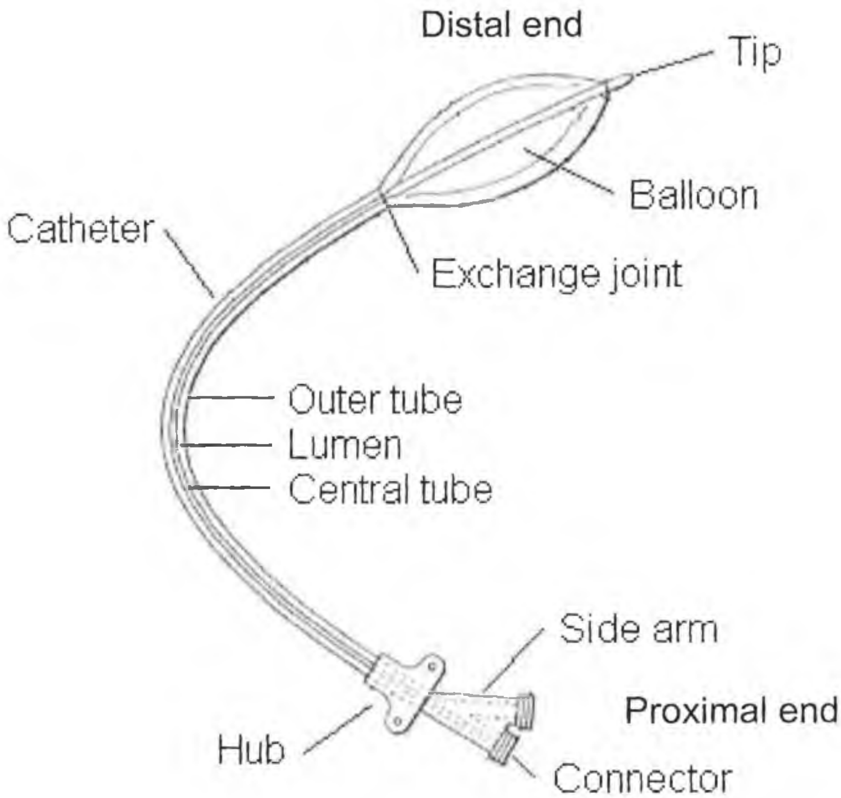


Figure 16: POBA Catheter (adapted from USPTO, 2004)

The POBA product line was designed and developed in Galway. It was launched in mid-2003 as a pilot line, manufacturing for design and process validation. It was commercially launched towards the end of 2003, hitting the majority of markets from January 2004 onwards, later launching in Japan. On the manufacturing side, it initially started as one assembly line. A second line was set up coinciding with the Europe launch, while a third line responded to increased demand from the new Japanese market. In the second half of 2005 a fourth line was available for the manufacture of POBA catheters, depending on demand.

The product is a labour-intensive and difficult product to build, but has been considered profitable. On launch, POBA dimensions had become smaller, particularly diameters, and yields initially were high. The next generation of POBA will be equally difficult to build. It will be a similar product, with different materials and smaller balloon diameters. Generally this type of product has a life cycle of 2-3 years before being replaced, but the POBA line outlasted this time frame. This was in part due to a Lean Six Sigma initiative implemented over the life of the product. This is further described in chapter six.

5.4.2 PROCESSES

The POBA line is a 23-step catheter manufacturing line. The assembly line is only part of the overall process from material to customer. The value chain from raw material to customer can be illustrated with the following flow chart:

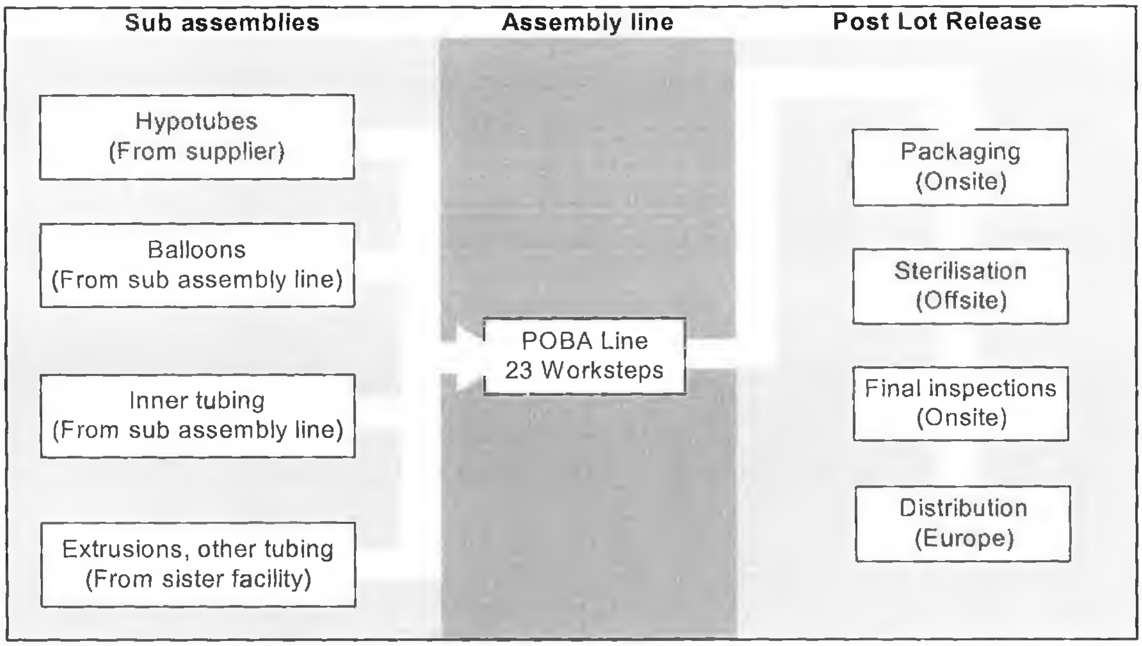


Figure 17: POBA Line

Sub assemblies and raw materials come from a number of sources, within and outside of the organisation. Some sub assemblies in the Galway plant directly feed the line, while other sub assemblies come from nearby outsource companies.

The line consists of manual, semi-automated and automated machinery. A finished POBA catheter involves assembly, laser welding, forming, coating, testing and packaging (Case Company, 2007b).

- Assembly: This is mostly manual, using hand tools including blades, callipers, templates, etc.
- Laser welding process: a semi-automated process, used to bond subcomponents together.
- Forming work step: also semi-automated, shaping the tip of the catheter.
- Coating work step: fully automated. The operator loads the catheters into this machine and a special coat is applied.
- Testing: machines are used to check the quality of the product. Some are destructive tests, but as confidence grows in the stability of the process, this is being employed less. Other machines range from test leaks and balloon strength machines to go-no gauges and micrometers.
- Packaging: a mostly manual process.

A simplified flow diagram of the process of assembly of the POBA catheter is illustrated below:

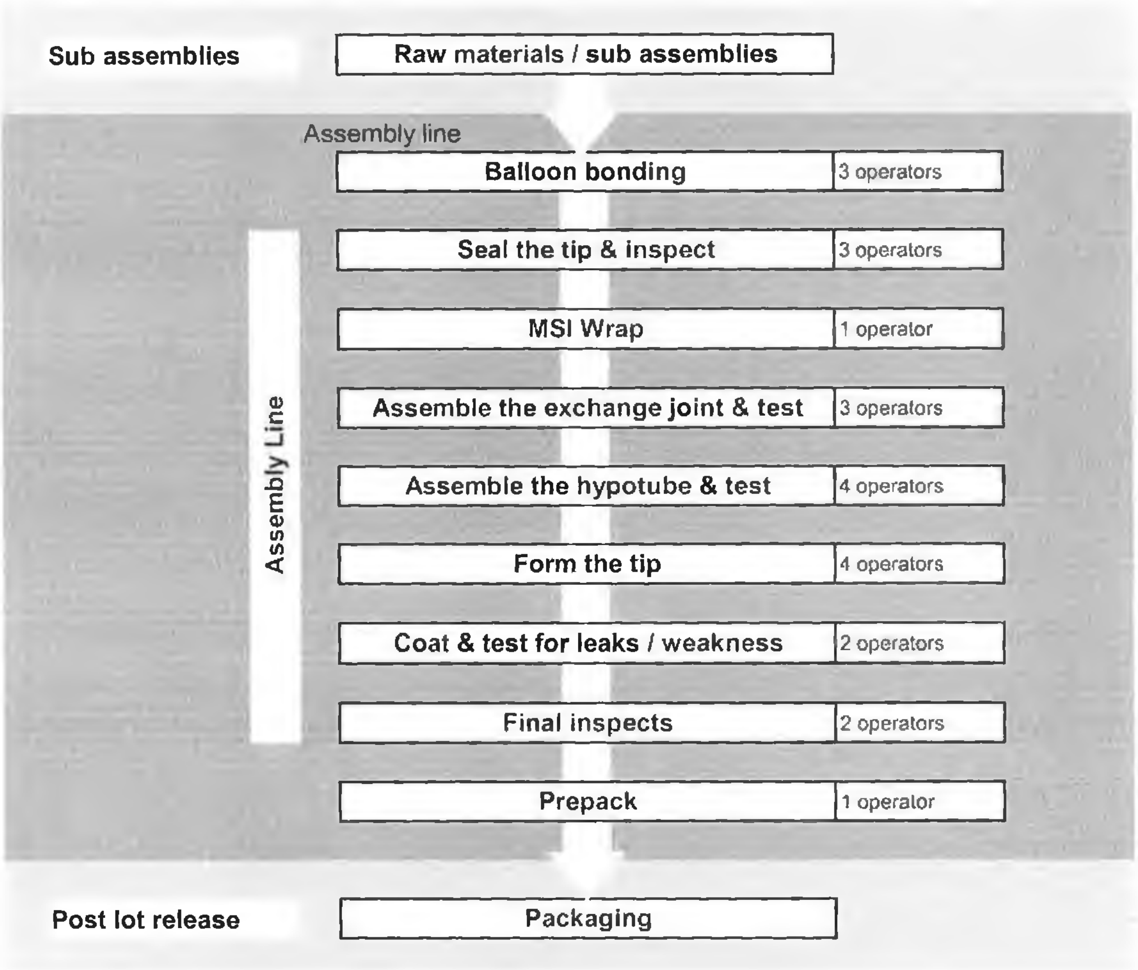


Figure 18: POBA assembly

Initially the POBA line operated in a 10-piece flow system. This meant each work step potentially had a tray with one piece being worked on and nine waiting. On a twenty-three step line, Work In Progress or WIP levels were 230 at a minimum. In other words, at any given time, 230 pieces were resting on the line waiting to be worked on. In situations where operators had trays of work waiting to be processed while they were working on their own tray, this WIP level could be double. To improve on these numbers, five-piece flow was attempted. It reduced WIP levels, yet they were still quite high. High levels of WIP led to increased lead-times. Visibility on the line was affected – it may have taken a number of days for the batch to get through the line. Additionally there were limited housekeeping initiatives carried out on the line with limited success in removing clutter from the workspace and reducing particulate.

Lean Six Sigma was implemented on the POBA line to reduce WIP and in turn lead-times for the product. The resultant process is a Lean one-piece flow system, with flexible response to demand and issues on the line. Chapter six explores this improved process in further detail.

5.4.3 People

There are 23 operators working in groups along the POBA line. A task team works alongside the operators. This team is made up of members from engineering, quality, training, and managers / supervision. They meet frequently with operators to plan day-to-day line running. This task team was heavily involved in introducing and implementing a Lean Six Sigma initiative. As a result of this, members of the task team, with operators, and other representatives from engineering, quality and operations were selected for interview as part of the case study.

This section summarised the line under the headings of product, process and people. The next section describes the case study of the line.

5.5 CASE STUDY ACCESS

The case study examines the assembly line, from initial launch to eventual transfer of operations abroad, focusing on workplace innovation on the line, and results of these efforts.

Based on the case study methodology outlined in chapter three, this section examines the 'Do' part of the research (see 3.2.3). The approach taken to 'Do' this research was as follows:

- Gain access to the company
- Gain access to people
- Gain access to relevant information
- Carry out research
- Validate interviews

5.5.1 GAIN ACCESS TO THE COMPANY

Access to data within the company was granted through a first meeting with senior management and human resources. From this they directed the research team to liase with the Industrial Engineering Department as a point of contact.

This department then provided access to people and information within the company:

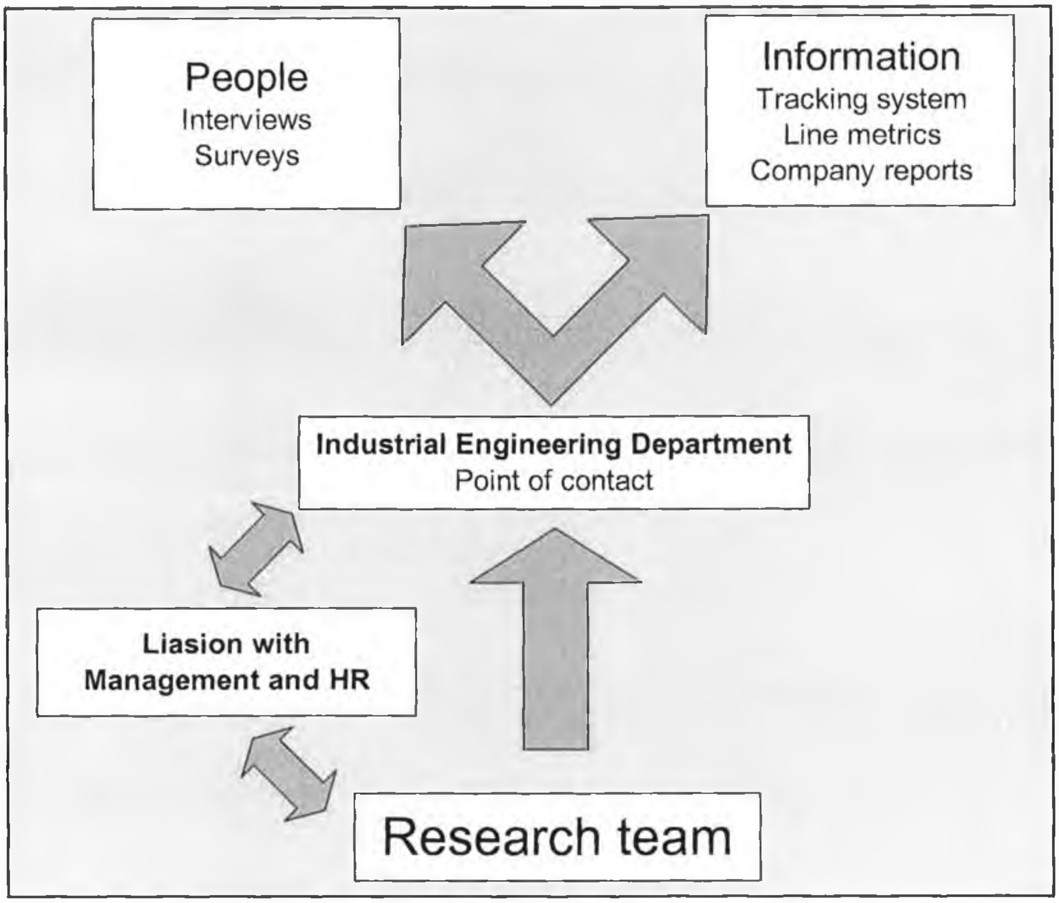


Figure 19: Access to the research

The study itself took approximately twelve months, from initial meetings in March 2006 until results and presentations in March 2007.

5.5.2 Gain access to people

Data was gathered from personnel through interviews. Preliminary interviews and surveys were carried out with the Industrial Engineering department to scope out a suitable area for research. The POBA line was identified early in the meetings. The suitable people to interview were then identified, and emails were sent out to arrange meetings.

Interviews were carried out with personnel working on and supporting the line. The interviewees were assorted into four groups: Operations, Engineering, Quality and Support, as illustrated in the diagram below.

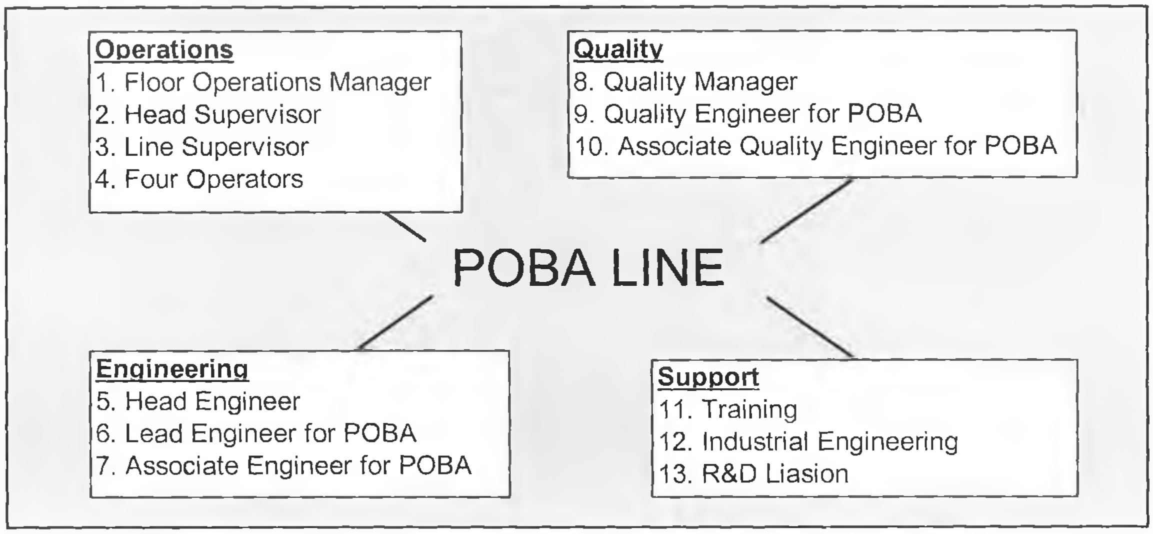


Figure 20: Interviewees

The Operations group consisted of four sets of people. The Operators assemble the product on the POBA line. The Line Supervisor oversees the Operators and is responsible for line targets. The Head Supervisor manages the POBA line and other lines on the shop floor, while the Floor Operations Manager is in the most senior position supporting the POBA line.

The Engineering group troubleshoot day-to-day problems on the POBA line. The Associate Engineer has a technician role, ensuring machinery on the line are running effectively. The Lead Engineer carries out improvement projects on POBA and reports to the Head Engineer.

The Quality group ensure that quality assurance is in place, and has a similar hierarchical structure to the Engineering group.

Support roles were interviewed as part of the case study. The Trainer ensures that the Operators are up to speed with current work instructions, and that the product is being built to current revision. Industrial Engineering carry out workplace innovations and line improvements, for both the POBA line and other areas within the organisation. The R&D Liaison, an engineer developing processes for the next generation POBA was interviewed to determine the level of transfer of workplace innovations onto new product introduction. There were 16 interviewees in total – four operators and twelve others.

5.5.3 Gain access to relevant information

The key sources of information came from a project tracking system, line metrics and company reports. Most of this information was accessed and provided by the Industrial Engineering department within the case company.

A tracking system is used to track the progress of Lean Six Sigma projects. The system is built around the Six Sigma methodology of Define, Measure, Analyse, Implement and Control (DMAIC), described earlier in chapter two. The following information is recorded for each project (Case Company, 2007b):

- Summary of the project. This records the project, start and end dates, and if the project is on schedule. Responsibilities are also assigned to a project leader (or 'Champion').
- Project charter: a statement of the problem, scope and goals are outlined.
- Project location information: the location of the plant implementing the project within the organisation is identified.
- Benefits: hard and soft benefits from completing the project / solving the problem are recorded. Hard benefits is a cash figure. Soft benefits consist of other macro benefits for the organisation.

- Attachments: any additional information, presentations, plans, charts, summaries are attached in the project file.
- Abandon project phase: to be recorded if the project fails or is closed out unexpectedly.
- Project approval phase: signed off for each of the phases within DMAIC. Approval dates are recorded, and comments are attached and signed off by the project leader and supervisors.

Within this system, projects are commenced and closed out, and outputs are measured, from line metrics to financial and market benefits. This system provided access to key information within the company, and a means to measure impacts of workplace innovations.

Line metrics in turn were accessed through the attachments module in the project tracking system (Case Company, 2007f). Other sources of information came from company reports. These were mostly Internet based and could be accessed outside of the company. These sites are not referred to in the thesis or references for confidentiality reasons. The internet-based company reports formed the basis for the earlier part of this chapter, while the description of the POBA line was gathered from the industrial engineering department, the in-company project tracking system and interviews.

5.5.4 Carry out research

The sixteen interviews were carried out based on the research questions developed earlier in this thesis:

Research	Questions	Study
1	What is the nature of innovation in this sector, particularly at the level of the workplace?	
2	A. What kind of workplace innovation happens in a medical technology organisation? B. How is it optimised?	
3	How effective are these workplace innovations? What is the impact on production and innovation measures?	
4	Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?	Case
5	Where is the emphasis? Is it on costs, new ideas, new product introduction etc?	

Figure 21: Case Study research questions

The interviews lasted 30 minutes each on average, and were developed from earlier Pilot Study questions. All interviews were taped and transcribed. The full list of interview questions can be found in the appendices.

The interview was made up of four sections:

1. General information: a means to get the interviewee comfortable with the interview process.

2. Workplace innovation: examining the line before and after the Lean and Six Sigma initiative was brought through.

3. Impacts on the 'bottom line' from the Lean and Six Sigma initiative

4. Innovative work practices

5.5.5 Validate interviews

After the interviews were carried out, they were transcribed and sent back to the interviewee for validation. Minor changes were made with the transcripts. These interviews were then ready for analysis.

5.6 DATA ANALYSIS

The interviews were then analysed using NVivo software. The NVivo analysis carried out was similar to the pilot study approach. Comments were categorised using open coding. These categories were grouped into trees and nodes, each tree representing a research question (Tappe, 2002). The research questions were explored and relative importance of the nodes was examined. Important themes and findings were grouped by research question. Cross checking between interviews and comparison with the literature and the in-company project tracking system were used to ensure validity (Silverman, 2000; Miles and Huberman, 1994). An example of this cross-checking was the analysis of the in-company project tracking system's metrics versus interviewee comments. Further details of this analysis can be found in the appendices.

5.7 VALIDATION

As well as sending back interviews to the sixteen interviewees prior to data analysis, a meeting was arranged with three senior managers to discuss research findings. Each research question was discussed and findings were presented. Feedback was given for each, and these were integrated into the research findings. A detailed description of this validation session is included at the end of the next chapter.

5.8 SUMMARY

This chapter introduced the case study company. The company itself is a major manufacturer of cardiovascular products including stents, angioplasty catheters and other accessories. The focus of the case study is a 23-step POBA line within the organisation, and the people who work on and support the line.

The Industrial Engineering department was a point of contact for access to the POBA line, providing company information and sixteen interviewees for the study. The study was carried out through interviews developed around the key research questions. These questions were explored, and findings were validated through follow-up meetings with three senior managers and other line information.

The results of this research – the interviews, in-company reports and NVivo analysis – are presented in the next chapter, segmented by each of the key research questions. This in turn is validated by senior management and develops research conclusions and recommendations.

CHAPTER 6: CASE STUDY FINDINGS

6.1 INTRODUCTION

This chapter examines the remaining research questions outlined in the previous chapter. The research questions were explored through analysing the case POBA line. Overall the line was successful in terms of sales, as a result of (according to the interviewees) two key events:

1. A competitor experienced problems with its POBA product and had to recall large numbers. This affected overall customer confidence and allowed the case company to gain market share.

2. At the same time of the recall, a Lean and Six Sigma initiative was being piloted on the Case Company's POBA line, allowing it to rapidly respond to changes in market share from the competitor recall.

These points are described in greater detail later in the chapter.

Post POBA launch, it was hard to produce to target under the batch system. Adding additional lines was seen as the solution to this capacity problem. At the same time a proposed new innovative work system – Lean Six Sigma – was being discussed by upper management. Drawing from the literature review, Lean Six Sigma is considered a workplace innovation for the following reasons:

- The POBA line represented the adaptation of this work system for the first time in the organisation.

- Change on the line took place in both in processes and administration.

- There were some innovative aspects in implementing the new work system, and the line had positive outcomes as a result.

This chapter explores workplace innovation in the case company, determining how workplace innovation is carried out. Its effectiveness and importance is examined. Its links to overall company competitiveness is explored. Finally the level of emphasis on bottom line outcomes is determined.

6.2 RESEARCH QUESTION 2A: WHAT KIND OF WORKPLACE INNOVATION HAPPENS IN A MEDICAL TECHNOLOGY ORGANISATION?

This research question is divided into two parts. This half examines the type of workplace innovation utilised by the case company. Lean Six Sigma is the key workplace innovation that has been used over the life of the POBA line.

The POBA line became the focus of the case study, as it was the first manufacturing line to successfully implement a Lean Six Sigma initiative as its key workplace innovation over its lifetime. This system is a combination of Lean Manufacturing and Six Sigma methods. It is sometimes referred to as "Lean Sigma" within the organisation. A unique combination of these methodologies was developed by the case company in order to address waste and variation issues within the organisation: Lean practices are applied using a Six Sigma DMAIC approach to the project.

Prior to the Lean Sigma initiative, workplace innovation was carried out on the product lines in the form of unstructured ad hoc 'quick fixes' – *"if you saw a problem you'd fix it"*. Innovation prior to the initiative was also described as *"bite-sized chunks of improvement"*. However there was not *"the resources or the time (available) to actually go into a change project"*, so *"there was an awful lot of fire-fighting... on a shift by shift basis"*. Innovations focused on *"major hitters, rather than the overall line performance"*. One interviewee described this as *"reactive to issues"* rather than *"proactive improvement"*.

However, workplace innovation changed from being reactive to being proactive, while still maintaining a manufacturing focus. This change was made through implementing Lean Six Sigma. An interviewee from operations described this change as *"better, smarter, faster – but still getting the product through"*. Senior interviewees described this workplace innovation as *"single piece flow"* and *"new layouts and improved flow"* – all elements of the Lean system. Less senior interviewees described innovation as making things *"easier for employee and product"*. Another interviewee described workplace innovation as *"making peoples jobs easier, taking away other responsibilities so that they can focus on the job at hand"*.

The Lean Six Sigma work system itself was made up of a number of elements. The DMAIC (Define, Measure, Analyse, Improve and Control) approach provided a structure to use both Lean and Six Sigma tools and solve problems more effectively. Some of the more innovative approaches taken with this system are mapped on to the list of Lean and Six Sigma tools described in section 2.3.1 in the literature review:

Lean Tools	Innovative approach
Waste minimisation tools	Line disruption taken off line An operator arrives in on the line early every morning to get the line ready for the day's production. This effectively takes the line set-ups off line – that is, the set-up is not part of the normal day-to-day operations on the line. Additionally when machines break down, spare equipment is ready to slot in and replace the equipment if they cannot easily be repaired.
Flow improvement tools	Dynamic Kanbans Kanbans or cards were introduced to the company for the first time. Kanbans control the amount of product that can be built at a work station at any given time. Standard Kanbans follow a one-piece flow approach, but these Kanban levels varied along the line depending on machine and process constraints. They were dynamic, and could be changed by the Industrial Engineering department depending on levels of output required on the line (Case Company, 2007e).
Layout improvements	Socio changes As well as technical changes, work rules changed. Before the Lean Six Sigma system was implemented, operators had freedom to walk away from the line and could build up their work in batches. Now operators now had to stay at their workstations and worked on one piece at a time. This had problems at the start, but solutions including cross training and floaters helped this change.
Six Sigma Tools	**Innovative approach**
Six Sigma DMAIC	Single project goal using a DMAIC approach The new work system was treated as an improvement project. The area defined for improvement was lead times, to reduce it by 50% (Case Company, 2007b). This approach was innovative and focused – and in order to reduce lead times, other issues would first need to be improved. These included the need to reduce inventories, improve set-up and changeover times, etc.

Figure 22: Innovative approaches to Lean and Six Sigma tools

Other innovations are described throughout this chapter.

In short, workplace innovation is carried out in the form of a Lean Six Sigma initiative in the case company. The Pilot Study determined that the sampled companies were implementing Lean Manufacturing in some form; the case company has adapted its Lean programme to incorporate Six Sigma methodologies. Prior to the Lean Six Sigma initiative improvements were unstructured and unplanned. Interestingly post Lean Six Sigma, senior interviewees describe workplace innovation as improving the process, while less senior interviewees describe it as improving the job for the person.

6.3 RESEARCH QUESTION 2B: HOW IS IT OPTIMISED?

The second part of this research question focuses on how workplace innovation or the Lean Six Sigma initiative was carried out. The case study determined that a number of steps must be carried out to ensure a successful workplace innovation is implemented:

1. Assemble a workplace innovation implementation team, led by a project champion
2. Plan the initiative in advance, and support the implementation
3. Change
4. Celebrate wins and apply elsewhere

The remainder of this section expands on these points.

6.3.1 ASSEMBLE A WORKPLACE INNOVATION IMPLEMENTATION TEAM, LED BY A PROJECT CHAMPION

The Lean Six Sigma initiative was driven from the top-down, aligning to company goals and vision at the time. Management focused on new business techniques that other companies were using, in order to improve productivity with less resources while maintaining quality. One interviewee commented that *"it's like everything else, if you* *don't change, you stand still, and you can't stand still in this business!"* Studies were carried out and it became apparent that the new work system would allow for increased output using the same amount of space – targets were set to achieve this.

An implementation team was assembled, and led by a Champion – a leader with experience in Lean and Six Sigma methodologies. This project Champion was described by one interviewee as a 'linchpin', helping to address obstacles, to go between cross functional groups and drive the project. A linchpin is a term used in mechanical engineering to describe a device that prevents a cog slipping off an axle. Using this analogy the Champion could be considered as an element that prevents the Lean initiative 'slipping' off course. Overall these cogs could be considered part of a 'Workplace Innovation Gear Train'.

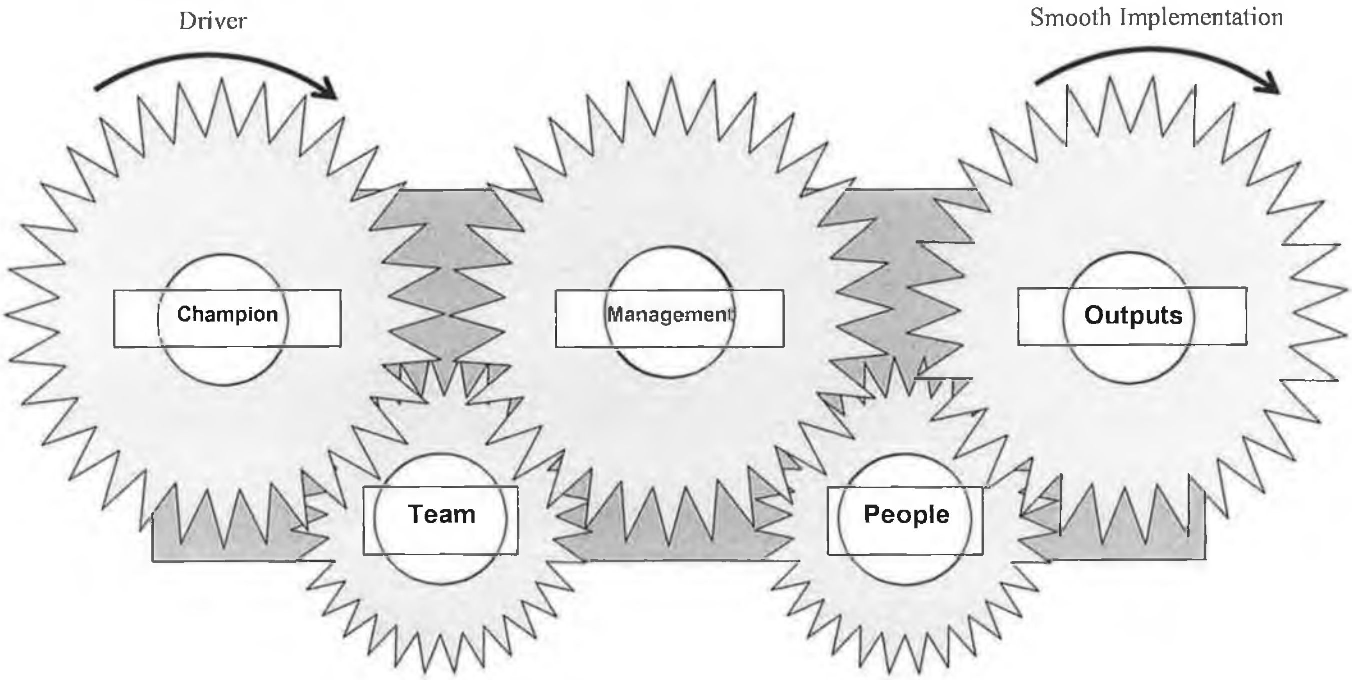


Figure 23: Workplace Innovation Gear Train

The 'gear train' consists of five elements / cogs:

- Champion: the Champion or project leader is critical to ensure targets are met. A senior interviewee commented: *"I firmly believe it's only when you have a* *champion of something, and they get measured on the performance of it, will it ever drive the project"*. A senior engineer described the Champion as a *"person of authority to go across the cross functional groups and to drive it"*. The responsibility of the Champion is to promote and drive the workplace innovation.

- Team: Before implementing the initiative, a core team must be assembled. This team consists of members from operations (management and supervisors), engineering, quality, and support. A senior manager described this cog as having a number of elements: get the best people, and the right mix of personalities, skills and experience. This team communicates and plans the initiative with support of the Champion.

- Management and people: these cogs are important elements of a workplace innovation initiative. The team works with the management to support people in implementing the workplace innovation. The operations manager is a critical linchpin – they must support employee buy-in and day-to-day running of the line. The people also need to be trained up in the initiative prior to its implementation. A senior interviewee described people as *"the cog in the wheel that moves it around. So if they're absent, everybody sits and waits, and stops"*.

- Outputs: A problem statement was developed for this line. It was identified that inventory was too high and output was too low. A target was set to reduce lead-time by over 50% (Case Company, 2007b). All the other cogs drive towards this target.

The 'champion cog' drives this innovation 'gear train'. If linchpins are missing along the train, cogs will fall off and the outputs cog will not move. Following this analogy, without planning, a team, operators support and a Champion to drive the initiative, positive outcomes associated with workplace innovation initiatives will not be met.

6.3.2 Plan the initiative in advance, and support the implementation

Once the team and project Champion were assembled, four weeks training was required in order for staff to understand the system and principles. This preparation was necessary. As one interviewee commented, *"an awful lot of things have to be right for a one-piece flow, for Lean to be introduced"*. A pilot project was successful in a nearby balloon room, but the POBA line was the first manufacturing line that changed with the new workplace innovation.

Process steps were scoped out for improvement (between balloon bond and pre-pack – Case Company, 2007b). A Value Stream Map was developed mapping out the process steps and recording relevant data, and various analyses were made (Case Company, 2007c). Presentations were given to management, support staff and operators. These presentations functioned as updates to all stakeholders (Case Company 2007c). Actual mock-ups of the line were built and demonstrated using toy bricks. Regular meetings updated operators.

The project was rolled out onto the line gradually. A senior manager described this roll-out as having a 'huge' amount of preparation. This phase took about three months, preparing for single-piece flow, changing work practices and modifying specifications. In the words of one operator: *"It wasn't just a case that it came in one day. It was gradual, so we were ready for it. It wasn't such a shock to our system. We had to get used to it... We were months getting ready for it... we were walked through it and there were trainers out, and there were people there, specialists, to help if you got stuck with anything. They put an awful amount of time into it. The engineers were on call, they were on the line, there was someone there all the time"*. Another operator commented that *"you need to tell the employees, and help them understand what they need to do, get them trained up. You need to show it to them in action... The only way to understand it is to do it"*.

A number of interviewees from engineering and management described the planning stage in similar ways: talk to the operator, and get their buy-in. Commit resources and have the documentation and structure in place. The most important thing for the implementation is to *"hit the ground running"*. This was echoed from the Managing Director of the site down to operator level.

To summarise, prior to changing, spend a considerable portion of time and effort planning, getting buy-in, and supporting the implementation.

6.3.3 Change

The actual change from batch to flow happened over a half a day (Case Company, 2007d). Half the line was drained from a previous shift. In Process Kanbans (IPKs) or cards were introduced – these cards had instructions for the operator to build to a certain batch size and not over. This typically had a quantity of one – one piece being worked on and one piece in an adjacent tray. This drastically reduced Work In Progress (WIP) levels. WIP is the inventory stored on the line waiting to be worked on, normally associated with large batches. Within three days with batches reduced to one-piece flow, and lead-time was reduced by over 90% (Case Company, 2007d). Three lines were permanently producing over six shifts, while an additional forth line was available as a support line when numbers were required. These efforts created a zero 'backorder', that is, the customer never had to wait longer than the time quoted for deliveries.

One interviewee involved in the transition described it as *"quite a sea change"*. The change was noticeable to operators also. One operator commented: *"with Lean, you're on top of your work the whole time – there's no big build-up. It's moving constantly"*.

While the change was positive, there was *"a lot of teething problems"*, or problems encountered during the change process. These problems were overcome and have been summarised as 'lessons' learnt:

- Lesson 1: Reduced WIP uncovers problems

With this Lean line, assembly times changed. Reaction times reduced sharply – problems needed to be addressed and solved in minutes rather than hours or days, *"otherwise things grind to a halt"*. This problem was overcome by having 'floaters' on the line – personnel ready to slot in and tackle issues. If machinery were causing problems, spare equipment was also made available to substitute in. Additionally changeover times were reduced on the line – that is, machines were quickly adaptable to changing specifications between batches.

- Lesson 2: Some operators are faster than others

In the old system, some operators would work at different paces during the day. The new system meant a quicker but steady work pace for operators. For operators it meant work on the line was *"constantly go"*. Problems emerged with the one piece system in the form of build-ups where some operators worked faster than others.

This was overcome by identifying the 'weakest link' on the line, and moving them to less critical work steps – as these operators set the pace of the one-piece flow line. Other changes were made to adapt to the change of pace on the line. Setup operators came in early to prepare the line for the day's work. The Kanban system meant paperwork was reduced while control on the line flow was increased. Responsibility to fill out forms went to the line floater and away from the operator. All these measures allowed the operator to concentrate on manufacturing the product.

- Lesson 3: People resist change

There was a lot of attention placed on the POBA line when the Lean Six Sigma initiative was implemented. A senior interviewee commented that if anything *"to start with, for the first few days, there may have been too much physical presence on the line and it might have put people off"*.

Initially the operators had less freedom to leave the line under the Lean system. Leaving the line outside of the standard break times caused build-ups or delays along the line. This problem was later overcome by allowing additional resources and time to cross-train operators and train up floaters. Cross-training meant every operator was trained to be able to respond to line shortages or absenteeism. The approach was to train one-up and one-down, or each operator would be trained in the work steps next to them. This led to problems on the line: if there was an absentee on the line, there would be a scramble to train someone else in. Also there were problems in the versatility – some work steps proved more difficult for less skilled operators. The solution was to group operators into blocks. The operators were cross-trained in these groups or blocks. This approach was better than conventional cross training, as operators gained a better knowledge of the entire line operated, rather than just their own work step. Floaters were used to support the groups of operators – these were free operators that were able to step in if a colleague needed to leave the line.

This transition was summarised by one operator: *"(in the beginning) it was terrible being stuck on the line. You couldn't leave... for toilet breaks and that you had to get cover, so that was a bit embarrassing. Now it's manageable... we're all cross trained now".*

In short, there was a level of resistance to the new system. There was some disillusionment with this new 'fad': *"some of these (operators) had seen World Class Manufacturing and other initiatives come and go"*. A senior manager described *"some resistance at offset, but its amazing how fast people will change. Now they won't go back to their old ways"*.

Interestingly, when an operator was asked what the change meant to them, they responded: *"work! ...we were the guinea pigs when it came in... we are kept on our toes"*. There seems to be an acceptance that change needed to happen, it was difficult to change, but most are happy not to go back to the old batch system: the same operator accepted that *"it does work"*.

6.3.4 Celebrate wins and apply elsewhere

'Wins' with this system were celebrated, but rewards were not monetary. Operators were given a night out to celebrate. Engineering interviewees were rewarded with more interesting work – less time fire-fighting and more time to continuously improve operations. Interviewees noted a faster pace and increased involvement on the line. For management the line has become *"a dream to run"*. Otherwise there were no tangible rewards given for the success.

Strength lies in the reward of doing a job well, and a pride for operators in being organised in what they do. Interviewees continuously highlighted the threat of losing company competitiveness and market share. In the words of a senior manager *"there was no rewards, we had been communicating that we are under serious price pressure, that we either make these changes, or we risk not being competitive in the marketplace. So it's not a point of being more profitable, it's being profitable to a point that we can maintain, keep going."* Operators responded well to this. A manager described the operators as being *"very proud of meeting the target, and if they didn't meet the target, they felt a certain sense of failure"*.

The Lean lines exceeded expected output. On completion, the project set the standard for other catheter lines in the organisation. The system was proven to work, and highlighted further projects to solidify and enhance gains. These projects were in the form of Six Sigma initiatives, and focused on yield issues (Case Company, 2007b).

Overall the initiative was seen as a success – it received a lot of attention within the organisation for its early achievements. The implementation team received an in-company innovation award for their success. On close out of the project, a control plan was put in place. This plan established specifications and capabilities for the process, how to monitor the process, and how to prevent and react to any deviations from the process. Preventative measures ranged from daily reviews to audits. Reactionary responses included further training and support, line stoppages, and disciplinary action in extreme cases (Case Company, 2007e).

The project closed out and responsibility for the Lean Six Sigma line was handed back to the line, with these controls in place. This model of bringing in the workplace innovation was moved across and applied to other product families and organisation-wide. The success was described enthusiastically by one interviewee: *"we're often inclined to think that we're the second cousin, America has it all; but it was great, a great sense of achievement that people had, that Galway was up there, leading the way"*. A Master Black Belt within the organisation summarised the success of the POBA line describing the final capability as *"better than we could have ever dream of"* (Case Company, 2007).

6.4 RESEARCH QUESTION 3: HOW EFFECTIVE ARE THESE WORKPLACE INNOVATIONS? WHAT IS THE IMPACT ON PRODUCTION AND INNOVATION MEASURES?

This section describes the effectiveness of workplace innovation within the case POBA line. Overall the Lean Six Sigma initiative increased efficiencies, made the line more responsive and increased visibility. The line became more responsive and visibility was increased through a reduction in WIP and lead-times.

The initiative also meant a refocus for the company on metrics and line outputs. An engineer noted that *"numbers, numbers, numbers"* have become an important focus for the company. Before Lean Six Sigma, it may have been more difficult to measure outputs from batches as they took a number of days to build. Now, with reduced lead-times, these outputs are measured on a daily basis, and visibility as a result increased. A senior manager highlighted the advantage of this increased visibility – *"now (the operators) see what comes off a line and they're all measured against that"* – previously they would not know exactly how they were performing.

Reflecting the company's focus, this section describes effectiveness in terms of line and company outcomes. The hard and soft benefits from the Lean Six Sigma initiative are summarised below in fig 18: These metrics came from an in-company summary of Lean Six Sigma achievements within the project tracking programme and through the interviews (Case Company, 2007f).

Line Improvements	*From the project tracking programme*
WIP	Reduced by 87-88% Measured by number of pieces on line at any one time
Lead-time	Reduced by 90%
Changeover time	Reduced by 85%
Output (products per operator)	Average output increased by 28-31% Maximum output increased by 43-50%
Downtime	Before: Slow response to breakdowns After: Line must now stop to fix problems
Space	Savings – approximate 50% reduction
Other improvements	*From interviewees*
Backorder	Reduced to zero (or 99.99%)
Yield & Scrap	Yield levels similar to those pre-Lean Scrap reduced

Figure 24: Line improvements from Lean Six Sigma Implementation

People benefits	*From the project tracking programme*
Operators	Before: Individuals working on individual work steps After: Interdependent teams, cross trained in cells and working together
Line	One more operator for increased output
Culture	Before: focus on Status Quo – current day-to-day issues After: Change is now a 'way of life'

Figure 25: People benefits from Lean Six Sigma Implementation

Other benefits	*From the project tracking programme*
Market benefits	In position to respond to competitor recall

Figure 26: Other benefits from Lean Six Sigma Implementation

These metrics are important as they link workplace innovation quantitatively to measured outputs. These improvements are discussed further in the next section in respective sub-sections, drawing on the interviews.

6.4.1 LINE IMPROVEMENTS

The measured line improvements from the in-company project tracking programme are summarised in the following chart:

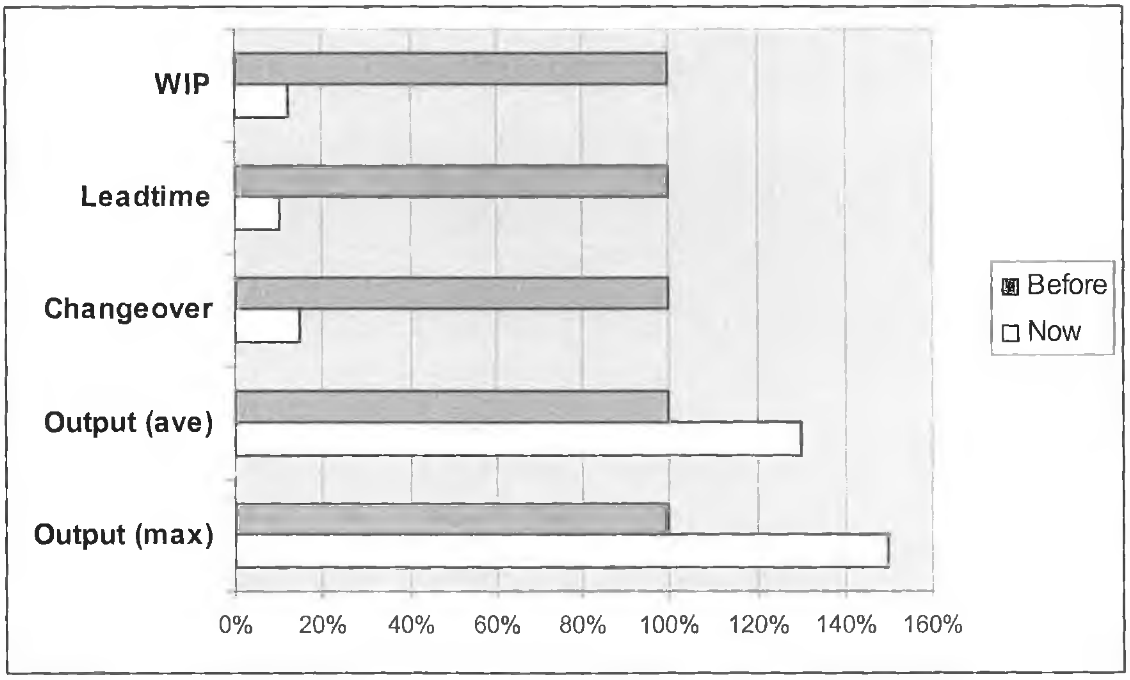


Figure 27: Line improvements

Line improvements are expressed as percentage changes, due to company confidentiality issues. Other metrics described below originated from the interviews.

- Work In Progress

WIP or Work In Progress is the level of inventory stored on the line waiting for work at any given time. WIP levels were reduced drastically with Lean Six Sigma. The reduced WIP was the metric of most benefit for the line. A senior supervisor described this benefit: "*when you introduce Lean, you reduce your WIP levels, and because you reduce your WIP levels, you see more of the problems that were probably hidden before because you had large WIP on the line.*" WIP levels are now controlled by In Process Kanbans.

These IPKs normally keep WIP levels down, but interviewees described difficulties in adhering to these levels, particularly when there is increased pressure on the line. The quality department are normally responsible for checking that these IPK levels are maintained (Case Company, 2007e).

- Lead-time

Lead time was defined in this case as the length of time the product spent on the line from sub assembly to lot release. Calculation took into account the level of WIP and time the product spent at each work step. The goal of the Lean Six Sigma initiative was to reduce lead-time by over 50% (Case Company, 2007b). Actual lead-time reduction was as high as 90%, far exceeding target (Case Company, 2007f). This reduction was calculated by comparing time studies and Value Stream Maps before and after the Lean Six Sigma initiative. This has led to a noticeable reduction on the amount of time the product stays on the line.

- Changeover time

Changeover time, or the time it takes to adapt machinery and operators to new batches decreased sharply. This 85% decrease was taken from the Lean Six Sigma project tracking programme, while this metric was not discussed during the interviews (Case Company, 2007f).

- Output

With lead-time and WIP drastically reducing, output in turn increased. Average output increased by about 30%, while maximum output was increased by up to 50% with additional headcount (Case Company, 2007f). Reflecting this increase in output, productivity (or the ratio of output per operator) increased by over 50% with the new system (Case Company, 2007g). A senior manager described this increase as having a *"dramatic impact with same head count"*.

- Downtime

Downtime is the length of time a machine is broken down before being fixed. Before the Lean Six Sigma initiative, the high WIP levels hid machine breakdowns, as inventory could be built up while the machine was being fixed. With a one-piece flow system operating with In Process Kanbans, the whole line stops until the machine is fixed. A metric on downtimes was difficult to find, but measures were put in place such as preventative maintenance and having spare equipment ready to respond to breakdowns.

- Space

The summary of Lean Six Sigma achievements described space savings (Case Company, 2007f). Senior management later described these savings as half the number of assembly lines needed to produce the same output. Savings were related to the increase in productivity – now the same amount of product could be built with fewer assembly lines. In terms of other space being used, some spare equipment needed to be stored offline – if a machine went down and couldn't be repaired quickly, a standby machine could be substituted in.

- Other improvements: Backorder

An additional benefit from the Lean system was that backorder reduced to zero. Backorder is a build up of demand from the customer, where the organisation is struggling to produce to meet it. Senior supervisors and management mentioned this benefit more frequently in the interviews. A manager quoted this line as being able to supply the customer 99.6% of the time.

- Other improvements: Yield and Scrap

Yield is the percentage of good product coming out of the line. Scrap is the percentage of damaged or bad product that cannot be reworked or fixed. As noted, yield levels disimproved with the implementation of Lean Six Sigma. When the WIP level was reduced, processes that previously hid defects became uncovered. Processes that were causing the yield issues were identified. A senior manager commented that *"these issues were highlighted by the Lean Manufacturing process, but would have been hidden before in the batch manufacturing system"*.

Two key Six Sigma projects were carried to try to improve on yield levels. The first solution improved an assembly aid that was causing defects. This consisted of using a simple stop to prevent the laser process burning the assembly aid. A second improvement project focused on bringing up yield levels on a critical work step. Both had a dramatic impact on overall yield levels. Other solutions included the use of visual aids and standards. Using these aids, the operator would quickly accept or reject product based on visual aids. This measure helped to speed up the quality process. These areas were addressed and improved, and yields went up again. Interviews with technicians and engineers agreed the same – *"We just hampered* [sic] *on and on about yields. Basically we made it as difficult as possible (to detect the problem) in hindsight, because we had huge WIP levels"*.

A second solution to these yield issues was to find the root cause of the problems, by moving the inspections closer to the source of the cause of the defects. This ensured that product with defects would be immediately detected before adding additional value to the product – therefore reducing the cost of rework.

An actual metric was difficult to find in the company records. Engineering interviewees described the yields as being *"comparable to levels before Lean"*, implying that the implementation had neither a positive nor negative impact on close off. While the yields have since remained unchanged, scrap has been reduced. This is in part thanks to the identification of problem steps, and moving the inspections closer to the cause of the defects. Again a metric on this was difficult to find – this result emerged through the interviews.

6.4.2 People benefits

The focus of this research question was on production measures. However from the interviews it was agreed that people benefits included the following:

- Operators & Line

The in-company summary of benefits described operators changing from working individually to working as interdependent teams (Case Company, 2007f). From the interviews, the headcount was increased slightly on the line, but this was necessary for the increase in outputs.

- Culture

Change became 'a way of life' with the close out of the workplace innovation initiative (Case Company, 2007f). A senior manager described this as a *"culture change and a culture shock"* for management. The culture change is in how management deal with people, how they train people, and how people operate. The shock came in the form of how Lean took away flexibility and freedom (see 6.3.3, lesson 3). However it has been seen as a success, a move away from the 'status quo', as described in the in-company report (Case Company, 2007f). An engineering interviewee described this success by commenting that *"people won't change back to batch"* or back to the old ways.

- Issues

This metric in the in-company results refers to access to information. Before, for example issues or problems may have been unclear for operators. Since the initiative was brought through, everybody became clear on issues (Case Company, 2007f). A manager described this increased access to information as leading *"to the requirement for faster decisions on line and better containment of issues"*.

6.4.3 Other benefits

- Market benefits

The external competitive environment for the POBA line is described in section 6.5.2. During the implementation of the Lean Six Sigma initiative a competitor experienced a product recall. The case company responded by filling this gap. Interviewees described benefits of this response through seeing up to a 30% increase in sales. From internal reports, hard benefits in cash were substantial (Case Company, 2007b).

6.4.4 Summary

To summarise, all aspects measured during the implementation of this initiative saw benefits. These ranged from line to people to market benefits. The only area that may have been negatively affected was yields on the line, but these have returned to levels found pre-Lean. Low yields meant costs in rework and scrapping products. Levels returned to pre-Lean levels from continuing successful Six Sigma projects.

6.5 RESEARCH QUESTION 4: IS THERE A LINK BETWEEN SUCCESSFUL APPLICATION OF THE PREDOMINANT BUNDLE OF TECHNIQUES AND THE EXTERNAL COMPETITIVE POSITION OF THE COMPANY OR SUBSIDIARY?

This section is divided up into three parts. The first sub-section examines the key bundles of techniques used by the case company. The second part looks at competitiveness for the firm, while the third sub-section links innovation to competitiveness.

6.5.1 Bundle of Techniques

This sub-section examines the bundle of techniques or practices in use in the case company. These techniques are based on interview findings. Eight out of the thirteen interviewee groups took part in this section. These interviewees were more senior level, consisting of Head Supervisor, Line Supervisor, Senior Engineer, Lead Engineer, Manufacturing Technician, Quality Manager, Quality Engineer, and Trainer. Results were tabulated and are included in the appendix. The main techniques used were grouped into three categories in order of their importance. These were:

1. Technical practices in place as a result of Lean Sigma

    - Lean tools (Womack *et al*, 2004). These tools are used when implementing Lean Manufacturing initiatives. They are grouped into waste minimisation and flow improvement tools:

        - Waste minimisation tools: Value Stream Mapping, Value-added and non-value added analyses, 5S housekeeping, etc.

        - Flow improvement tools: One-piece flow, pull production, Total Productive Maintenance (TPM), error proofing (Poka-yoke), Single Minute Exchange of Dies (SMED), set-up reduction, Just In Time (JIT) principles, etc.

    - Six Sigma tools (Quality Council of Indiana, 2006). These tools are used in various stages of Six Sigma implementation, from defining the project to improving and controlling it. They can consist of the following:

        - DMAIC approach: Define, Measure, Analyse, Improve, Control.

        - Total Quality Management tools: Fishbone diagrams, Brainstorming, Failure mode and Effect Analysis (FMEA), Quality Function Deployment (QFD), etc.

        - Statistical Process Control tools: Control Charts, Statistical distributions, Gage R&R, Process capability indices, etc.

    - New layouts. These can range from basic work step improvements to entire line reengineering. Tools used to achieve this can include the following:

- Flow charts, computer-aided designs, line balancing, continuous improvement, etc.

Of all the practices discussed in the interviews, Lean and Six Sigma tools and methodologies emerged in the organisation as a result of implementing the Lean Six Sigma initiative. New layouts also became a common practice since implementation.

2. Socio practices in place (not as a result of Lean Six Sigma)

    - Performance related pay. Bonuses and pay increases awarded annually based on good individual and company performance.
    - Personal development plans. Continual training and professional development.
    - Coaching / mentoring. Assistance and support offered to new employees.

This category lists the key techniques being used in the company, that did not particularly result from new workplace innovations. These are mostly human resource type techniques, outside of the scope of this thesis. Coaching and mentoring is closely related to line operations, while performance related pay and personal development plans are human resource techniques.

3. Socio practices in place always (before Lean Sigma)

    - Teams. Operators and line support teams working / collaborating together.
    - Regular meetings. Meetings are held daily on the line, weekly by department, and quarterly by company division.
    - Horizontal communication and regular feedback. Communication is less hierarchical and vertical. Communication is open and feedback is given in groups at the meetings, and individually as part of performance appraisals.

These three techniques have been described by the interviewees as the main bundle of techniques or practices that have been in place since before the Lean Six Sigma programme initiated. These relate to groups of people working and communicating together. Without the correct communication channels in place, workplace innovation will be difficult to achieve or sustain.

An interesting note here is that while teams, regular meetings and good communication channels are in place in the organisation, the use of quality circles has reduced since Lean Sigma implementation. Quality circles are problem-solving groups using members from operations, engineering and operators to trouble-shoot and solve specific problems. Quality circles were used widely before the initiative, but formally discontinued after implementation. The Lean initiative uses teams to deal with these problems, but direct operator involvement has reduced as a result.

6.5.2 External Competitive Position of POBA

The medical technology sector is extremely competitive. Based on accounts of the interviewees, cost pressures are paramount. Some Governments are trying to reduce costs in their health sectors. An extreme example of this is the German system, where they demand catheters for a fraction of the price of other countries. An interviewee quoted this cost at about $100, where catheters normally retail between $800 and $1,000 apiece. If a company loses its market share, it is very difficult for it to regain it. As a result, competing companies constantly drive down their prices to compete against one another. This is compounded by the fact that some competitors even bundle catheters for free with their more expensive drug coated stents. All these pressures drive down the cost of the product and put pressure in company to reduce overhead costs. A manager described this situation as a challenge, to *"be able to build a competitive product with the labour costs that are associated with it"*. Another manager described the key to gaining market shares and increasing sales is having *"flexibility without compromising quality"*.

An advantage of this POBA catheter is that it is a more complex catheter suitable for more complex procedures. This gives the company an advantage in having better quality in its costing of the product. Before Lean was implemented, the company had a small share of the overall balloon catheter market. At the time the workplace innovation was being implemented, a competitor experienced problems with their catheter and announced a product recall. The POBA line, with its increased flexibility and output, was in a position to move in and take this market share. Competitor customers lost confidence with the competitor's product and started to purchase the POBA catheter. In a short period of time the catheter gained the competitors market share. These new customers discovered the advantages of the POBA in terms of quality. The case company has since been able to maintain the share, and respond to increased demand, primarily because the new Lean lines allowed this increased flexibility and outputs. A senior supervisor described this success: *"it wouldn't have been possible without Lean Sigma"*.

6.5.3 Linking Workplace Innovation to Competitiveness

In this case, workplace innovation and competitiveness were linked by the competitor recall. Without the workplace innovation in place, the case company would not have been able to respond as quickly to fill in the gap in the market. In the latter half of the POBA's life, it emerged that the product would be outsourced to allow for the launch of the next generation more complex POBA catheter. In effect POBA 2 would be produced in the highly skilled and experienced Galway facility, while the successful POBA 1 catheter would be transferred to a sister facility. The key advantage the sister facility has over the Galway plant is that it is a much cheaper cost base. Through studying the successful application of the Lean Six Sigma initiative on the POBA line, a strategic model for continuing long-term cost competitiveness has been developed by the researcher:

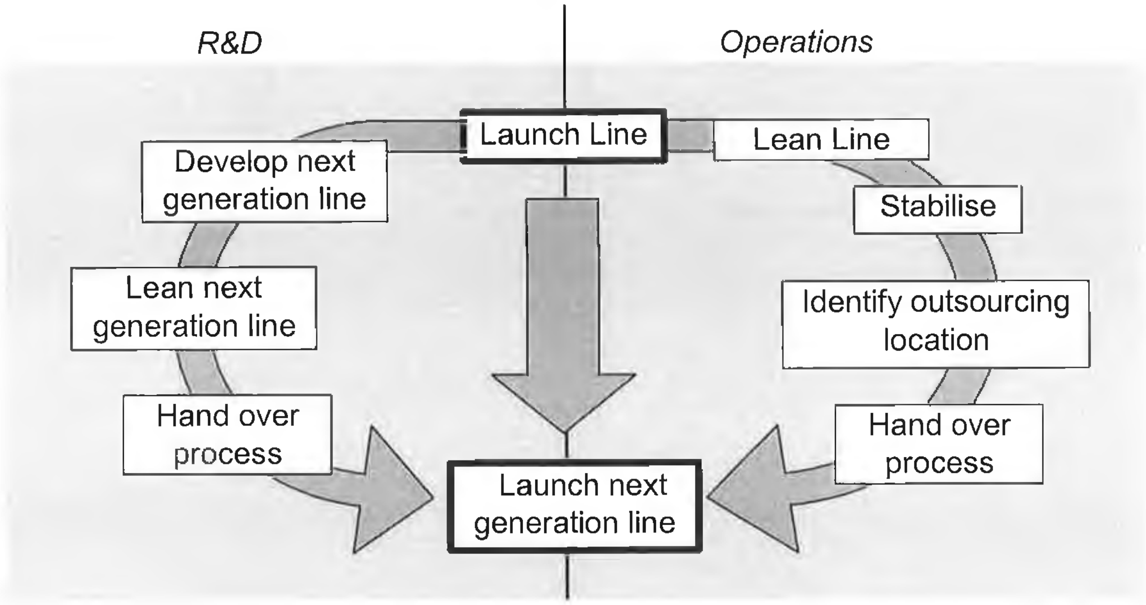


Figure 28: Strategic model for continuing competitiveness

- Operations

This cycle describes the steps which should be taken by operations over the life of the product to continuously remain cost competitive.

- Launch line: the POBA line is launched, processes are stabilised and the line has a steady customer demand.
- Lean line: Lean Six Sigma is implemented on the line, improving efficiency while dramatically reducing waste. Costs at this point are vastly reduced.
- Stabilise process: stabilise variances using Six Sigma projects. Further costs from process instabilities are addressed.
- Identify outsourcing location: at a certain point it becomes difficult to continually improve the line. When line is 'leaned out' next phase is to outsource. Once it becomes viable, the process is prepared for transfer abroad

to cheaper cost bases. This allows new and more complex products to be developed in Galway.

- Hand over process: when ready, responsibilities are assigned to the sister plant. The process is handed over, while the Galway plant acts as support (troubleshooting etc) for the sister plant.

- Research & Development

The R & D department works on developing new products. This cycle should be in motion at the same time as the operations cycle. Both operations and R & D should work together towards the next generation launch milestone.

- Develop next generation line: once the product is launched, the R & D department should be working on the next generation line. This ensures ongoing long-term competitiveness for the organisation.

- Lean next generation line: this strategic model suggests carrying out the workplace innovation prior to launch of the next generation product. An interviewee in the area of R & D described this as an area that the organisation needs to develop. Changes that are constantly being made online should feed back to new product introduction. Next generation product would then tackle these issues pre-launch, rather than in the more expensive production stage.

- Launch next generation line

Now the old product is transferred to the cheaper cost base, the Galway plant can focus on launching the next generation product, in a much leaner form than the last generation. The Cycle is complete.

6.6 RESEARCH QUESTION 5: WHERE IS THE EMPHASIS? IS IT ON COSTS, NEW IDEAS, NEW PRODUCT INTRODUCTION ETC?

6.6.1 YIELDS AND COSTS

Throughout the interview process it became apparent that the emphasis of workplace innovation was more process and people improvements rather than technical solutions. A senior engineer described the Lean Six Sigma initiative as not being driven by new technology. That is, the introduction of Lean Six Sigma did not coincide with the introduction of new innovative machinery. The main emphasis of workplace improvement for the case company has been on yields internally, and costs externally.

The first key emphasis is yield improvement. This metric was discussed in section 6.4. In the words of one engineer, the engineering group *"focus a lot of (their) innovative ideas around yields, trying to improve the yields"*. A Senior Manager described yield levels throughout the implementation of the Lean Six Sigma project as *"disappointing"*. At close out of the Lean Six Sigma project, yields remained low due to high rejects, but scrap drastically reduced. In other words, the same levels of product were being rejected, but less were scrapped.

The second key emphasis is cost reduction. Labour cost reduction has been mentioned frequently as a threat to Irelands competitiveness in manufacturing. Lean Six Sigma has reduced other costs overall. These costs pressures are described in more depth in section 6.5.2.

6.6.2 ANALYSIS

Yield improvement, cost reduction and other metric improvements have had positive outcomes for the company as a whole. Lead-time has also been improved; sales have been increased while costs have been decreased. However, referring back to the literature review, these improvements could be considered as resulting from low road improvements (low road innovations solely aim to cut costs, allowing the business to become more efficient and flexible).

On the other hand, the line does display some high road elements – Lean and Six Sigma are used as a 'bundle', demonstrating synergistic positive effects. Additionally POBA is now a rapid response manufacturing line – it has proven that it can respond quickly to competitor misfortune in the market, while turning around product daily.

From the literature review, 'high road' innovation aims to expand the organisation through innovation. Although it may not yet be 'high road' innovator, certain work practices could be used by the POBA line to provide it with more high road outcomes, e.g. autonomous work teams, flatter management structures and increased employee involvement

The next generation POBA product is due to launch in the coming months. 'High road' improvements are being implemented into the process. Changes on the current POBA process are constantly feeding back to new product introduction. It is the aim of the case company that the next generation product will tackle these issues pre-launch.

Changes are easier to make in the research and design phase rather than post product launch. In the medical technology industry small process changes are easy to make, but large changes require specification changes and process validation. As this validation could take months to bring through, it is difficult to get approval on changes. This is an obstacle that must be overcome to truly move towards 'high road' process improvement.

6.7 RESULTS / VALIDATION WITH SENIOR MANAGEMENT

The results from this chapter were presented to senior management. The Lean Champion, a Six Sigma Black Belt and the Senior Human Resources Manager attended the presentation. Feedback was given on each of the research question findings. The feedback is described in this section under the headings of the research questions.

6.7.1 Research question 2: What kind of workplace innovation is in these companies and how is it optimised?

The research described Lean Six Sigma as the workplace innovation that had greatest impact on the POBA line in the case company. Section 6.3 describes the process of implementing this workplace innovation as assembling the team and Champion, planning and supporting the initiative, changing and celebrating wins, and later, applying elsewhere. Senior management accepted the findings and gave additional feedback on this.

They described their experience of encountering differences between theory and practice of applying a workplace innovation. They found that the key ingredient is people and their willingness to change with the initiative – *"it's a very human thing that there's differences"*. *"Everyone will not be smiling and holding hands"*.

A philosophy that seems to be adopted in the company is *"if you can't change the people, change the people"*. The Lean Six Sigma Champion gave an example of how difficult it is for people to change. He challenges the person to try sleeping on the other side of their bed for a number of nights. At first it is uncomfortable, but the person will get used to it. This applies the same to a new way of doing work. As mentioned earlier in this chapter, people will not go back to the old ways of batch manufacture.

In a recent survey carried out in-company, the Senior HR Manager quoted that about two thirds of the operators were genuine supporters of the initiative, about a fifth were reluctant but did it, and the rest moved on. However he stressed that no employee was let go as a direct result of the initiative.

Overall the initiative seems to have been accepted. There are now waiting lists for people to undergo Lean and Six Sigma training. The Six Sigma Black Belt described this demand as a 'pull', where perhaps two years ago the improvement team were trying to 'push' the Lean Six Sigma training in the organisation. This demand filters from the top down in the organisation. The Senior Operations Manager won't allow a new line in unless it is Lean. Changes can be made to these lines in a three to six month timeline. The Senior HR Manager described the Champions driving these projects as *"guiding lights"*.

6.7.2 Research question 3: How effective are these workplace innovations? What is the impact on production and innovation measures?

This research question explored the effectiveness of the workplace innovation in terms of line, people and market outputs.

Most interestingly, senior management mentioned it becoming more difficult to measure the effectiveness of continuously improving lines. If costs are continuously being reduced, it becomes more difficult to measure the scale of the effectiveness of workplace innovation. In effect this could be symbolised by a set of goalposts continuously being moved.

Concurrently they agreed with the findings – they would have seen and been aware of line improvements. They described the savings from the initiative in terms of space saved. The initiative halved the number of assembly lines needed to produce the same output. On a higher level in the organisation Lean Six Sigma is seen *"in the accounts"* – in other words finance recognise savings from the initiative, by allowing high labour variances during implementation.

According to the senior HR manager, the workplace initiative implementation has made the line more equitable to work on – everyone must do their job and are clear of responsibilities. Operators have more autonomy – whereas in the past they would have had less responsibility to make line changes. In effect the dynamic between management and staff has changed. Management share openly with staff, and staff have become more engaged – the company *"wouldn't be in business otherwise"*.

6.7.3 Research question 4: Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?

This research question explored bundles of practices in use in the organisation. The most important were grouped in to categories. According to the interviewees, layout changes, Lean methodologies and Six Sigma tools were the most important practices used in implementing the Lean Six Sigma initiative. This section also linked competitiveness to workplace innovation and developed a model for continuously developing newer generation products with Lean Six Sigma methodologies.

The success of POBA and the workplace innovation implementation was in part thanks to a competitor recall. However the Champion noted that other lines and products have had external shocks, and Lean Six Sigma has allowed them to respond quickly to gain market share. An example he gave was a dry stent product which had a sharp increase in demand when safety issues arose with drug coated stents and thrombosis.

The Senior Managers agree that costs are a huge issue in the sector. They have found that cheaper cost bases such as Mexico and Puerto Rico are suitable for mature products and products which require less technical ability. The POBA catheter is a good example of product which is suitable for transfer abroad. There are however downsides to transferring products abroad. The Black Belt mentioned how Womack (2005) described the real cost of transfer as being much higher. It is difficult to budget for things going wrong, e.g. expedited shipments. Also it is difficult to control these issues from far away. Regardless, the POBA is being transferred, while Galway leads cost reduction programmes for other products.

6.7.4 Research question 5: Where is the emphasis? Is it on costs, new ideas, new product introduction, etc?

Senior management described costs as being the key emphasis and reason to innovate. There is increasing pressure in the industry to drive down costs. In discussing this section the managers agreed that the organisation was a low road innovator with elements of high road innovation. However there is *"no hope on the high road without the low road"*. In other words, in order to become a high road innovator, the senior managers insist that the organisation must be a low road innovator first: costs must be reduced, wastes eliminated, processes stabilised etc. Only then can they focus on high road activities. The Senior HR manager described this low road to high road transition as *"winter training for summer skills"*.

A natural progression from here for the organisation is to concentrate on reducing labour costs through automation. Additionally they need to implement Lean Six Sigma before product launch, effectively 'Designing for Lean Sigma' (or DFLS). This parallels with the strategic model for continuing competitiveness described in section 6.5.3.

6.7.5 Post validation

The presentation to the Senior HR manager, the Champion and the Six Sigma Black Belt concluded and comments were recorded. This meeting also marked an exit from the Case Company. Prior to submission of the thesis, the Case Company had a final review and changes were made. The thesis findings were then completed, and conclusions from these are made in the next chapter.

6.8 SUMMARY

This chapter addressed the remaining four research questions through studying the case study POBA line. Interviews and analysis of in-company data for each question were carried out for each of the research questions, and results were validated by the Senior HR manager, Lean Six Sigma Champion and a Six Sigma Black Belt.

The next chapter describes conclusions to the thesis, based on findings from the case study in this chapter and the pilot study in chapter four.

CHAPTER 7: CONCLUSIONS

7.1 INTRODUCTION

This chapter outlines conclusions to the findings from both the pilot study and the case study. Conclusions are grouped by research question. The majority of the pilot and case study findings were extracted in previous chapters. This chapter is summarised with future recommendations and directions for research in this area.

7.2 CONCLUSION 1: WHAT IS THE NATURE OF INNOVATION IN THIS SECTOR, PARTICULARLY AT THE LEVEL OF THE WORKPLACE?

The pilot study was carried out to explore the first two research questions. It was also a means to refine the case study methodology and interview questions. There is workplace innovation in some form in all of the companies interviewed in the pilot study. The need to innovate was identified through continually competing and reducing costs. All interviewees identified Lean Manufacturing as the way in which they innovated in their workplaces in order to meet these needs.

This is consistent with a low road approach described by Brödner and Latniak (2003), Di Martino (2001) and Totterdill (2000). However this approach may not be consistent in terms of the need to constantly be able to compete in the long term – it is not just enough to be able to reduce costs. Lean Manufacturing has been used by these companies to achieve this, road mapped by the deployment of the Workplace Innovation Life Cycle.

The case company can also be mapped on to the WILC, towards the extension stages. However, more research needs to be carried out to develop this WILC model. It broadly maps the pilot study companies, but more companies need to be examined to verify its consistency. The improvement axis needs to be better defined and will change depending on the workplace innovation being improved. Perhaps an ideal measure would be level of innovation, but defining this comes with its own difficulties. Overall the validity of the Product Life Cycle has been questioned in the past (Dhalla & Yuspeh, 1976), but may be a useful tool to benchmark and broadly plan the next stages and of the company's workplace innovation development.

7.3 CONCLUSION 2: WHAT KIND OF WORKPLACE INNOVATION HAPPENS IN A MEDICAL TECHNOLOGY ORGANISATION? HOW IS IT OPTIMISED?

The pilot study developed five key enablers to workplace innovation. These included driving the innovation from the top down, support the initiative with champions, support the human element, have an innovation team in place, and innovate daily. The case study further refined these points. A similar four step approach to implementing a workplace innovation initiative was outlined, identifying the Champion as a 'linchpin' or 'guiding light' to its implementation, and documenting lessons learnt during the change process.

A common thread between the pilot study and the case study is that both sets of interviewees emphasised socio / people rather than technical practices: it was not enough to implement the technical tools of Lean or Six Sigma – the socio or people elements must first be in place and ready to change. In a sense, without the right culture in place, change cannot happen.

Whether a four step or five step approach is carried out to change work systems, the outcome is the same. A lot of preparation needs to be done before implementation. Successful systems must focus on people using them. A culture of continuing change must be instilled to ensure continuing competitiveness for the organisation. In a larger sense, the need for manufacturing sectors in Ireland to continuously innovate has been reflected by research from Forfás, outlined in chapter one (Forfás, 2004).

The key conclusion from this is that it is easy to describe how to implement a new workplace innovation, but actual practice does not go as smoothly. Senior management agreed with this finding. The POBA line was not without problems during implementation. People resisted changes, and problems arose when WIP levels were lowered. The key lesson coming from the implementation is that the change does not just happen – it needs to be continuously worked on. Sustaining the change is difficult: the POBA overcame this by installing control systems.

A potential future direction for research is to examine the culture within organisations when changing work practices. It may be interesting to further examine whether culture in an organisation has a major impact on the success or failure of a workplace innovation.

7.4 CONCLUSION 3: HOW EFFECTIVE ARE THESE WORKPLACE INNOVATIONS? WHAT IS THE IMPACT ON PRODUCTION AND INNOVATION MEASURES?

The main focus for everyone in the case company is numbers – being able to measure improvements. Benefits of the Lean Six Sigma system were described in terms of line, people and market. All outputs were positive, but yields unexpectedly did not reduce with the new workplace innovation system.

The POBA improvements are compared with Lean improvements described by Liker (1998) and Berger (2002) in the literature.

	Lean Improvements (Literature)	Lean Improvements (POBA Line)
Productivity	Increased between 10-100%	Increased between 28-50%
Throughput times	Decreased between 40-90%	Decreased by 90%
Inventories	Decreased between 40-90%	Decreased by 87-88%
Scrap	Reduced between 10-50%	Reduced, unknown
Space savings	Between 30-60%	50%
Overtime	Decreased up to 90%	Unknown, zero backorder
Safety-related injuries	Decreased up to 50%	Unknown
Product development time	Decreased up to 30%	Unknown

Figure 29: Comparing POBA savings to the literature

The savings experienced with the POBA line are consistent with the literature. However, overtime, the level of safety related injuries and overall impact on product development time is unknown. Overtime may be decreased completely as the line now has zero backorder, but this is not confirmed. Given the nature of POBA assembly, machine-related injuries are minimal. Repetitive Strain Injuries may be more common, but ergonomics initiatives aim to reduce these. Experiences from the POBA Lean Six Sigma initiative are filtering back to the next generation product, but the extent of this in terms of time savings is unknown. Further research is recommended to explore the impact of new workplace innovations on these measures.

Yield savings are not widely mentioned in the literature, and minimal savings were found in the POBA line. It may be that Lean has a negative effect on yields, while Six Sigma aims to improve this measure. Is a Lean system with low yields better than a batch system with high yields? A separate study focusing on yield levels when implementing a Lean initiative may uncover interesting results.

People or socio benefits were also discovered during the interview process. Benefits included the development of interdependent teams, ready for change, with increased involvement and access to information. These benefits could be considered high performance or 'high road' outcomes, as described in the literature review. In effect, with the implementation of the workplace innovation, the company experienced low road outcomes consistent with the literature, with some high road benefits consistent with High Performance Work Systems.

7.5 CONCLUSION 4: IS THERE A LINK BETWEEN SUCCESSFUL APPLICATION OF THE PREDOMINANT BUNDLE OF TECHNIQUES AND THE EXTERNAL COMPETITIVE POSITION OF THE COMPANY OR SUBSIDIARY?

The main bundle of technical practices that were used while implementing Lean Six Sigma consisted of Lean tools, Six Sigma tools, and new layouts. These techniques had a synergistic performance-raising effect on the organisation, consistent with the description of bundles in the literature (ILO, 2000; MacDuffie, 1995). They were brought together through the Lean Six Sigma initiative, an optimisation which produced high performance and competitiveness for the firm (Nadler *et al*, 1992). Socio practices were listed by the interviewees, consistent with the socio elements explored by earlier research questions.

A model was developed to strategically continue competitiveness through workplace innovation. The POBA line benefited from a competitor problem, but management has seen similar opportunities when implementing Lean Six Sigma elsewhere in the organisation.

Further research must be carried out to link Research and Development to Operations through workplace innovation. Greater collaboration would happen between R & D and Operations. Only then can large savings be seen – product development would become quicker and more reactive to customer demand. Problems with production would be 'leaned out' before product launch. R & D could offer novel solutions to day-to-day operating issues. Overall this increased collaboration would have greatest effect on company competitiveness.

7.6 CONCLUSION 5: WHERE IS THE EMPHASIS? IS IT COSTS, NEW IDEAS, NEW PRODUCT INTRODUCTION ETC?

Finally the focus for the company seems to be on costs and yield reduction. This focus aligns to a 'low road' focus as described in chapter two. Senior management agree, but insist low road elements must be in place and stable before moving to the high road.

A recommended approach for the medical technology sector may be as follows:

- Implement workplace innovation
- Stabilise low road benefits
- Aim for the high road

The medical technology sector is following what the literature broadly refers to as the 'low road of innovation', that is through cutting costs and increasing sales, at least in the shop floor context (Totterdill, 2000).

If the primary focus at the moment is the 'low road', where does the sector go from here? Are these cost-reducing and sales-increasing efforts actually innovative? Perhaps the sector is arriving at a 'middle road'; it shows elements of High Performance 'bundles', particularly the people element, and continuous improvement programmes such as Lean Six Sigma. A final conclusion would be the need to establish a benchmark for the sector, as a means to head towards the 'high road' of innovation.

7.7 LIMITATIONS OF RESEARCH

Three points could be considered as limitations to the research findings.

Firstly, the pilot study consists of a small number of medical technology companies in the West of Ireland. While it is not a representative sample for the west, selection was based on ease of access to the companies, and other reasons outlined in the pilot study chapter.

A second point follows from this. There were limitations on the scope of the research within the pilot studies due to the short two-year time frame of the Masters. Emphasis was placed on the case study research.

Finally, since validation came from senior management within the case study, some of the comments may have been biased and positive towards the findings. Regardless, each finding was discussed, validated and amended where necessary.

7.8 SUMMARY: FUTURE DIRECTIONS OF RESEARCH

This chapter describes conclusions from each of the research questions. Future directions of research are described in each. Two papers based on research carried out over the course of this thesis are included in the appendices. A third research paper is due to be submitted to the Irish Academy of Management conference in Belfast in September 2007, summarising research findings. A second researcher has also commenced work in

Galway-Mayo Institute of Technology based on the impact of innovative Human Resources practices on competitiveness to compliment this work.

Recommendations for future directions of research as follows:

1. Development of the Workplace Innovation Life Cycle (WILC) model
2. Research on the culture within changing and innovative organisations
3. Impact of workplace innovation on workplace related injuries and new product development
4. Yields and Lean - are they negatively correlated?
5. Research on enhancing Operations and R & D collaboration through workplace innovation
6. Further research into benchmarking middle road innovation the medical technology sector

Workplace innovation is a means to sustain competitive advantage in the medical technology sector in the west of Ireland. Brödner and Latniak (2003) analogised that *"competitiveness is not so much a question of how the winds are blowing, but rather how one is setting ones' sails"*. But as Forfás (2004) warned, Ireland's manufacturing industries must innovate to remain competitive. For this to happen the medical technology sector must set sail towards the 'high road' (or perhaps high seas) of innovation. The west of Ireland is seen as a 'centre of excellence' for medical technology, and there is scope for further research in this area. The bundles are there, the drive is present, and the future for the sector looks positive.

APPENDIX A: INTERVIEW QUESTIONS – PILOT STUDY

1 General information

1.1 How has the company been doing since setting up? (Got bigger or smaller? Expansions, more people etc)

1.2 Has the decision to set up in Ireland been a good decision for the firm?

1.3 In the last three years has the labour force been increased, decreased or remained constant and why?

2 How is this site a competitor in the market?

2.1 Who is the main competition for this firm's product? *How has this changed in recent years?*

2.2 What share of the market does the firm have and how does this compare to competitors' share? *Is it bigger / smaller? How has this changed?*

2.3 How does the firm differentiate its products from those of competitors? *How are you doing things differently?*

2.4 How does the subsidiary maintain its competitive edge in relation to other manufacturing sites within the parent multinational? *Or how does this site create competitive advantage company / firmwide?*

2.5 What competitive pressure if any is the site experiencing? *Or what threats is the site experiencing with regards to competitiveness in the west of Ireland?*

3 **Workplace Innovation**

3.1 Innovation in the workplace, to us, means new business practices, ways of running the organisation, or the creation of new organisations. What term do you use to describe this? *What term does this company use?* (*is it Lean, Lean services, Business improvements etc?*)

3.2 What are the main workplace innovations / ways of manufacturing smarter being brought through at the moment? *What did you do before? Why change?*

3.3 At what stage is this initiative at? *Pilot, rolling out? Is it in Galway, or firmwide?*

3.4 How has the implementation of innovations gone?

Poor		Ok		Well
1	3	5	7	9

How has it gone well? In terms of...

3.5 What are there drivers to the implementation of these innovations? *These are examples: Champions, Bottom up drive, Top down drive, Communication, Competitive threats, Reward systems, Motivation, Autonomy Who is driving the process, why drive the process?*

3.6 Are there any challenges in bringing through these innovative work systems? List. *With regards to Sociotechnical?*

4 Impact of innovations on the bottom line

4.1 How do you measure new work innovations success? List metrics…

4.2 Have workplace innovations (such as Lean) affected cost reduction?

4.3 Have workplace innovations (such as Lean) affected sales increases?

Or the end product / market strategy? Internal only with possible external effects?

4.4 Have the innovative work practices had an effect on the following?

1 is Very bad effect, 9 is very beneficial effect

Costs	1	3	5	7	9
Productivity	1	3	5	7	9
Lead-times	1	3	5	7	9
Labour costs	1	3	5	7	9
WIP / Inventory	1	3	5	7	9
On-time deliveries	1	3	5	7	9
Inventory turns	1	3	5	7	9
Quality	1	3	5	7	9
People utilisation	1	3	5	7	9
Machine utilisation	1	3	5	7	9
Efficiency	1	3	5	7	9
Space	1	3	5	7	9
Other1	1	3	5	7	9
Other2	1	3	5	7	9
Other3	1	3	5	7	9

Sales	1	3	5	7	9
New product intro	1	3	5	7	9
Time to market	1	3	5	7	9
Delivery lead-time	1	3	5	7	9
Customer satisfaction	1	3	5	7	9

Any other measures?

O1	1	3	5	7	9
O2	1	3	5	7	9
O3	1	3	5	7	9

4.5 Which of these measures are the most important?

4.6 On a scale of 1 – 9, where 1 is you disagree and 9 is you agree, does this innovative work system uses / affects the following practices? Or does it make use of alternative similar practices? *E.g. 6-Sigma rather than TQM?*

	Disagree				Agree	Alternatives?
Quality circles	1	3	5	7	9	________
Total Quality Management	1	3	5	7	9	________
Teams	1	3	5	7	9	________
Self managed work groups Or Autonomous work teams	1	3	5	7	9	________
Open systems planning	1	3	5	7	9	________
New plant designs	1	3	5	7	9	________
Flat management structures	1	3	5	7	9	________
Job rotation and multitasking	1	3	5	7	9	________
(Horizontal replacing vertical) communication channels	1	3	5	7	9	________
Greater employee participation at all levels within the organisation	1	3	5	7	9	________
Regular meetings / updates	1	3	5	7	9	________
Regular feedback on performance	1	3	5	7	9	________
Performance related pay	1	3	5	7	9	________

360-degree appraisal	1	3	5	7	9	____________
Personal development plans	1	3	5	7	9	____________
Coaching / mentoring / training	1	3	5	7	9	____________

Any other practices?

O1	1	3	5	7	9	____________
O2	1	3	5	7	9	____________
O3	1	3	5	7	9	____________

4.7 Again which of these are the most important?

That's it, thanks for all your help in this. If possible will I be able to call / ask some follow-up questions later this week or early next week?

All the results will be anonymous and I can send back a transcript of the interview if you want.

APPENDIX B: INTERVIEW QUESTIONS – CASE STUDY

Note: Some questions were omitted during interviews, dependant on interviewee

1 General information – Introduction to Interview

1.1 How has the line been doing since setting up?

1.2 What competitive pressure if any is the line experiencing?

1.3 What is stopping this line from moving to a cheaper cost base abroad?

2 Workplace Innovation on the line

2.1 What does workplace innovation mean to you?

2.2 Prior to the Lean Six Sigma initiative, how was the line improved?

2.3 Since the Lean Six Sigma initiative how has the implementation of innovations gone?

2.4 Overall what were the drivers to the implementation of these innovations?

2.5 Were there any challenges (or problems) in bringing through these innovative work systems?

3 Impact of innovations on the bottom line

3.1 Costs (*with examples*) Have workplace innovations (such as Lean Six Sigma) affected:

3.1.1 Costs: overall production, product cost, labour cost, budget or others?

3.1.2 Productivity / Efficiencies: people or machine utilisation?

3.1.3 Time: lead-times, throughput / cycle times, ontime deliveries?

3.1.4 Inventory: WIP, inventory levels, inventory turns?

3.1.5 Quality: scrap, yields, equipment downtimes, returns?

3.1.6 Space / layout

3.2 Sales (*with examples*) Have workplace innovations (such as Lean Six Sigma) affected:

3.2.1 Or the end product / market strategy?

3.2.2 New product introduction?

3.2.3 Time to market?

3.2.4 Delivery lead-times?

3.2.5 Customer satisfaction?

3.3 Soft benefits (*with examples*) Have workplace innovations (such as Lean Six Sigma) affected:

3.3.1 Absenteeism?

3.3.2 Access to information?

3.3.3 Morale / team spirit?

3.3 Which of the above measures (in 3.1 – 3.3) are the most important?

4 Workplace changes and improvement techniques

4.1 How has your job changed with the implementation of Lean Six Sigma on this line?

4.2 What changes or improvements were made to this line over the years?

4.3 What improvement to the line, in your opinion was most beneficial to it?

4.4 Were any of the following practices used in improving the line?

Or were these already in place before the Lean Six Sigma initiative?

Teams?

Self managed work groups / Autonomous work teams:

Layout / new plant designs

Flat management structures

Quality (TQM) tools

Six Sigma tools

Automation / New technology

Lean tools

Open systems planning

Quality circles (similar to tech teams but with operator involvement)

4.5 Again which of these innovations are the most important?

4.6 Were any of these practices used in improving the line?

Or were these already in place before the Lean Six Sigma initiative?

(Horizontal replacing vertical) communication channels

Job rotation and multitasking

Greater employee participation at all levels within the organisation

Regular feedback on performance

Personal development plans

Coaching / mentoring / training

Performance related pay / reward

Regular meetings / updates

360-degree appraisal

4.7 Again which of these innovations are the most important?

4.8 What are the most important things that must be in place prior to bringing in an innovative work system (such as Lean Six Sigma) to ensure its success?

That's it, thanks for all your help in this. If possible will I be able to call / ask some follow-up questions later this week or early next week? All the results will be anonymous and I will send back a transcript of the interview thereafter.

APPENDIX C: LINKING PILOT AND CASE STUDY TO RESEARCH QUESTIONS

1. How much innovation is happening in this sector, particularly at the level of the workplace?

Pilot Study questions

How has the company been doing since setting up? (Got bigger or smaller? Expansions, more people etc)

Has the decision to set up in Ireland been a good decision for the firm?

In the last three years has the labour force been increased, decreased or remained constant and why?

How does the firm differentiate its products from those of competitors?

How does the subsidiary maintain its competitive edge in relation to other manufacturing sites within the parent multinational?

What competitive pressure if any is the site experiencing?

Innovation in the workplace, to us, means new business practices, ways of running the organisation, or the creation of new organisations. What term do you use to describe this?

What are the main workplace innovations / ways of manufacturing smarter being brought through at the moment?

How do you measure new work innovations success? List metrics…

Have workplace innovations (such as Lean) affected cost reduction?

Have workplace innovations (such as Lean) affected sales increases?

Which production measures are the most important?

2. What kind of workplace innovation is in these companies and how is it done?

Pilot Study questions

At what stage is this initiative at?

How has the implementation of innovations gone?

What are there drivers to the implementation of these innovations?

Are there any challenges in bringing through these innovative work systems? List.

Which work practices are the most important?

Case Study questions

How has the line been doing since setting up?

What does workplace innovation mean to you?

Prior to the Lean Six Sigma initiative, how was the line improved?

Since the Lean Six Sigma initiative how has the implementation of innovations gone?

Overall what were the drivers to the implementation of these innovations?

Were there any challenges (or problems) in bringing through these innovative work systems?

Have workplace innovations (such as Lean Six Sigma) affected:

Absenteeism? Access to information? Morale / team spirit?

How has your job changed with the implementation of Lean Six Sigma on this line?

What are the most important things that must be in place prior to bringing in an innovative work system (such as Lean Six Sigma) to ensure its success?

3. How effective are these workplace innovations? What is the impact on production and innovation measures?

Case Study questions

Have workplace innovations (such as Lean Six Sigma) affected:

Costs: overall production, product cost, labour cost, budget or others?

Productivity / Efficiencies: people or machine utilisation?

Time: lead-times, throughput / cycle times, ontime deliveries?

Inventory: WIP, inventory levels, inventory turns?

Quality: scrap, yields, equipment downtimes, returns?

Space / layout

Have workplace innovations (such as Lean Six Sigma) affected:

The end product / market strategy?

New product introduction?

Time to market?

Delivery lead-times?

Customer satisfaction?

Have workplace innovations (such as Lean Six Sigma) affected:

Absenteeism?

Access to information?

Morale / team spirit?

4. Is there a link between successful application of the predominant bundle of techniques and the external competitive position of the company or subsidiary?

Case Study questions

What competitive pressure if any is the line experiencing?

What is stopping this line from moving to a cheaper cost base abroad?

Have workplace innovations (such as Lean Six Sigma) affected:

New product introduction?

Time to market?

Delivery lead-times?

Customer satisfaction?

Were any of the following practices used in improving the line?

Or were these already in place before the Lean Six Sigma initiative?

Teams?

Self managed work groups / Autonomous work teams:

Layout / new plant designs

Flat management structures

Quality (TQM) tools

Six Sigma tools

Automation / New technology

Lean tools

Open systems planning

Quality circles (similar to tech teams but with operator involvement)

Again which of these innovations are the most important?

Were any of these practices used in improving the line?

Or were these already in place before the Lean Six Sigma initiative?

(Horizontal replacing vertical) communication channels

Job rotation and multitasking

Greater employee participation at all levels within the organisation

Regular feedback on performance

Personal development plans

Coaching / mentoring / training

Performance related pay / reward

Regular meetings / updates

360-degree appraisal

Again which of these innovations are the most important?

5. Where is the emphasis? Is it on costs, new ideas, new product introduction, etc?

Case Study questions

Have workplace innovations (such as Lean Six Sigma) affected:

New product introduction?

How has your job changed with the implementation of Lean Six Sigma on this line?

What changes or improvements were made to this line over the years?

What improvement to the line, in your opinion was most beneficial to it?

(Research question 5 also based on findings from Q1 – 4)

APPENDIX D: INTERVIEW RESULTS – BUNDLE OF TECHNIQUES

Technique	Not used	In place now (but a separate initiative)	In place always - before Lean Six Sigma	In place now (as a result of Lean Six Sigma)	Most important technique	Skip
Teams			8		2	
Self managed / autonomous teams	3	1	2	2		
New layouts		1	2	5		
Flat management structures	5	1	2			
Quality (TQM) tools	1		6	1	1	
Six Sigma tools				8	2	
Automation	1	3	4			
Lean tools			1	7		1
SAP systems	2	3			1	3
Quality circles	3*		4	1		
Horizontal communication channels	1		7		2	
Job rotation and multitasking	2		5		1	1
Greater employee participation		2	4	1	1	1
Regular feedback on performance		2	6		2	
Personal development plans	2	4	2			
Coaching / mentoring	1	3	3			1
Performance related pay / rewards	2	5	1			
Regular meetings / updates			7			1
360-degree appraisal	6	1				1

Figure 30: List techniques (from interviewees). See section 6.5.1.

Participants:	Head supervisor, Line supervisor, senior engineer, lead Engineer, Manufacturing technician, Q manager, Q engineer, Trainer
Non Participants:	Ops manager, operators, Q Technician, Industrial engineer, R&D Liaison

APPENDIX E: NVIVO ANALYSIS FOR CASE STUDY

NVivo was used to group recurring ideas and themes in the interviews into ‘Nodes’, similar to the approach taken with the pilot study. These Nodes were then grouped into ‘Trees’, each tree representing one of the four research questions. This grouping made it easier to arrange themes and research outcomes when developing chapter six. The grouping is summarised in the diagram below:

- Research Qns
  - Q2 What kind and How is WI done
    - **Before lean**
    - **Barriers**
    - **Examples of innovative projects**
    - **Practices in place**
    - **Workplace innovation definition**
  - Q3 Effectiveness of WI ~ Measures
    - **Measures**
    - **People issues - absenteeism**
    - **People issues - access to informatio**
    - **People issues - Buy-in**
  - Q4 Link WI to Competitiveness
    - **Competition**
    - **Move to cheaper cost base**
    - **Responding to demand**
  - Q5 Emphasis of WI
    - **Lean HPWS ideally**
    - **Drivers**

Figure 31: NVivo Case Study tree

Research question two was made up of five nodes. The 'Workplace Innovation definition' node was used to describe section 6.2. 'Before lean' included any mention of workplace innovation before the Lean Six Sigma initiative was implemented. 'Practices in place' was used to describe any mention of practices currently being used by the company (this node was also used in describing 6.5.1). These nodes formed the steps to implement workplace innovation as described in section 6.3. The 'Barriers' node encompassed any problems experienced during the implementation of Lean Six Sigma. This formed the basis for the 'Lessons Learnt' in section 6.3.3. 'Examples of innovative projects' were also used in this section to describe how these problems were overcome.

Research question three was made up of four nodes. The 'measures' node encoded any mention of metrics, improvements or measures used in the interviews. This formed the basis for the line and market improvements in section 6.4. The remaining nodes described people issues including 'absenteeism', 'access to information' and 'buy-in', forming the people benefits subsection in 6.4.2.

Research question four encompassed three nodes. The 'competition' node included any mention of competitors or competitiveness of the company. The 'responding to demand' node included the competitor recall and how the case company responded to the gap in the market, both nodes forming subsection 6.5.2. The 'move to cheaper cost base' node developed from interviewees continually mentioning that the line would eventually be moved to a cheaper cost base. This formed the basis for the development of the strategic model for continuing competitiveness in subsection 6.5.3.

Finally research question five was developed from two nodes and research question three. Yields and costs were the main 'drivers', and a reduction of these would result from a 'Lean HPWS ideally' or the ideal workplace innovation.

A further diagram is included below to demonstrate the model developed from the research questions tree and nodes.

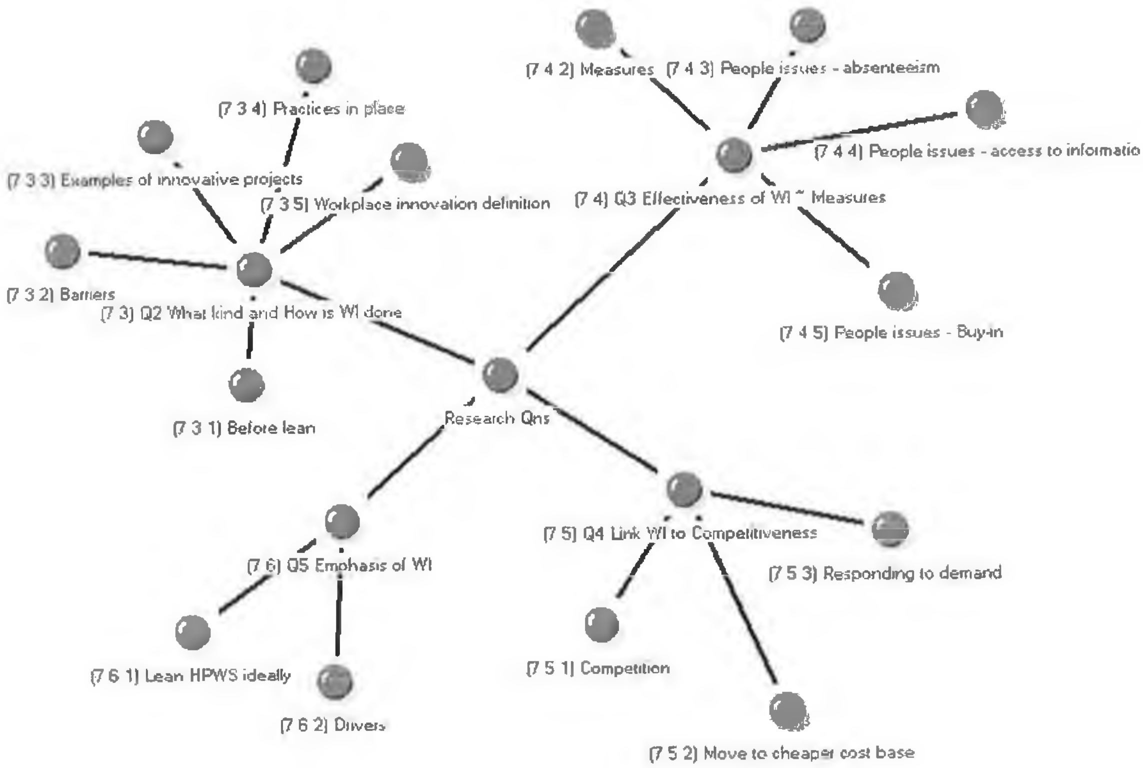


Figure 32: NVivo Case Study model

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