



Provided by the author(s) and NUI Galway in accordance with publisher policies. Please cite the published version when available.

Title	Evaluating the development of metrics within the new product development process to reduce time to market
Author(s)	Mitchell, Paul
Publication Date	2008
Item record	http://hdl.handle.net/10379/356

Downloaded 2018-06-21T20:17:56Z

Some rights reserved. For more information, please see the item record link above.



Evaluating The Development Of Metrics Within The New Product Development Process To
Reduce Time To Market.

By

Paul Mitchell

A Thesis submitted for the Degree of Masters of Technology Management
(Masters of Science.)

University Of Limerick.

Facility of Science & Engineering,
Dept of Mathematics & Statistics

University Supervisor
Dr. Ann Ledwith.
Course Director B.Eng in Manufacturing Engineering

Submitted: September 2008.

Final Project/Thesis Submission

MSc Technology Management, **University of Limerick**

Student Name: Paul Mitchell

Telephone: 087-2843993

E-mail: paul_mitchell@USCI-Ireland.com

Date of Submission: 1st September 2008.

Title of Submission: Evaluating the development of metrics within new product development process to reduce time to market.

Supervisor Name: Dr. Ann Ledwith

Certification of Authorship:

I hereby certify that I am the author of this document and that any assistance I received in its preparation is fully acknowledged and disclosed in the document. I have also cited all sources from which I obtained data, ideas or words that are copied directly or paraphrased in the document. Sources are properly credited according to accepted standards for professional publications. I also certify that this paper was prepared by me for the purpose of partial fulfilment of requirements for the Degree Programme.

Signed: Paul Mitchell

Date: 31st August 2008.

Acknowledgements.

I would like to thank my thesis supervisor Dr. Ann Ledwith for her encouragement, guidance and knowledge on the subject. Thank you for your helpful discussions and patience throughout the thesis.

Thank you to everybody at USCI Ireland who helped me to the finish line. Thank you to Mike in Cappella & Denise in Proxy Biomedical for allowing me access to their new product development process.

To Mum, Dad and Caroline for the encouragement from the start in Athlone to today.

To Sinead. Thank you for the support encouragement and motivation.

Dedication.

To Mum & Dad, thank you for the investment in my education.

Table of Contents.

Acknowledgements. -----	3
Dedication. -----	4
Table of Contents.-----	5
List of Tables. -----	6
List of Figures. -----	6
List of Appendices. -----	6
Abstract. -----	7
Chapter 1. Introduction. -----	8
1.1 Aims and objective of the research -----	8
1.2 Research Background. -----	9
1.2.1 The “Celtic Tiger” years. -----	9
1.2.2 The changing manufacturing landscape in Ireland. -----	9
1.2.3 The need to develop knowledge based economy. -----	10
1.3 The Need for Research -----	11
1.4 Scope of Study -----	13
1.5 Research Methodology -----	14
1.6 Chapter Overview. -----	15
Chapter 2: Literature Review. -----	15
Chapter 3: Company Background/ Industry Analysis -----	16
Chapter 4: Research Mythology -----	16
Chapter 5: Results-----	16
Chapter 6: Discussion -----	17
Chapter 7: Conclusion and Further Research -----	17
Chapter 2 Literature Review. -----	18
2.1 Introduction. -----	18
2.2 Innovation. -----	18
2.3 Voice of the customer. -----	21
2.4 New Product Development Process. -----	24
2.5 Time to Market. -----	31
2.6 Design for Six Sigma. -----	35
2.7 Stage Gates. -----	40
2.8 Performance metrics - Balanced Scorecard. -----	43
2.9 Conclusions -----	49
Chapter 3 Industry/ Company Analysis. -----	51
3.1 Industry Analysis. -----	51
3.1.1 Brief history of minimally invasive surgery. -----	51
3.1.2 The Current global market and future trends. -----	53
3.2 Company Background. -----	55
3.3 Product Portfolio. -----	56
3.4 Innovation Needs- Opportunities. -----	57
3.5 The need for innovation and NPD within USCI. -----	58
Chapter 4 Research methodology. -----	60
4.1 Introduction -----	60
4.2 Research Question. -----	60
4.3 Research method used. -----	62
Chapter 5 Results. -----	64

5.1	Is there a formal voice of the customer activity within the organisation? -----	66
5.2	Are there upfront targets for product yield and product cost?-----	68
5.3	Are there upfront targets set for process capabilities?-----	70
5.4	Is there an ongoing measure of the project spend through the project? -----	72
5.5	Is there a formal technology requirements assessment conducted? -----	73
5.6	Are there formal “Stage Gate” reviews through out the project? -----	75
5.7	How is the project leader selected?-----	75
5.8	What is the make up of the team? -----	77
5.9	Does the team use metrics to track the progress of the project? -----	78
5.10	What metrics are used to monitor the project? -----	79
5.11	Organisational Factors.-----	79
5.12	Development Process Factors. -----	80
5.13	Skills and Capabilities. -----	80
5.14	Marketing and New Product Characteristics. -----	81
5.15	Review and analysis of questionnaire. -----	81
5.16	Assessing the difference in response between USCI & Cappella. -----	83
5.17	Assessing the difference in response between USCI & Proxy. -----	86
5.18	Assessing the difference in response within USCI. -----	88
	Chapter 6 Discussion. -----	90
	Chapter 7: Conclusions and further research. -----	93
	7.1 Further Research. -----	93
	Chapter 8 Bibliography.-----	95
	Appendix. -----	99

List of Tables.

Table 1: Factors required for successful new product development process.....	27
Table 2: USCI Ireland Product Portfolio.	57

List of Figures.

Figure 1: Cost of Design Change V’s Product Stage.....	38
Figure 2: New Product Development Process Overview.....	47
Figure 3: PTA Balloon Catheter Operation.	55
Figure 4: Survey Results; USCI V’s Cappella & Proxy Biomedical.....	83
Figure 5: Difference between answers from USCI, Cappella & Proxy Biomedical.....	84
Figure 6: Difference in answers within USCI Ireland.	89

List of Appendices.

- Appendix A, Statistics for Cardiovascular Disease Statistics
- Appendix B, Questionnaire presented to Cappella, Proxy Biomedical & USCI.
- Appendix C, Cappella performs better than USCI Ireland in the following areas.
- Appendix D, Proxy Biomedical performs better than USCI Ireland in the following areas.
- Appendix E, Difference in results (low-high) within USCI Ireland.

Abstract.

The manufacturing landscape is changing in Ireland. Ireland has enjoyed huge prosperity through the “Celtic Tiger” years as large multinational organisations set up manufacturing plants in Ireland. With the emergence of lower cost economies pressure has been put on Ireland’s position as an attractive location for manufacture. With this change opportunities to innovate are being presented to Irish companies. As the economy changes to knowledge based economy entrepreneurs are setting up small development medical device companies exploiting opportunities within an ever expanding and technologically advancing field of minimally invasive surgery.

Introducing new products to the market requires successfully developing the product from the concept phase through to the commercialisation phase. Introducing well designed product onto the market place in a short time as possible maximises the products financial potential in the market.

This research utilised a case study approach to examine of the development of metrics to reduce the time to market for new products within these small Irish organisations. Investigating both traditional project measurement methods (Gantt Charts) and new techniques, such as stage gates, design for six sigma and balanced score cards, the study investigated the potential of tracking project outputs to reduce time to market.

The case study shows the small Irish indigenous organisations studied has a high level of technical expertise and innovation potential and has successfully commercialised its first internally designed product.

The measurement and analysis of the new product development process suggests the development of a system which will incorporate traditional and new methods. The study also indicates the development of new product development metrics will increase team communication, increase project execution efficiency and reduce time to market for substantially more robust products. The development of this new product development will incorporate the voice of the customer activities through the development process. The study indicates the learning’s conducted for large organisations can be transferred to small Irish organisations.

Measuring and continuously improving the new product development process increases product success and reduces the time to market.

Chapter 1. Introduction.

This study will evaluate the development of metrics to measure the process of innovation management, taking the idea from concept through to product commercialisation, in a young medical device organisation in an increasingly competitive global market in 2008.

1.1 Aims and objective of the research

Ireland has developed a reputation for excellence in the manufacture of medical devices. It is now gaining a reputation as an innovative country with substantial amounts of new products being developed in third level institutes or in small indigenous companies. “13 of the world’s top 25 medical technology companies are located in Ireland and many of these companies have entered into a symbiotic relationship with indigenous medical technology companies”. (EMCC 2008)

As the demographics of the Irish medical device industry changes there is now a realisation that innovation is only one step in developing successful commercial products.

This realisation is now relevant in industries all over the world as they know they are faced with two choices, either they can either do things the way they always did them, stand still or realise that through increased global competition there is a need not only to have innovative products but also to have innovative processes to achieve success.

The development of appropriate metrics to measure innovation and the new product development process is critical to the success of the organisation. “Effective measurement must be an integral part of the measurement process..... what we measure is what we get.” Kaplan et al (1992)

If an organisation does not measure what it is doing it will not be in a position to identify product deficiencies at an early stage in the process, it will not analyze customer requirements or the budget set out for the project.

This study will measure product development and innovation performance within the organisation. It will investigate what are the appropriate set of metrics for a small organisation which can

measure the performance of the innovative and new product development process within the organisation.

The study will assess the current performance of a young organisation with a short history of product development, its interaction with customers, meeting customer expectations and the development of applicable project performance metrics.

1.2 Research Background.

1.2.1 The “Celtic Tiger” years.

Ireland has enjoyed the benefits of the “Celtic Tiger” economy from the middle of the 1990’s GDP grew 10.9% in 1997 and 11.1% in 1999 (Central Statistics Office 2004) This growth in the economy was like the rising tide and lifted the majority of boats, with an improvement in living standards The Central Statistic Office (2004) shows the average wage rose from €348 per week in 1996 to €499 in 2003. If success breeds success then the Irish economy was a self propelling snowball rolling down the hill gathering momentum.

Unprecedented growth in the manufacturing sector saw almost full employment through the mid to late 1990’s. Ireland had become a hotbed of manufacturing activities, attracting many of the leading software, computer, pharmaceutical and medical device manufactures to set up manufacturing facilities. Medical device became a key stake holder within the Irish economy and the growth of this sector under pinned the success of the Irish economy.

“The sector exports products valued at €6 billion per annum” and the Irish medical device workforce represents “10% of the total manufacturing workforce”. (EMCC 2008)

The low cost of wages as Ireland came out of the economic recession, the favourable corporate tax position adapted by the government and the reward for investing in third level presented too good of an opportunity for future investors.

1.2.2 The changing manufacturing landscape in Ireland.

Ireland enjoyed unprecedented growth through the “Celtic Tigers”. As the cost of living spiralled higher demands were put on the industry which was the foundation of the success.

Ireland, which had been a very attractive location for manufacturing world class products is now feeling the pressure of higher wage demands. The growth in wages coupled with the slowing down in the Irish economy, (GDP growth slowed to 5.7% in 2001 (Central Statistics Office, 2004)) has now presented international companies with the dilemma “is Ireland still attractive to continue to manufacture in?”

The emergence of the lower cost economies as an alternative manufacturing base has put pressure on the Irish economy. Countries like China has seen the opportunity of improving quality as an opportunity to gain market share. The addition of a lower wage structure is an additional and substantial bonus.

The Irish economic landscape is changing in a more significant and potentially important way. As employees in these large multinational organisations mature, learn, move through their careers and gain financial stability an entrepreneurial culture is starting to gain momentum.

Opportunities are being presented to young Irish business to become suppliers to larger multinational organisations. These small indigenous industries are taking the opportunity to become local suppliers offering opportunities for both the supplier and large organisation. “The Irish sector has a comparable scale to the largest clusters globally in Minnesota and Massachusetts”. (EMCC. 2008)

As young Irish companies have gained a foot hold in the supply chain their next logical step is to move further up the supply chain and become a valued partner in the supply of manufactured medical device goods.

Being a local supplier to a large multinational medical device manufacture is no guarantee of success. Quality, cost and the ability to deliver will be the yard stick these Irish companies will be measured by and loyalty will not be important.

1.2.3 The need to develop knowledge based economy.

As Ireland moves away from its dependency on foreign multinationals it is recognising a knowledge based economy is required to allow us develop into the future. “The share of turnover

under foreign control in the manufacturing sector ranges from about 70% in Hungary and Ireland to under 2% in Japan”. (OECD 2004) There is a strong reorganisation that Ireland needs to reduce its dependency on foreign multinationals and develop a self sustaining manufacturing base.

It is recognised to move up the supply chain of these multinational organisations and to become direct suppliers to customers, Irish companies must invest in innovation. This innovation needs to be in the form of product and process innovation.

The growth in knowledge gained from working in large multinational organisations and the limited research and development facilities and resources in Ireland has prompted some of these employees to exploit opportunities and develop their own products.

There is no guarantee that these products will ever reach commercial success. There is a long and expensive path to product launch in the medical device industry. As medical device products move through their development cycle many fail for various reasons including, no finance, technology not fully developed, no competitive advantage or no marketing strategy to name but a few. Cooper et al (2004, p34) show through research that “approximately one in ten product concepts succeed commercially while only one in four development projects is a commercial success”

1.3 The Need for Research.

To take advantage of the growing opportunities, the growing markets and the advances in medicine, Indigenous Irish companies must be innovative in all aspects of their business. There is no option or opportunity to develop products ad hoc with no careful planning, no concept analysis or development.

The Irish government has identified the necessity to develop indigenous innovative Irish companies. The west of Ireland, Limerick, Clare, Galway and Mayo has seen a large cluster of medical device companies locate in the region. There are several success factors associated with this cluster. There is a large presence of multinational medical device companies located in this region. “The medical device cluster is expanding, with many start-ups and scaling-up of existing companies (EMCC. 2008). This affords many indigenous Irish companies the opportunity to become suppliers of choice.

The presence of two universities and three institutes of technology within the region provides an environment where pure research and development can take place. These third level institutes are providing formal education through diploma, degree, masters and PhD levels. While there is strong formal education in this sector the EFGSN (2008),(Expert Group on Future Skills Needs) recognise there a requirement to up skill operators, assemblers, and technicians currently working in this sector.

The Atlantic coast is developing a reputation for small start up medical device companies similar to California ad Minnesota in the US.

While Irish entrepreneurs are developing ideas for medical devices they need to recognise there is a deficit in skills level in developing these inventions into successful commercial products. The Forfás Innovation Survey (2006), states the lack of skills as the third largest factor hampering innovation in Ireland.

There is a large block of research conducted on innovation in large companies and improving time to market within these large organisations. There is a lack of data and research on the nature of innovation, the management of this innovation, or the development of successful commercialisation systems for small organisations.

Measurement of innovation and how successfully and quickly this innovation can be brought to market is also seen as the preserve of the large organisations. Large organisations have the budgets and resources required to successfully manage complex new development projects. They also have the resources and budgets to manage several large key projects at the same time.

While inferences and comparisons can be drawn between large multinational organisations and small organisations there is still a large gap in terms or resources, technology and finance.

Best practices can be benchmarked and adapted into the small organisation on an ad hoc basis. This will not guarantee success in fact this cherry picking will probably cause more confusion, innovation melt down and slower time to market.

As the demographics of the Irish manufacturing landscape changes from a largely manufacturing base to a knowledge driven research and development base it is essential dedicated research and

learning's are presented to develop successful innovative indigenous organisations. EMCC (2008) indicate that over 80% of companies in this sector are active in innovation.

Innovation is seen as a key driver of success in the medical device industry in Ireland. While innovation is critical the management of this innovation will determine if an idea moves through its phases to a commercial product.

This case study will investigate and present detailed research on the factors which drive success. It will focus on the management of innovation and examine the key factors for successful innovation management and provide a real life example of the workings of the innovation development process within a micro-organisation.

The case study will focus on taking the innovation through the process within the organisation and focus on how an organisation can effectively measure innovation within the new product development process.

The case study will look at the current system of monitoring projects as they move through the product development process. It will look at the current project management methods and measurements and benchmark these practices against best practice.

1.4 Scope of Study

This research will examine the nature of innovation through the new development process within a young Irish micro-organisation. The research will also focus on the key metrics to measure the product development process within the organisation.

To this point the following are the principle areas of study within this research

- Innovation in SME
- Innovation and the Customer
- Innovation and process knowledge
- Key drivers to successful products
- Metrics to measure the product development process and reduce time to market

The study will look at the use of metrics within the product development process with a view to reducing time to market while still meeting customer requirements.

The study will present data and identify measures to help organisations to eliminate non value add activities from the new product development.

The development of the metrics will also offer an opportunity to further redesign the product development process.

The case study will investigate through a questionnaire the level of new product development metrics and controls utilised in other medical device organisations.

1.5 Research Methodology

A case study analysis has been chosen as the method of carrying out research and analysis into this subject. The method was chosen as it allows the author to gain an understanding of a complex subject. It allows further exploration of a subject and examines the previous findings in the context of smaller organisations.

The case study will offer the opportunity to empirically test the metrics and processes in a real life environment. This will help provide real learning's for the organisation in methods of measuring the process development process and reducing the time to market for new product launches.

The case study will examine the research questions and will provide an analysis of the current product development process within the organisation. The case study will provide an opportunity for the organisation to assess where their time is spent in the development process.

The case study will look at methods to control the development process as it moves through the phases. It will also look at metrics to manage and measure the product development process.

The case study will use a number of research techniques within the area of study providing a comprehensive view of the product development process within the organisation and provide future opportunities to critically assess and measure the product development process.

1.6 Chapter Overview.

The research will be presented in the following chapters:

Chapter 2: Literature Review.

Chapter 2 will present a review of the relevant literature available to examine the new product development process; this will give rise to the questions posed by the research.

The literature will be reviewed under the following headings:

Innovation – the study will look at the creation of knowledge to help develop innovation within USCI. It will look at the commercial advantages of developing innovation.

Voice of the Customer- research will be conducted to investigate the significance of voice of the customer within the new product development process.

New product development process – a review of the research available will develop systematic questions which will be used to review the new product development process within USCI.

Time to Market – the research will analyse the data available on the factors critical in reducing time to market while developing a highly innovative product, which meets customer requirements.

Design for six Sigma – design for six sigma is a statistical tool used to develop robust processes and products in the product development process. The research will look at the application of this tool in a real world example.

Stage Gates – The research will review the Stage Gates process and investigate the adoption of this project review system into the USCI product development process.

Performance metrics – the research will look at the necessity to measure the innovation activity especially the new product development process. The case study will look at the new product development process and the metrics required to reduce time to market by eliminating waste at the

start of the project and monitoring the key requirements, quality, cost and delivery to ensure the commercial launch is a success.

Through the research in the literature review a set of questions will be developed which will represent best new product development practices. The current USCI process development process will be analysed through these questions and recommendations and observations will be discussed in the discussion section of this case study.

Chapter 3: Company Background/ Industry Analysis

This chapter will give background information on the medical device industry in which USCI operates. It will provide a context within which the research is carried out. It will also give a more focused review on the company itself detailing its history and current activities.

Chapter 4: Research Mythology

This chapter presents the research questions which will be developed through the literature review. It will present questions which the research is attended to address, offering a detailed exploration of the new product development process within USCI.

The chapter will discuss the methods of research chosen, including explanation of the tools and metrics which will be used to determine the answers for each of the questions developed out of the literature review.

The chapter will present data on the limitations of the research methodology chosen.

Chapter 5: Results

The results of the examination of the new product development process within USCI are presented within this chapter. The chapter will also analyse the results of the data presented in the questionnaire.

Chapter 6: Discussion

This chapter will discuss the findings of the research and presented in results chapter. It will examine the potential significance of the research and discuss the findings of the case study.

Chapter 7: Conclusion and Further Research

This chapter will present conclusions drawn from the research within USCI and extrapolated from the questionnaires sent to other small indigenous Irish medical device companies. The chapter will recommend further study as a result of the findings of research presented in this case study.

Chapter 2 Literature Review.

2.1 Introduction.

The literature review will search the body of knowledge available and will research the development of innovation under the following headings:

- Innovation
- Voice of Customer
- New Product Development Process
- Time to Market
- Design for Six Sigma
- Performance Metrics

The literature review will investigate the body of knowledge in broader new product development process. It will investigate if this research is relevant to small innovative organisations. The literature review will investigate the systems available to increase innovation efficiency and reduce time to market. The literature view will also investigate the use of metrics to capture these systems and their effect on reducing time to market.

2.2 Innovation.

Innovation could be described as turning an invention into a reality. Freeman-Bell et al (1996, p366) tells us “Innovation is associated with inspiration, imagination and originality”. There are nearly as many definitions for innovation as there are types of innovation. The word innovation conjures up the idea of doing something new which is more advanced to what is already in existence. This can range from what is viewed as very simple to very complex products, the change in design on the ring pull on soft drink cans from one that fully detaches, causing litter to the current one that stays attached could be seen as a low level of innovation. The development of a formula one car could be described as a higher level of innovation.

Innovation is described by Holt (1973) as “the use of knowledge for creation or application of new technology in connection with products or processes”.

Tidd (2006) tells us “Companies achieve competitive advantage through acts of innovation. They approach technology in the broadest sense, including both new technologies and new ways of doing things”

Tidd (2006) describes four headings in which innovation takes place; these are product, process, position and paradigm. Product and process would be the most common innovation methods, where new products are developed to offer the customer some advancement, while new processes are developed to make the product more robust to manufacture.

Innovation is seen as a key business driver, there is a strong link between business growth and the development of innovation. This is particularly true for medical device companies where, developing new innovative products and gaining large market shares has led to higher profits and growth in share price. Reviewing the share price for some of the leading innovative medical device companies over the last 6 years shows a sustained growth which is paralleled with the launch of new innovative products.

From goggle finance we see the following:

- Boston Scientific share price rose 21.67%
- Johnson & Johnson share price rose 55.25%
- Medtronic’s share price rose 42.21%
- The NASDAQ fell in value during this period by 25.55%

Technological innovation can come from either a technological push or a market pull. Ulrich et al (2003 p19) describes a technology push product as one in which the team begins with a new technology and finds an appropriate market. A product which is described by Ulrich et al (2003 p19) is one in which a market opportunity is seen and appropriate technologies selected to meet the customer needs.

In the medical device industry the majority of innovations seen are either the development of products which are new to the market or the advancement of new processes which reduce the costs of products thus allowing them gain further market penetration.

Due to the close working relationships between doctors and medical device industries there is a very close interaction between the market pull and technology push of product innovation.

The process of innovation can be described as idea generation and idea evaluation. Ideas can be generated from a number of sources, both internally and then externally. The ideas then need to be evaluated and critically assessed to ensure they fit into the companies capabilities and also to ensure there products will be successful in the market place. Pessemier et al (1973) says “New product planning activities must provide the information link between the economic and technical capabilities of a firm, and the aesthetic social, and economic perceptions of customers”

The product development process is an extension of the innovation process. Development stages and introduction to the market is added to the initial two stages once the idea has been given the go ahead.

Ulrich et al (2003 p2) describes product development as “the set of activities beginning with the perception of a market opportunity and ending in the production, sale and delivery of a new product”.

A generic product development model consists of the following steps as described by Ulrich et al (2003 p14) Planning, concept development , system level design, detailed design, testing and refinements and production ramp up.

Innovation is the life blood of a company. As the economic landscape is changing in Ireland we can see the market changing from a manufacturing-based economy to a knowledge-based economy. The medical device industry is built on foreign investment and with multinational organisations employing the majority of people in this sector. Indigenous Irish companies need to innovate new products to compete on a global scale with these companies. “Our national ability to innovate will determine our competitiveness in the future global market place” Cuddy (2004)

Innovation while helping the Irish economy move from a manufacturing-based economy to a knowledge-based economy is critical from an individual companies’ point of view. Cooper (2001 p4) shows 33% of companies’ sales are from products that have been introduced in the last five years.

Innovation is necessary for a technology company to survive in the medical device industry. Companies can stand still and hope they will survive doing what they always did or they can develop a culture of innovation to develop a strong relationship with the market and become a market leader.

Innovation and advancements in the fields of practiced medicine is driving medical device manufacturing companies to be more innovative to keep their products in a strong market position.

Cooper (2001 p8) describes four key drivers of innovation which are: the speed of technological advancement is giving more product possibilities; the once impossible is now becoming possible. Customers' needs are changing and the desire to have new products with significant improvements is driving innovation. As the customer needs are getting more demanding product life cycles are getting shorter, this is pushing companies into a continuous development cycle to keep product updated. As there are opportunities for companies to sell into greater markets, thus there are threats coming from these markets.

2.3 Voice of the customer.

Identifying the needs of the customer is a key part of developing successful innovative products. Meeting and exceeding the customer's expectations while still giving value for money. Meeting these customer needs requires an understanding of what the customers spoken and unspoken needs are.

Griffin and Hauser, (1993) describe customer needs are a description in their own words, the benefit to be fulfilled by the product.

The "voice of the customer analysis as a method of identifying the key drivers of customer satisfaction. This enables the organisation to effectively design, deliver and improve its products and services". Watson (2005 p396)

The process of identifying customer needs is a continuous process that runs the entire length of the development process. The product development team will continuously measure the current product specifications against the requirements of the customer.

Particular emphasis should be placed on meeting the voice of the customer requirements at the concept generation, concept selection phase of the project. Koen et al (2002) describe ideas in the idea generation phase as being built up, torn down, modified, upgraded combined and reshaped and may go through several revisions and changes as it is discussed and developed into the concept to be sent forward for development. Product testing throughout all the phases of the project and especially at the concept should be measures against the customer requirements.

Identifying the customer needs is a process in itself and serves several internal and external requirements. There are several important outputs of identifying customer needs correctly.

- Ensure the product development remains focused on the customer needs.
- Identify hidden needs as well as the obvious ones.
- Develop justifications for developing specifications.
- Develop a history of the needs activities through the development process.
- Ensure all critical specifications are met.
- Develop universal language for customer needs within the project teams.

Identifying the customer needs within the medical device industry is critical. As many doctors expand their scope of practice and practice on different areas of the body they still hold onto the preferences they have developed in their original field. Many development companies are changing from the traditional market research techniques and working with lead users to develop their concepts and validate it against market and customer requirements. Lilien et al (2002) state that traditional market research techniques , which involve collecting data from users in the target market is being replaced by “lead users” techniques, where data on needs and wants is collected from leading edge specialists in the target market and markets facing similar problems.

When a lead user is identified it is important to ensure it is not just their preferences that are put into the product specifications. The reverse of this is very important, it is also very important to identify these preference may be now accepted as product requirements which are accepted as the norm.

At the early stage of the project there is an interaction between customers, marketing and the development department all aiming to identify the new product opportunity. This stage of the process is typically the fuzzy front end. Dahan and Hauser (2001 p9) conclude that at this stage in the process marketing’s task is to reduce the amount of uncertainty and allow the design team to

find the winning product concepts by accurately capturing the point of view while accurately communicating their preferences to the design team.

Koen et al (2002) states there has been a lot of work done in reducing time to market and product development process. Many companies have dramatically improved cycle time and efficiency in new product development by the implementation of stage gate techniques in their approach of the new product development process.

Koen et al (2002) conclude the fuzzy front end is generally regarded as one of the greatest opportunities for improvement of the overall innovation process. The identification of customer needs and the development of fact based measurements to accurately develop product specifications can serve two purposes. Firstly it will ensure successful products are commercialised which will have new innovative features but will still meet and exceed the customer requirements. Secondly time to market should be significantly reduced as there will be no confusion as to the final product specifications and technologies and processes can be identified and made robust to ensure the quality and cost portions are met.

Companies in industries who have short product life cycle “have devised several strategies to compress product development time:

1. Listening to the voice of the customer to identify customer needs early in the development process.
2. Investing in engineering capabilities for rapid learning and translation of customer needs into product designs.
3. Developing cross-functional teams for concurrent engineering.
4. Promoting continuous learning through rapid product modifications and line extensions.”
Dater et al (1997).

These learning's has been backed up by research by other authors.

Ulrich et al (2003 p55) present a five step method of identify customer needs. These are:

1. Gather data from the customers.
2. Interpret the raw data in terms of customer needs.
3. Organise the needs into a priority of primary, secondary needs.
4. Establish the relative importance of the needs.
5. Reflect and review.

There are several methods to gather the data, interviews, focus groups and observations. Ulrich et al (2003 p56) recommend using one to one interviews followed by one to two focus groups as the most efficient method of gathering the data.

Research and development and product development itself, within the medical device sector is very expensive for several reasons, firstly the technology is being pushed to the very limit often requiring significant developments and substantial investment in technology to meet customer requirements. Secondly development costs are increased substantially due to the regulation within the industry. Safety and efficacy standards must be met through stringent testing.

The development of accurate and detailed customer requirements upfront and throughout the design process will help reduce the time to market, reduce the number of design changes required and decrease the design and manufacturing costs. Curtis et al (2006) give the example of companies with advanced voice of the customer methods having dozens if not hundreds of voice of the customer cycles built into their development process.

Developing and integrating customer needs into a set of requirements in the project measurement metrics will ensure the product specifications and test results can be measured against the customer requirements through out the phases of the project.

2.4 New Product Development Process.

Innovation is a cornerstone in building a knowledge-based economy. As Ireland begins to shift from a manufacturing based economy to a knowledge based economy, companies, the government, educational institutes and indeed large non Irish multinational organisations are seeing that innovation is a key factor to developing a successful transition.

Innovation is the process of making an invention a reality. Many inventions never succeed through various reasons such as technology not advanced enough to develop potential fully, no market for the invention, inventor did not have the knowledge to develop it into innovation.

Developing innovation and managing the process of innovation is becoming a key factor to the success of an organisation. It is critical business opportunities are turned into reality. The process of

turning the invention into an innovation and then further on to a commercial success is called the new product development process. Tidd et al (2005 page 84) describes the product development system as a flow of ideas constantly entering the new product pipeline and flowing through path of building, resting refinement of the innovation through to commercial success contributing towards the growth of the organisation.

As more and more research and development is being carried out in Irish educational institutes and in small Irish indigenous companies it is now becoming critical to understand the steps necessary to transfer the innovation into a successful commercial product which meets and exceeds customer's expectations, has high potential for market growth and satisfies the financial desires of the organisation.

Through the research conducted the majority of the literature published discusses new product development in large organisations. It discusses systematic approaches to maximise to opportunities for success within these organisations. It offers suggestions on tracking these products through the various stages and organisation metrics to measure these projects against the customer and company expectations. "Systematic and continuous learning about how a firm creates new products is the basis for more rapid and commercially successful product development. In turn, learning cannot be achieved without clear and purposeful measurement" Meyer et al (1997).

There is a need for research or analysis to investigate if the new product development strategies can be transferred across and successfully implemented in small indigenous Irish companies. There is also the question if there is a successful mechanism for measuring new product development within these organisations.

The product development process is described as a well defined set of activities which either happen concurrently and or in sequences, which require integration across an organisation to successfully design, develop, and launch a product for its market.

Ulrich et al (2003 p2) describe product development as "the set of activities beginning with the perception of a market opportunity and ending in the production sale and delivery of the product".

Process development is not an activity that just takes place within the four walls of the organisation; there is an interface with the customer at the beginning of the process and again at the end of the

process. There is also a requirement for all functions within the organisation to get involved in the new product development process. Krishnan & Ulrich (2001) show there is a need for four common functions to work together in the design and development community, marketing, organisations, engineering design and operations management.

This research will look at the new product development process within a small Irish indigenous organisation, it will provide data to investigate if the new product development process described in the literature and predominately geared towards large organisations can be successfully adapted into a small organisation. The research will also investigate and develop metrics to measure the new product development process within USCI Ireland

Cooper (2001 p115) lists seven goals of a new product development process, these are:

1. Quality of execution.
2. Sharp focus, better prioritisation.
3. Parallel processing at fast pace
4. Cross functional team approach.
5. Voice of the customer built into the process.
6. Upfront homework
7. Develop product with competitive advantage.

Developing a new product development process helps reduce the chaos, reduces the risk and helps managers allocate resources and funding to achieve a successful commercial product. It will also help all functions involved in the product development process have a clear roadmap to where they are going and can help all functions operate together and coordinate their activities to achieve product success. Cooper (2000) recommends moving to a team approach that cuts across all functions within the organisation and the emphasis should be on the autonomy of the team and the authority of the project leader.

As the concept moves through the product development process from the idea generation at the fuzzy front end to the scale up and commercialism the flexibility and innovativeness of the team lessens and the activities become more rigid as the product takes its final shape.

For a new product development process to be successful it must be flexible and be able to adapt to a changing environment.

Ledwith (2000) presents, that there are certain factors that must be present for a firm to implement an efficient and successful new product development process. These factors are presented in the table below.

<p>Organisational Factors.</p> <ul style="list-style-type: none"> • Internal/external relations. • Inter functional department communications. 	<p>Development Process Factors.</p> <ul style="list-style-type: none"> • Top Management support/skills. • Speed to Market. • Financial support.
<p>Skills and Capabilities.</p> <ul style="list-style-type: none"> • Technology synergy. • Marketing Synergy. • Company resources. • Strategy. 	<p>Marketing and New Product Characteristics.</p> <ul style="list-style-type: none"> • Product advantage. • Market potential. • Market competitiveness. • Environment.

Ledwith (2000)

Table 1: Factors required for successful new product development process.

In addition to assessing the new product development process within USCI under the previously described headings the new development process at USCI Ireland will be assessed, as described Ledwith with reference to the above factors and discussed in the reports section. These factors present both internal and external forces for the new product development process.

Construction of a new product development process within a small organisation must be an integral part of the organisations strategy as there will be a conflict in interest between the departments for the finite resources available in the company.

If the company has a strategy of developing new innovative products and developing these innovations into successful commercial products then it must prioritise the new product development process and provide resources, support and skills to the projects to ensure the project meet their launch date and maximise their potential in the market. “With such close links between product innovation performance and the organisation’s overall success managers and decision makers must ensure that this process is well managed and successful”. Cormican Et al (2003)

The goals of the new product development process should fall into the overall strategic goals of the organisation. Smith and Reinersten (1995) identify the process development process should fall within in the context of the overall goals of the organisations.

The four strategic goals which Smith and Reinersten (1995) describe as needing consideration when designing a new development process are:

1. Time to Market
2. Product Cost
3. Customer Benefits Delivery
4. Development Costs.

On entry into new product development process the company will need to balance all four objectives and attempt to maximize all four.

Ulrich et al (2003 p12) tells us every organisation employs a product development process at least slightly different from that of every other organisation.

While the new development process may be modified to suite the type of innovation or business sector it is essential they contain the same basic steps. By developing a well defined product development process, with guidance for the project team the probability of success increases greatly. Booz et al (1982) studies into the new product management reveals that what happens in the steps from idea to product launce is key to success.

By using a stage gate mechanism through the development phase of the project allows the project team to analyze data and make decisions at early stages of the project and throughout the project and adjust the scope and priority as required.

Ulrich et al (2003 p12) Tell us a well defined product development process is useful and provides the following project management tools which help achieve the teams goal:

Quality assurance – the product development process specifies the phases the project will pass through and the checkpoints it must meet. Choosing the phases and checkpoints carefully quality will be built into the final product.

Co-ordination – a clearly developed process works as a master plan, giving each team member defined roles and responsibilities. The plan will inform team members and managers clear indication when their contribution is required.

Planning – The new product development process contains milestones which correspond to the completion of each phase. The timing of these milestones develop the schedule for the overall project.

Management – The new product development process is a benchmark for assessing the performance of an ongoing development project. Comparing planned activities against the actual events can help identify problem areas and help ensure the team can react to them.

Improvement – carefully documenting the new development process gives the team to implement improvements in the next project.

Small Irish indigenous medical device companies often begin business with a concept which they perceive as having an advantage which will give them a competitive advantage in the market place. A small core team is assembled to develop the concept through to commercial launch. Medical device regulatory bodies, such as the FDA & TUV require certain prescribed information in the product submission. This data is generally broken into separate project blocks, e.g. clinical data, design validation and process validation. These are typically the milestones that are built into the project plan.

The questions developed from this literature review will investigate the extent of the project planning at USCI. It will investigate if there is a substantial plan behind meeting these milestones.

The ability to adapt the new development process to the type of product that is being developed is critical to the success of the product portfolio. Examining the portfolio of USCI (table 2) it can be observed there are different types of development projects within the portfolio which will require different development processes, the allocation of resources and position on the priority list to ensure it is successfully complete. Cooper et al (2006) concludes that business that are top performers in the R&D field have a systematic approach to portfolio management, bringing discipline to project selection decisions and efficiently guides the allocation of resources.

Ulrich et al (page 35) tell us there are four different types of development projects which can be processed through the organisation, they are:

- New product platform – these projects involve major development efforts. These products are aimed at a familiar market and product category
- Derivative product platforms – these products extend the current matrix to address further customer needs.
- Incremental improvements to existing products – these products may only involve adding or modifying some features to an existing product to maintain competitiveness within the market.
- Fundamentally new products – These are radically new products or production technologies to help develop new products for new markets.

The purpose of the literature review is to investigate the methods of measuring the generic new development process. “Measures of the effectiveness of research and development should demonstrate firm performance in this critical dimension of the new product development and point the way to improvement” Meyer et al (1997).

As the majority of the literature is focused on the new development process within large organisations the research will investigate if this process can be transferred to small Irish indigenous organisations. It will also investigate the metrics necessary to measure new product development projects, which will gauge success, alert the team to problems as early as possible and readjust plan to get the project back on schedule.

The generic new product development plan is described as a set of activities with milestones which are conducted in series and concurrently to take an idea from concept through to commercial launch.

Measuring a new product development process in the traditional way would involve a tool similar to a project Gantt chart generated in Microsoft project or a similar software package. This will give the project team information on the progress of the project from a time point of view but does not tell the team anything about any other critical factors within the scope of the project. Zirger et al (1990) presents success factors for new product development success, management excellence, superior benefit to cost ratio, strategic focus, development of products for entry into early growing

markets. These factors cannot be measured through traditional Gantt charts. These factors must be measured as part of the new development process and appropriate measures must be developed in parallel with traditional measures.

Research has demonstrated that a more holistic approach to new product development is required to achieve product success. To achieve these goals the new product development process must include more measurements than purely time. The measurement system for new product development must assess the project from a quality, cost and delivery point of view.

Within the small Irish indigenous organisations, management must recognise the importance of looking at the voice of the customer, the product development process and the building in of quality, process capability and the reduction of product cost as key attributes of the new product development process. This product development process must prioritise the high return products and must be flexible to shift priorities quickly if required, “A recent McKinsey study reports that, on average, companies lose 33% of after tax profits when they ship products six months late, as compared to losses of 3.5% when they overspend 50% on product development”. Cohn et al (1996) the development of a successful innovative organisation necessitates the development of a product development system which can be measured and assessed. Metrics must be developed to measure and track the progress of the project. The purpose of these metrics must be to help reduce time to market with high performing products.

2.5 Time to Market.

“The success or failure of new product development indicate that performance outcomes are heavily influenced by the products quality and uniqueness and the development practices used by the organisation” Ittner et al (1997). The combination of good development practices and efficient project execution will help ensure the new project development process delivers successful products to the market place.

Maximising the time a product is in the market place helps maximise the profit and helps grow the reputation of the company. Hitting the product launch date which will achieve these goals is critical. “Speed is the pivotal competitive weapon” Cooper (2001 p108). The new product development process is critical to the commercial success of the product.

Failure to launch within the window of opportunity or delivering a product within this window of opportunity which does not meet customer expectations will have similar devastating consequences for the company. Cooper (2001 p108) again tells us speed is a vital competition weapon.

Reducing time to market has become a strategic objective of many project teams, Cooper (2001 p109) indicates that many firms have reduced their product development process cycle times over the last five years, with the average reduction being about one third.

As many small indigenous Irish medical device companies are in the development phase of their operation moving the product through this phase to commercial launch in a quick time as possible is critical. Ittner et al (1997) state there are significant economic advantages that stem from faster new product development, including improved profitability by extending the time on the market, an opportunity to charge a premium price and have the advantages of development and manufacturing cost advantages.

Financial stability and income generated from commercial sales for USCI will help generate profits for the company which can be invested back into research and development thus allowing further growth. Management has recognised the need for speed to market as an ultimate measure of the project development success and is using this as a key drive to time to profit.

The terms time to market and time to profit may be identified incorrectly as the same metrics but there is a substantial difference in the fundamental meaning of these terms. Time to market can be defined as the duration a project takes to get from the initial concept to having the product launched on the market. This metrics does not ensure commercial success “but many of the practices naively employed to reduce the time to market ultimately cost the company money; they achieve the interim objective – bringing the product quickly to market – but fail at the ultimate objective – profitability”. Cooper (2001 p109). The product may be launched in record time for the company but in doing so the company may have omitted fundamental parts of the new product development process critical to the commercial success of the product.

On the other hand time to profit captures the time the product will be in development as well as the length of time it will be on the market before it penetrates the market substantially to make a profit. Cohen (1996) tells us Stalk (1988) coined the term “time-based competition” to highlight the importance of quick to market in today’s competitive environment.

Time to market could be identified as having some fundamental flaws in its methodology, it could be considered that time to market does not guarantee product success as it does not guarantee the product will be a success when it reaches the market. It may have left out the fundamental step in the product development process of voice of the customer, so when it reaches the market it is not what the customer wanted at all and fails.

Speedy time to market may also give the impression of cutting corners and leaving out fundamental steps in the new product development process or reducing the work done in them, leaving a poor quality product on the market when it is launched.

Time to profit on the other hand gives confidence in the process that due diligence has been performed, taking into account the critical features of voice of the customer and the quality and process capability requirements necessary for the product to succeed. Hinkle (2008) gives five practical methods to reduce the time to market for new product development processes:

1. Eliminate waste such as unproductive meetings, inefficient processes or poor communication.
2. Speed vs. efficiency trade-off keep a balance between speed and efficiency
3. Invest in project planning, conduct substantial project up front and monitor this plan during the duration of the project
4. Foster collaboration and commitment, proactive team building will help reduce time to market
5. Assess the cost of delays, track the loss of revenue for each day the project is delayed this will help improve team performance

Cooper (2001 p110) describes five methods to increase the odds of winning at the new product development process and reduce the time to market. These methods will in essence reduce the time to profit:

- Do it right the first time.
- Do homework and definition.
- Organise around a cross functional team with empowerment.
- Conduct parallel processing.
- Prioritize and focus.

To minimise rebuilds it is essential to develop a set of quality requirements upfront in the project. It is also important to develop a set of increasing yield requirements for each milestone through the project. This will ensure quality is built into the product development process thus ensuring high quality, high process capabilities and lower costs while ensuring all customer requirements are met. Ittner et al (1997) state that lower conformance quality, less innovation in product design and diminished returns to scale for additional resources (putting additional resources on project to avoid rising development costs) all play to reduce the benefits of trying to reduce time to market. It is essential to develop a metrics for expected delivery schedule, quality, cost and customer requirements are built into the front end of the project.

Developing a strong understanding of the customer requirements up front will eliminate or reduce the project time lines by ensuring strong product and process inputs are obtained.

Inefficient teams with little coordination is one of the significant reasons for slower time to market. The lack of power to make decisions within the scope of the project is also another significant reason for projects failing to meet their time lines. Cooper (2000) suggest it is necessary for project leaders to have authority to make decisions for new product development process to be successful. Cooper (2001a) backs this up further by suggesting 75% of delays encountered within a project is due to delays in making decisions. Developing the correct project team structure is essential for developing a successful new product development process.

Deciding on the priority of projects and assigning resources to them accordingly will increase the quality of the speed and quality of the work. Spreading resources across to many projects or too many simultaneous activities within a project will cause delays and poor quality execution of tasks. Prioritizing and focusing on the key strategic projects may force decisions to kill of lower priority resources as there are not enough resources to work on all projects and hiring additional resources cannot be justified.

Within small Irish medical device companies where only a small core team has been assembled to develop the product it is not easy to maintain such a structure as all hands are expected on deck. Cooper (2001) suggests some “nuts and bolts tools” to help reduce cycle times.

- Use flow charts – map out each step of the process.
- Use planning tools – utilize critical path planning software, look for opportunities for concurrent task execution.

- Add flexibility – move tasks around to increase chances of completing long lead time tasks sooner.
- Deadlines are sacred – put extra resources on delayed tasks, put extra effort into get them completed.
- Make funding flexible – keep funding flexible to reduce time waiting for new budgets.
- Move ahead anyway – if gatekeepers fail to make decisions move ahead, this will force timely decisions.
- Keep it simple – project complexity doubles and trebles the cycle time of projects, reduce complexity of projects.

As with other parts of the new product development process it is essential to have a procedure that the project teams can use to develop project plans and track their progress against them.

Reducing time to market is a key aspect of continuous improvements within the organisation. It is essential to be able to measure activities within the new product development process to monitor progress and make improvements for future projects. The use of SMART metrics are essential as they help identify issues quickly and early in the process, it also provides stretch goals for the project team thus reducing time to market and increasing quality of product.

2.6 Design for Six Sigma.

For a new product development process to be successful from an internal point of view it must achieve the targets set out at the beginning of the project for product quality, cost and delivery. If a new product development project charter was to focus on these three deliverables alone it would have a successful product transferred into manufacturing. The success of the product in the market place would also depend on how well they met customer expectations.

Within the current climate in Ireland in the medical device sector there are two challenges facing development and manufacturing companies which are of particular concern. As the global economy hits a down turn there is increasing focus on manufacturing costs. This is particularly true for the Irish economy, who has an over dependency on foreign multinational companies, as several large multinational companies look to move their manufacturing to low cost countries. The Central Statistics Office (2004) has shown GDP peaked in 1999 at 11.1% and has slowed to 5.7% in 2001.

This growth has continued to decline and potentially there will be no growth in the Irish economy this year.

The other key factor is driven by regulations within the medical device industry driven by the FDA and TUV mean medical device manufacturers must prove a high level of confidence in their product to ensure there is no adverse for patients.

Building in quality is now a key component of the design process. There is now a firm move away from the mind set of designing the product first and then designing the process afterwards. “Costs are inevitably incurred ensuring that products or services meet the customers requirements, in most companies the majority of quality related costs are incurred putting things right after they have gone wrong” Munro-Faure et al (1992)

Design for six sigma is now becoming an integral part of the product development process. Watson (2005 p67) describes the objectives of a design as meeting the needs of others in a manner that is commercially viable. Watson (2005 p13) goes on to conclude that design for quality is the combination of both innovation excellence and operational excellence.

Kiemele (2003) describes design for six sigma as follows:

- A methodology for designing new products and/or processes.
- A way to implement the Six Sigma methodology as early in the product or service life cycle as possible.
- A way to exceed customer expectations.
- A way to gain market share.
- A strategy toward extraordinary ROI.

Combining innovation with operational excellence will help achieve financial success and customer satisfaction.

As discussed previously “getting it right first time” is critical from a customer perspective as design costs and time can spiral out of control if proper voice of the customer analysis is not conducted.

Design for Six Sigma is a methodology which follows a road map, using data to drive decisions and statistical tools and analysis to improve the robustness of the product and process.

The road map uses the Arcanum DMADV,

Define: Define the project goals and customer (internal and external) deliverables

Measure: Measure and determine customer needs and specifications.

Analyze: Analyze the process options to meet the customer needs.

Design: Design (detailed) the process to meet the customer.

Verify: Verify the design performance and ability to meet customer needs.

<http://www.isixsigma.com/library/content/c001211a.asp>

The six sigma methodology has gained popularity within manufacturing circles in the recent past as a methodology for improving processes and increasing yields. While some of the tools are similar the road map is different. The manufacturing six sigma methodology follows the following road map.

Define – Measure – Analyze – Improve – Control.

Both programs can achieve excellent results in their respective fields as they examine the relationships between the inputs to the process and the outputs and set about controlling the inputs to ensure the desired output is reached, put simply this can be represented as:

$$Y = f(x)$$

Your outputs Y are a function of our inputs x.

The main differences in the approaches are where it is done in the process.

The earlier six sigma is done in the process the lower the cost is to the company and greater benefits can be achieved. Traditionally process improvements were the remit of the manufacturing department where the development team would hand over the product and manufacturing would increase yields and improve robustness. This has posed many problems as often there is a misalignment between meeting the design specifications and being able to improve process capability. If we improve this parameter we will have to change a specification. We will have to live with the yield as we would have to submit a process change to the regulatory body. It will cost

too much to change the process now are all typical examples of hair pulling moments in manufacturing.

As described by Kiemele (2003) and illustrated below the cost of improving the product and process capabilities increase significantly the further into the development phase it is undertaken.

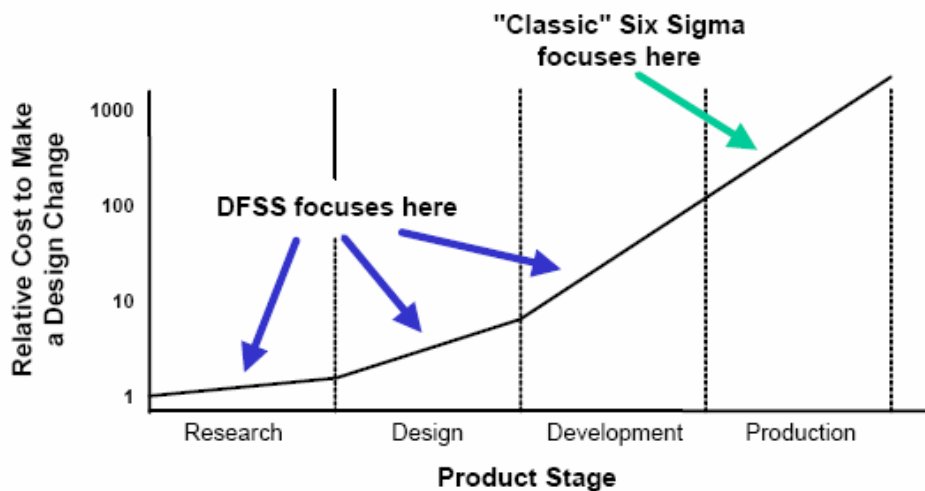


Figure 1: Cost of Design Change V's Product Stage.

Watson (2005 p70) concludes that using design for six sigma improves competitiveness by improving product technology and the process technology which deliver the product to the market.

Reducing the time to market will lead to:

- Increased product life-cycle time revenue and market penetration
- Success in time sensitive markets due to reliable market launches
- Lower engineering costs
- Better use of resources and less waste Watson (2005 p71)

While the six sigma process itself is critical to the success of the team it will fall down if proper measurements are not put in place. Six sigma relies heavily on data to drive decision making within the process.

Within the six sigma road map for both operational and design purposes there is a section where the measurement systems used to generate data is analysed and improved if necessary. This is a critical step in the process as all decisions will be based of this measurement system. If the measurement system is not accurate the data it generates will be false and the decisions made based on this data will be incorrect.

Just as it is important to have good measurement systems within the six sigma process it is important to be able to measure the process as a whole. This is the measurement of the performance of the organisation. It is fundamentally these measurements that will drive the company forward. Watson (2005 p107) Performance management is measured by the results that it generates in terms of both short-term profit and long-term strength.

Watson (2005 p111) Indicates there are five areas to consider which contribute to the overall performance of the organisation, these are:

1. Financial
2. Market
3. Customer
4. Productivity
5. Employee Perspective.

The overall performance of the design process will be discussed in more detail later in this review.

Design for six sigma will not be a stand alone program within the design process it will form a integral part o the design where with voice of the customer activities, new product development management and “Stage Gate” reviews will form the basis of the design activity. The combination of these activities will be measured monitored and tracked through the life cycle of the product development process.

To achieve the goals and objectives of the organisation and I fact to know when the have achieved these goals we need a sound measurement system.

As the six sigma portion of the new product development process will focus on the use of data to engineer the system to meet the internal and external requirements it is probably most appropriate to discuss the development of a measurement system here.

Watson (2005 p139) Describes the principles of a sound measurement system.

1. Measurements must be realistic
2. Measurements must be accountable
3. Measurements must be quantitative
4. Measurements must be capable of going through third party scrutiny
5. Measurements must be standard across all organisations.
6. Measurements must be reliable
7. Measurements must be a timely indicator of performance
8. Measurements must be capable of external validation
9. Measurements must be described in terms of quality, cost delivery
10. Measurement must be owned by managers
11. Measurements must be indicators of intended business results
12. Measurements must reflect the expectations of shareholders
13. Measurements must drive management accountability.

Measurements developed can be presented in a simple scorecard which will allow easy access to the current performance against the expected performance. It will allow managers deploy more resources to projects if required. It will indicate if the design specifications are not met and further design work required.

The development of medical device products requires the input of several departments and areas of expertise. To achieve optimal performance of the project team.

2.7 Stage Gates.

Reducing time to market is critical to the sustained success of the organisation. In a time where there are continuous and growing threats from new emerging lower cost economies, more efficient innovative companies and greater product choice, excellence in the new product development process is essential to sustain growth within the market.

The process development process is a fundamental roadmap to achieving this commercial success. Cooper (2001 p50) tells us that the ability to develop and launch new products quickly and

successfully is the key to business success. It is a journey from idea, to concept through innovation break through to process development to commercial launch. As with any other road trip undertaken a certain routine is followed. Do we have all the equipment we need, spare tyre, petrol, money, food. We would routinely stop along the way and consult the road signs to see how much progress we have made, if we are still on the right road. We would periodically check our fuel level and potentially phone ahead if we are behind schedule due to traffic.

The new development process is no different we need to continuously need to monitor our progress, make decisions and adjust our expectations based on the information developed in the past. Unlike our road trips, new product development projects are often a trip into the innovation unknown thus there is a certain amount of uncertainty involved.

Developing new products need to have goals which will help develop a profit stream for the company, fundamental to these goals are meeting customer requirements and producing a product within a cost base which will ensure a profit.

It would be disastrous to reach the end of the project and find the product which cost time and money to develop does not meet the customer requirements or it is too costly to manufacture let alone buy.

There are several widely used process development process in use in new product development process today, namely, Phase Review, Pace and Stage Gates.

As many of the medical device products being developed need to meet regulatory requirements, which drive the process to a stage gates types of reviews we will focus our research on the stage gate new product development process as developed by Robert Cooper.

Robert Cooper first used the term “Stage Gate” in an article in the Journal of Marketing Management in 1988 Cooper (2001 preface). Since then the face of product development has been changed with many large organisations following the Stage Gates process.

The Stage Gate process was developed by Robert Cooper and built on the best new product development process review of 2000 projects. The Stage Gate process is commenced at the concept phase and finishes with product launch.

Cooper (2001 p261) tells us the stages represent cross functional and concurrent product development activities.

The gates are the decision points within the process. Decisions are made at the gates by “gatekeepers” who are representatives of senior management. A go decision – proceed to the next stage, a hold decision – do not move forward until requirements are met or a kill decision – dissolve the project as it will not meet the requirements.

The stage gates will act as a formal project review which will be used to track the progress of the new development project. The Stage Gates process will have formal reviews. Resources finance and expertise will be allocated to the project if driven by the reviews. This study will investigate if there is a formal stage gate review conducted during the USCI new product development process and if this gating process is present and sufficient to drive correct decisions within the project.

Cooper (2001 p113) describes the Stage Gate process as a blueprint for managing the product innovation process to improve effectiveness and efficiency. The study will focus on the development of the stages. It will also review the structure of the project team and how management deal with delays and the disciplined response required to keep the project on track.

Cooper (2001 p113) further describes the Stage Gate process as a process which breaks the “innovation process into predetermined set of stages, each stage consisting of a set of predetermined, cross functional and parallel activities”

While the Stage Gate process gives the project team a structured set of activities within each stage and predetermined formal questions at the gates, metrics are critical to review the ongoing project process. These metrics should be linked to the formal questions at the gate phase so no major surprises are encountered at the formal review.

The body of the literature shows evidence that the new product development process begins with strong voice of the customer and ends at the time to profit (commercial launch). To achieve shorter times to market several project management and new process development activities are recommended. While it would be impossible for a small medical device to implement all these initiatives into their product development process it is clear measuring and reporting the key project

drivers is essential for commercial success and reducing time to market for current and future projects.

2.8 Performance metrics - Balanced Scorecard.

Measuring the performance of the organisation is essential and necessary to support the mission and objectives of the organisation. “A systematic approach to measuring organisational performance is fundamental to the pursuit of business excellence”. Dransfield et al (1999)

While performance metrics are particularly focused on the manufacturing side of the organisation it is becoming more and more important in measuring the design capability of the organisation. Hauser (1998) indicates that many firms have recently introduced development metrics, comparing their development costs to market outcomes.

The use of metrics in the development phases of the new product development process is becoming more common. Reducing time to market is seen as a critical driver to market success and is measured and tracked closely. “Project metrics selected should reflect the voice of the customer (customer needs), as well as ensure the internal metrics selected by the organisation are achieved” Phadnis (2008)

As more indigenous Irish medical device companies are setting up development operations it is critical for the success of their operations to develop key metrics to measure their performance in the development phase. While the main body of knowledge is based around large organisations it is necessary to understand if these same measurements are accurate to small organisations and if it is possible to use these measures.

The development of these accurate metrics in small organisations is necessary as it allows an understanding of the nature of innovation within the organisation and it allows effective measurement of this innovation. It is necessary to have strong metrics which give an accurate account of the innovation potential within the organisation and it allows for the measurement of development performance to ensure funding is achieved from financial institutes, government agencies or venture capitalists.

Metrics serve several purposes within an organisation they are there to measure performance and to track performance against agreed goals. They also serve the purpose of identifying problems early in the process and allowing the team to react and get the project back on track. Phadnis (2008) says the metrics selected should create a common language that the whole diverse team will understand.

Metrics can serve another purpose and that is to motivate the staff to achieve greater performance. In developing performance metrics they should have a stretch goal within them to allow team members be innovative in achieving them. It is therefore important to have performance metrics that measure the right things and drive the right behaviour within an organisation. “Metrics should be based on what, in fact, needs to be measured to improve the process, rather than what fits the current measurement system.” Phadnis (2008)

It is key that the performance metrics for the new product development process being developed can be used and understood at all levels of the organisation. It is also necessary to understand how these metrics tie into the customer requirements and how they tie into the companies goals and help managers make strategic decisions to achieve these goals. Lipe et al (2000) conclude that the use of a balanced scorecard to record the metrics should improve management decision making by aligning the performance measures with the goals and strategies of the firm.

When developing metrics for the organisation it is important they are set out with SMART objectives, i.e. they are Specific, Measurable Attainable, Realistic and Time Bound.

- Does the metrics identify barriers?
- Does the metrics focus the team to focus priority on the improvements?
- Does it drive the correct behaviour within the team?
- Does it align work with the company values?
- Are they easy to understand?
- Do they involve everybody. AUA (2004)

As the majority of small indigenous Irish companies setting up in the medical device industry are development based and extremely focused on getting their design to market it is highly unlikely they are producing metrics to assess exactly where along the design process they really are. AUA (2004) indicate by developing a good set of metrics elevates the understanding of the performance of the enterprise from lip services onto a more quantitative plane. Measuring what the team is doing

offers opportunities to identify barriers and technical difficulties early, it will eliminate the doubling up of work and it will identify poor performing process early allowing mitigation to take place. The culmination of these metrics and the mobilisation of the team will help increase performance by identifying project priority issues, and allocating resources, finance and materials to the projects to help reduce time to market. Tidd et al (2005) state that scarce personnel, materials, and financial resources should be managed closely and carefully in organisations which seek to grow and develop.

Performance metrics work well from both the management and employee. The management team can clearly identify what their goals and objectives are for a product development team and the team working with management can develop a set of metrics which will drive them to achieve the goals.

Performance metrics help managers improve control on key processes, identify clear roles and responsibilities, ensure work tasks are strategically aligned with objectives, identify the capability of the organisation, improve product quality during the design process and be able to efficiently delegate the finite pool of resources.

From a team point of view they will use the metrics to identify their clear roles and objectives, have greater empowerment to make decisions related to the project, track tasks and monitor accomplishments and allow their work to be assessed objectively.

“The performance measurement system (metrics) should be unique to the organisation or business unit being measured, reflecting critical success factors and business processes.” AUA (2004)

Within the product development process financial measurements are important element in assessing the performance of the team. Is the development team over budget because they had to hire additional staff or because they failed to achieve a specification and had to repeat a build and retest?

Measuring from a pure financial basis alone will not give all the information required to critically assess the project. Financial measurements will not reflect customer requirements, identify problems or support the problem solving process.

If a company is to be successful in the new product development field it is necessary to meet customer expectations, deliver the product to market within the window of opportunity and allow the product be manufactured at an acceptable cost and to high quality standards.

“Effective measurement must be an integral part of the management process...what you measure is what you get” Kaplan et al (1992)

The product development process is hard to navigate through let alone do it without a map, but there is no point having the wrong map or making the map too complicated to read or even hide it some where you can't read it. Voss (1998) states knowledge and information management has the potential to be a catalyst for organisational innovation.

Therefore good metrics should have the following characteristics, it should be easily accessible, answer the questions and drive team to right results.

From the review of the literature a large body of work is resented on developing performance metrics for manufacturing and development within a large organisation. Can this work be transferred to small indigenous Irish organisations? For these small organisations to excel or even survive they need to develop metrics which will develop their organisation into a strategic supplier to a large multinational or as a successful entity in its own rights.

Voice of customer, design for Six Sigma and a form of stage gate reviews form part of the new product development process. The combination of these factors will achieve a reduction in the time to market and achieve customer satisfaction.

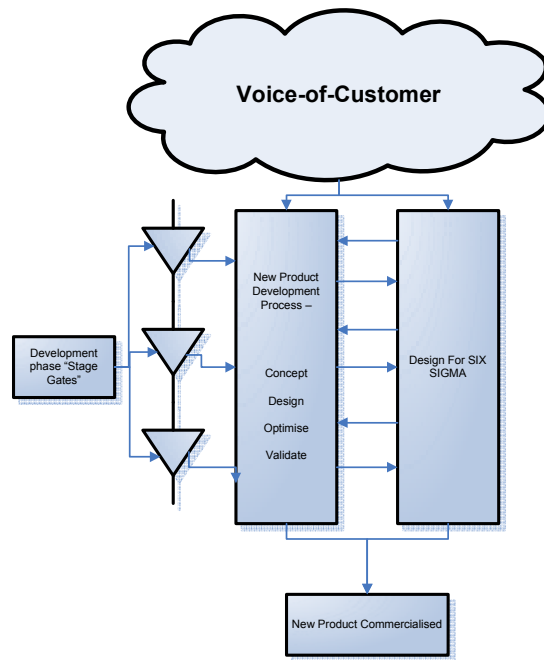


Figure 2: New Product Development Process Overview.

While the project team will be drawn from various departments within the organisation the project leader will have to track and measure all the input and outputs to allow the team track their progress Management will also be interested in tracking the process of the project and offer support when necessary.

A scorecard can be developed, which will identify key metrics which need to be measured in the new development process and report these metrics to the project team. The scorecard can also serve two additional functions. It can be used as a formal and informal review mechanism by senior management. The scorecard can also be used as a new product development process improvement tool, where it will identify and highlight opportunities to reduce time to market and increase process capabilities.

The scorecard will measure the performance of the product development activities. Building this scorecard into the Stage Gate mechanism will give the new product development team real time data to make decisions. It will also present management with data to base their decisions on at the gate review phases. “The scorecard contains a diverse set of performance measures, including financial performance, customer relations, internal business processes, and learning and growth”. Lipe et al (2000)

“The Balanced Scorecard” as designed by Kaplan and Norton (1992) contains four key groupings of performance measurements. These groupings are considered sufficient to track the key drivers of the current and future financial performance of the organisation. This balanced scorecard can be applied new product development activities of the organisation. They are:

- Financial
- Customer
- Internal business process
- Innovation/learning

From a new product development point of view the financial perspective will focus on the financial budget of the project. It will look at the actual spend versus the targeted spend. It will look at the cost to make the units versus the target. It will also track the return on investment time of the project. Kaplan and Norton (1996) advocated using measures that are relevant to the business unit being measured.

The customer focus will look at how the company is satisfying the customer and meeting their expectation. The scorecard will develop a set of metrics which will show the already identified design specifications which represent the customer requirements as defined in the voice of the customer activities.

The internal business process section of the balanced scorecard focuses the activities of achieving the internal manufacturing requirements which will help make the product manufactured to the desired yield and process capabilities. The scorecard will look at defects, cycle time and cost of components. Some of the customer requirements could be driven down to this section and become manufacturing specifications. Lipe et al (2000) indicate the components of the internal business measures must relate specifically to the processes within the unit.

As project teams move through the phases to complete the project they will learn by exposure to new processes and techniques. The fourth panel on the balanced scorecard will focus on the innovation and learning aspects of the project team. It will recognise upfront what learning's are required for the project to succeed. This will allow for greater efficiency in the project team and will show management's commitment to continuous improvement within the company.

The goal of the scorecard is to trap and measure the key business indicators for the project development process. To successfully implement a business scorecard it must be recognised not as a barrier to doing critical work, or a stick for management to beat teams with but as a tool that will pull all key measurements into one location and will drive the project in the right direction.

Developing a realist and competitive new product development process requires measuring what the company currently has and adjusting the process to make it more efficient. As the quantity of small indigenous Irish medical device companies spring up through out the country and especially in the west of Ireland changing the landscape from a manufacturing base to a knowledge based economy it is important to develop competitiveness in the new product development process field.

These companies need to look at their strengths, the development of new product concepts and continue to fill this pipeline with new ideas for future success. These companies must also look at their weaknesses, which could be the new product development process or part of this, identify these weaknesses and develop a process and method of measuring this process to ensure product success in the commercial fields.

It would be criminal for good products to fail because of the companies new product development process.

2.9 Conclusions

The literature review investigated the new product development process under the following headings:

- Innovation
- Voice of Customer
- New Product Development Process
- Time to Market
- Design for Six Sigma
- Performance Metrics

It is observed through the research there are potential opportunities to reduce the time to market through the development of a systematic new product development process. The research this new product development process needs to be monitored and tracked. The development of appropriate metrics is essential to monitor and improve the new product development process.

The literature review indicates the majority of research carried out is in large organisations. This case study will investigate if this research can be adapted to small innovation organisations.

Chapter 3 Industry/ Company Analysis.

3.1 Industry Analysis.

USCI Ireland develop and manufacture medical products for the minimally invasive medical market. These products typically consist of an inflatable high pressure balloon attached to a hollow catheter which is inflated through a manifold at the other end of the catheter.

3.1.1 Brief history of minimally invasive surgery.

Throughout history medicine has advanced and evolved through research and development and in some cases through trial and error. It is human nature to experiment and investigate the causes and cures of illness.

As more and more research was carried out into disease and illness surgical procedures became more advanced. As surgical procedures became more advanced the opportunity to treat more complicated cases presented itself to surgeons.

A key part of treating these diseases and speedy recovery was to reduce the amount of trauma the patient suffered during the surgery. Less trauma meant a quicker recovery and less time is spent in the hospital. This means the patient is able to return to normal activities quicker than major surgery.

Minimally invasive surgery is conducted through a small incision away from the disease site. The treatment or investigation equipment is normally transported to the site with a long catheter. Specialised techniques are then used to open blockages, take tissue samples or administer drug medications.

Catheterization has been performed in its simplest form through to the complex procedures since man began to experiment with medicine. As the technology advanced, the use of minimally invasive surgery grew in popularity as a true alternative to highly traumatic surgery. Rodengen (2001) describes the tension between the traditional surgeons and the new kids on the block as follows “since these new procedures were being performed by non surgical specialists in a new

environment. the cat lab, the endo suite... tension rose, controversy and turf battles with surgeons became common place. This was truly “disruptive technology” at work”.

This disruptive technology grew through technology push and market pull. As popularity grew young entrepreneurs saw the opportunity to develop the technology further and move into areas of medicine not already served with the new devices. Small medical device companies started to open during the 70’s and 80’s. Advances in technologies allowed product improvements and thus increased the popularity of minimally further. Rodengen (2001) describes an example of this as “Schneider and Gruenzig develop the first steerable guide wire”. This technology advancement gave surgeons a new tool to advance their practices further.

Market pull also drove the industry on further. The catheter interventionalists worked with companies to help them conceptualise their ideas Rodengen (2001) describes his communications and communications with Dr. Richard Myler during the development of the PTCA products and processes during the 1970’s

Rodengen (2001) tells us that in 1994 Boston Scientific held 90 US patents and 85 foreign patents and had 102 US and 131 foreign patent applications pending. This was only just 25 years after the company was formed. This shows a massive drive for innovation to gain market share. Similar trends were observed in other medical device organisations.

With the growth of the less invasive medicine sector, companies have developed and grown into multi billion dollar corporations.

As seen in the recent history of the devices the companies developed balloon catheters to treat peripheral diseases primarily (PTA) and as technologies were developed and advanced they began to treat the smaller more tricky vessels around the heart.

This technology advanced further with the introduction of stenting. This technology was further advanced through further research and development and collaborations with other technology development companies.

The development of the drug eluting stent offered companies with the technology huge market shares in the coronary stenting market (PTCA). The development and introduction of this

technology offered the medical practitioner the most effective way to reopen narrowing coronary vessel and with the addition of the drug with controlled release an effective treatment for preventing the blockage reappearing.

Industry leading companies such as Medtronic, Abbott, Boston Scientific and J&J develop and grow market share in the fast growing market.

3.1.2 The Current global market and future trends.

As the current market still grows and the market evolves large corporations are dominating the market as they flex their innovation muscles and develop the cutting edge technologies. In the minimally invasive surgery field 4 large organisations dominate the landscape. These organisations are Boston Scientific, Johnson & Johnson, Medtronic and Abbott.

As minimally invasive surgical techniques advance and new technologies are developed new opportunities in disease treatment are becoming the norm. As the minimally invasive technology grew, it gained huge popularity with the cardiologists who saw this technology as a real alternative to open heart bypass surgery as it reduced the procedure time, trauma suffered and recovery time.

Companies saw this growing market as an opportunity to grow market share and increase profitability. Companies invested millions in research and development developing the cutting edge technology firstly in angioplasty balloon technology, then stent technology and currently in drug eluting stent technologies.

While market share was dominated by large organisations, innovation was not. Small innovative companies developed technologies which were compatible with large corporation's development strategy. Mergers and acquisitions of smaller organizations allowed large organisations gain vital technologies without the effort of research and development. This ensured that the technologies purchased had a high probability of success. This also promoted collaborations and licence agreements between the large organisations and smaller organisations. This promoted innovation with the motive to develop a successful product and be purchased by a larger organisation.

Minimally invasive companies are continuing to develop highly innovative technologies for current established markets. As technologies improve, enhancements to current products can be developed and launched into the market and derivative products can also be developed.

Large medical device corporations are developing strategies to offer customers products in current markets but are also poised to exploit future markets in emerging fields of medicine such as further developing drug eluting stents for use in patients who have suffered Acute Myocardial Infraction and patients who have multi vessel cardiac disease, developing advanced implantable cardiac defibrillators for patients prone to sudden cardiac arrest, the development of devices to help in the treatment of colon cancer treatments.

As with Cardiovascular disease (CVD) which effects the central cardiovascular system of the body, peripheral artery disease (PAD) affects the outer extremes of the body. The blood flow to the arms and legs is restricted due to the restriction of the blood vessels due to the build up of fatty deposits. This can lead to extreme pain in the effected limb, ulcers and in extreme cases gangrene which may ultimately require amputation.

As with CVD the risk factors for PAD are identical. Irishealth.com tells us they are:

- Family history of disease
- Smoking
- Diabetes
- High blood pressure
- High Cholesterol
- Being overweight

Appendix A further details the Statistics for Cardiovascular Disease Statistics.

To treat these diseases minimally invasively a catheter is inserted into the diseased vessel some distance from the disease (typically at the groin) and is pushed through to the disease site. A balloon is then inflated to push the build up out against the vessel wall. In some instances a small meshed metal device called a stent is propped open to help keep the vessel open. Currently in CVD treatment the best practice is to use a drug coated stent which has a controlled release of drugs which reduce the rate of the vessel enclosing at that point.

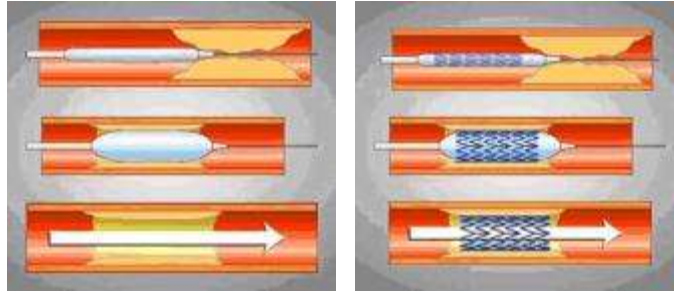


Figure 3: PTA Balloon Catheter Operation.

http://www.main-taunus-privatklinik.de/cgi-bin/mtkp/custom/pub/content.cgi?lang=1&oid=328&ticket=g_a_s_t

3.2 Company Background.

“USCI (Universal Sciences Catheters and Instruments), is an independent Japanese company, dedicated to the improvement of patient quality of life”. www.usci.co.jp

USCI has changed and evolved throughout its history. At the start of the company in 1941 in America the company developed and manufactured catheter technologies. “From the outset, USCI has been a leader in medical device development for the treatment of cardiac diseases. Since the introduction of percutaneous transluminal coronary angioplasty (PTCA) in 1977, USCI has been at the forefront of this field and will continue to innovate in these and other vascular therapies well into the future”.

USCI has contributed to the continued progress of percutaneous coronary intervention (PCI) techniques through a series of mergers and acquisitions involving CR Bard, Arterial Vascular Engineering (AVE) and Medtronic Inc.

In 2006 USCI has established its R&D and Manufacturing Centre of Excellence in Ballinasloe, County Irish, Ireland. “This facility is dedicated to the development and manufacture of vascular intervention devices with goals to expand into new therapies”.

This facility operates with an Irish management team and will be treated as an indigenous Irish medical device company.

”Amidst the rapid global changes surrounding medical services including environmental factors such as an aging global society and increases in health care costs, USCI is proactively promoting leading-edge medical devices that will ultimately reduce the strain on health care systems”.

USCI employs 60 people at its R&D and manufacturing facility in Ballinasloe. The facility has received ISO certification and has recently received FDA approval for its first internally designed product.

The facility has a strong R&D presence with highly skilled, PhD, Masters & Degree level engineer with several years of experience in the design, development and manufacture of medical devices.

Company information from USCI (www.usci.co.jp) reproduced with permission from USCI.

3.3 Product Portfolio.

USCI is a distributor of medical device products in the Japanese market. The core business of USCI within this market is interventional cardiology. While providing a high quality of service for interventional cardiologists USCI is expanding its expertise into other technologies.

USCI has a large distribution network in Japan and has built up strategic alliances with other medical device companies. This strategic alliance is a win-win situation for both companies. USCI have the distribution rights to these new advanced and more clinically relevant products in Japan and through its large sales force offers a large complement of medical devices to its customers.

Through its vast knowledge and experience with the Japanese Medical Regulatory Body, USCI can then offer the supplier access to the Japanese market.

USCI through its R&D centre in Ballinasloe Ireland is currently developing its own portfolio of products. Several products are in the advanced stages of development. USCI sales and marketing Japan work closely with the R&D team to identify, investigate and innovate to meet the ever changing product requirements from customers.

Product	Treatment Area	Product Development Phase
A	Haemodialysis Access. Management	Development Phase
B	Peripheral Artery Disease	Validation & Ramp Up
C (matrix extension of B)	Peripheral Artery Disease	Development Phase
D	Coronary Artery Disease	Validation & Ramp Up
E	Peripheral Artery Disease	Concept Phase

Table 2: USCI Ireland Product Portfolio.

3.4 Innovation Needs- Opportunities.

As the age of the population increases and the prevalence of heart disease and diabetes's there is a strong need to develop products which will prevent, treat and cure these diseases. There is now also a growing desire to improve quality of life for patients.

There is also a need for innovation to help drive down the trauma of treating these diseases. Reducing the stress put on the patients body, through minimally invasive surgery, shorter procedure time, shorter time in hospital and shorter recovery time will, increases their chance of making a full recovery.

The need for innovation within the minimally invasive field is also driven by the requirements to deliver cost effective treatments for patients. Hospitals and medical boards are looking for greater cost efficiencies within their departments.

As discussed above the large medical device companies are pursuing the real research and development opportunities. This is possible through large R&D budgets and R&D structures which increase the level of success.

Small innovative indigenous companies are starting development and manufacturing operations. These companies may have an innovative idea for a particular part of the device, i.e. a new stent or a technology for activating the drug.

As the large organisation and small indigenous companies focuses on the core technology, be it both the advancement and development of treatment methods or the development of new innovations in critical components of the catheter there are opportunities for USCI.

Through the marketing research and strong relationship with doctors gained through its sales force in Japan USCI has the opportunity to develop product enhancements and new product which will develop their product portfolio and increase their manufacturing performance.

There is also the opportunity for USCI to develop strategic partnership with innovative companies. USCI is building its core competencies around the catheter manufacture and angioplasty balloon technologies. This offers them a unique opportunity to develop a strong position within the medical device development and manufacturing arena.

As the larger medical device manufactures peruse new product development there is a growing requirement to offer a full suite of devices for the treatment of a particular disease. This offers opportunities to USCI to form collaborations and OEM development and manufacture of products which may be inside the core competencies of the partner but through strategic planning and resource constraints have chosen to pursue the higher return product but require the additional product to be developed at the same time.

3.5 The need for innovation and NPD within USCI.

USCI has identified an opportunity to develop medical devices. The R&D and manufacturing centre in Ballinasloe has been developed to help meet this strategic need.

As ideas and problems from doctors are fed back through the sales team to the R&D team innovative solutions need to be developed to design these products to meet the customer requirements.

As more advanced medical procedures are being developed more advanced solutions are required, this required innovative “outside the box” thinking.

Time to market is critical to ensure maximum sales are realised. The new product development process must be innovative to allow product ideas be developed into concepts and then through the system, ensuring they meet the customer requirements and regulatory requirements while being manufactured at low cost, high process capabilities and reaching the market in an appropriate time.

Chapter 4 Research methodology.

4.1 Introduction

The research question will investigate the product development process employed in USCI Ireland. This chapter will investigate the methods used by USCI to introduce new products to from planning phase through to commercialisation. It will examine if the current methods of assessing the technologies and product capabilities throughout the life cycle of the product development activities are capable of ensuring only high yielding and high capable processes and product move through the product development cycle through to the customer.

USCI Ireland is a research and development company developing medical devices. This industry is highly regulated. All products designed must meet strict requirements set down by regulatory bodies in countries which the product will be sold.

With this in mind the product development process must ensure the product meets the regulatory requirements while being able to be scaled up to full production manufacturing.

4.2 Research Question.

The purpose of the research being carried out is to investigate the new product development process in a small indigenous Galway medical device organisation, namely USCI.

The research questions will focus on the new product development process from concept through to commercialisation, specifically focusing on voice of the customer activities, the process of turning the ideas into concepts and then bringing it further through the development process, the use of process optimisation tools such as design for six sigma during the new product development process. The research will investigate if there are “Stage Gate” reviews during the life cycle of the new product development process.

The research questions will investigate if the development of a set of metrics specific to product innovation and the new product development process will reduce time to market, increase customer satisfaction and meet the internal product requirements for cost and process capability. The research will also investigate if the inclusion of personal performance measures, such as training and development will help reduce time to market for the new product being developed.

The research will look at the key metrics which monitor and track the new product development process and build an innovation scorecard which will be used to guide and direct the project team through the new product development process. The innovation scorecard will be based on the balanced scorecard developed by Kaplan and Norton (1992).

Based of the literature review a set of critical questions will be developed. These questions will focus on the critical aspects of the new product design process. The products which are currently undergoing development in the new product development process in USCI will be critically assessed with these questions.

The research will investigate if the use of these metrics within the new product development process will help reduce the time to market. The research will look at developing generic questions templates which can be implemented into the project at the start of the concept phase of the new product development process and track the project through to completion.

The questions will examine the new product development process from the following points of view.

- Innovation

- Voice of the Customer

- The New Development Process

- Project time to Market

- Design for Six Sigma

- Stage Gate reviews

- Balanced Scorecard.

The questions will examine the current system in place within USCI to gain an understanding of this process. The author will conduct this research himself examining the current new development process.

1. Is there a formal voice of the customer activity within the organisation?
2. Are there upfront targets for product yield and product cost?
3. Are there upfront targets set for process capabilities?
4. Is there an ongoing measure of the project spend through the project?
5. Is there a formal technology requirements assessment conducted?
6. Are there formal “Stage Gate” reviews through out the project?
7. How is the project leader selected?
8. What is the make up of the team?
9. Does the team use metrics to track the progress of the project?
10. What metrics are used to monitor the project?

The questions will be further expanded to gain a full understanding of the development process. The investing will be further interoperated to develop a balanced innovation score card which will track the key project indicators. This new set of metrics will be introduced into the new product development process for future projects.

Due to the time constraints of this case study it will not be possible to assess the projects introduced with the new metrics, this will be the responsibility of the company.

To benchmark the USCI new development process against other medical device manufactures within the region a survey was developed. This survey covers the subjects above and discussed in the literature review. This survey was distributed to the management and research and development engineers, this survey were also distributed to two senior management in other innovative medical device companies. The survey is presented in Appendix B.

4.3 *Research method used.*

The majority of the research conducted into innovation is focused on innovation and new product development in large organisations. There is a deficit in the research carried out on the new product development process in small organisations.

The research takes the form of a case study, focusing on the new product development process within the USCI organisation. The research will compare the findings, where appropriate to the data

presented in the literature review. Using case studies as a method of research offers an opportunity to study the organisation and the workings of the new product development process in very close details.

The case study will give a detailed insight into the innovation and new product development practices of the organisation.

Chapter 5 Results.

The results of the research into the new product development process are detailed in the following chapter. The results chapter present the data analyses for the questions presented to investigate the extent of the new product development process within USCI Ireland. The second part of the chapter will analyse the response from the survey to other medical device innovative companies and distributed within USCI Ireland.

Through investigation for this study it was found the nature of innovation within USCI-Ireland typically focused on products rather than the processes. This type of innovation and matching of technology to is seen as necessary to meet customer requirements and expectations.

As with many other small indigenous innovative organisations selecting the right projects is critical to the success of the organisation. There is not an abundance of resources available that would be available in larger multinational organisations thus careful selection of projects is required.

Cooper et al (2004 p34) states that “approximately one in ten product concepts succeed commercially while only one in four development projects is a commercial success” therefore a company with limited resources needs to choose their new product development process carefully to ensure it will become a commercial success.

Throughout this study it was observed extensive business development and investigations were carried out to aid project selection. Based of the initial assessment USCI-Ireland can be classified as an innovative company that successfully takes concept ideas and develops them through the new product development process through to commercialisation.

The initial assessment of the new product development process shows there are reviews held at various development phases of the new development process. These phase reviews while carried out by multifunctional teams they are predominantly focused on the regulatory aspects of the product. The reviews are carried out by the project teams and management on an irregular basis throughout the project life cycle. Review of these reviews shows there are no kill/hold decisions but action items are recorded and carried on through the next phases.

The ability to develop expertise and core competencies is also critical for the success of the organisation. Within USCI Ireland as the projects move through the phases core competencies have been developed in the area of polymer manufacture for use in medical devices. Expertise has been hired in and developed to give a competitive advantage to the organisation. While the development of core competencies is critical it is also critical for management to have the ability to recognise market opportunities, this is the entrepreneurial ability to recognise opportunities to develop innovations into commercial success.

It was observed that innovation within the organisation is driven by effective leadership. The responsibility for the discovery of new technologies lies with the senior members or the research and development department and senior management, with senior management having the responsibility for the strategic direction of the organisation. Senior management meet on a weekly basis to discuss company operational performance, strategy and future development opportunities.

The strategy for the organisation is developed through long term plans as well as short term plans and objectives.

Examining the idea generation system used in USCI Ireland shows the customer is responsible for the initial concept generation, this can be done through direct contact with the company or through the marketing department. The development of unique novel innovative solutions are encouraged by the management team.

The next section of this chapter will review the new product development process for USCI Ireland through the questions developed in the previous chapter.

The final section of the chapter will review the responses of the questionnaires received from employees and management within USCI and two other innovative medical device development companies within the Galway region.

5.1 Is there a formal voice of the customer activity within the organisation?

Developing products that are successful from a commercial point of view requires three critical inputs. The product must give the customer the functions it requires in the product, meet the regulatory requirements while still being cost effective.

The voice of the customer is becoming a critical part of the new product development process and is often forgotten about or not given the level of attention it requires to ensure the product is a commercial success. The “voice of the customer analysis as a method of identifying the key drivers of customer satisfaction. This enables the organisation to effectively design, deliver and improve its products and services”. Watson (2005 p396)

Listening to and gaining an understanding of customer requirements is an activity which takes place at the front end of the project before any concepts or prototypes are made. It is often described as the “fuzzy front end” of the project. This is the point of the project where there is very little certainty, there is a lot of interrupting of customer desires and needs. The purpose of this is to turn these desires “fuzzy ideas” into specifications which can be used by the engineers to develop products and processes.

Summary of Results.

USCI as a unique relationship with its customers through its relationship with its marketing department. A number of USCI Ireland product development activities are being conducted through an OEM contract with external organisations that do not have the core competencies, development capacity or manufacturing capacity to build these products. The OEM partner is responsible for conducting the market research, developing the voice of the customer responses and turning them into product specification. Based on the research conducted it is the OEM partner's responsibility to confirm there is market potential for this product, develop the product specification and provide the development finance for the product.

USCI Ireland provides the technology and expertise to meet the product specification requirements. The OEM partner becomes the customer for these projects. There is some interaction between both

parties at the beginning of the project and there are periodic updates and reviews of results through the duration of the project.

Previously in the early projects there had been no formal voice of the customer activity between USCI and the OEM partners. Commitment was given to meet these customer expectations and the development process began. On the initial project there were some manufacturing challenges to meet the customer requirements, these caused delays to the project as additional development activities had to be undertaken to meet the product requirements set down by the OEM partner. There was no voice of the customer activities through the duration of the project which would have allowed the team discuss the challenges with the OEM partner and investigate if this feature was critical to the success of the product in the field or if there could be some design trade-offs made to keep the project on schedule and allow it launch in its agreed time frame.

Review of the design documentation within USCI Ireland shows that the market specification documentation, which is included in the design history file is written from a customer perspective but does not require input from the customer.

Based on the successful launch of the first product development within USCI a project review was held to identify opportunities to be further successful in project going forward. Increased contact with the customers was identified as a potential source of gaining quicker time to markets.

Following this review senior management and senior research and development engineers travelled to several interventional medical conferences to gain an insight to the medical procedures and to hear surgeons speak on what are the key features on the products they see as important.

This gap analysis allowed the development team to review the shared (USCI Ireland & OEM partner) current perception of what is critical to the customer and identify features which were not significant to the design features which they currently thought were significant. It also identified key features that the customers thought were significant which the design team did not consider significant.

Currently there is no continuous voice of the customer activity through the duration of the project. This has a significant disadvantage as during the duration of the project there are significant lost opportunities for product design optimisation. This would allow decisions to be based on results of

testing, speed up decisions and develop products which will meet customer requirements and reduce time to market.

Review of the methods used to get product knowledge from voice of the customer is very limited. Through the research there are several opportunities identified to make the voice of the customer more realistic and beneficial. These include market surveys, reviews of interventional procedures carried out by volume per year, focus groups, key lead user one on one interviews, observing surgeons behaviours and reverse engineering of successful products.

Through the review of this question it has been identified there are substantial opportunities to increase the function of voice of the customer through the duration of the project.

There is currently no method to measure the voice of the customer activity through the duration of the project. This shows a deficit in the opportunity to reduce time to market and increase product time on the market and increase profit for the company.

It is recommended through this review to develop stronger voice if the customers function within the new product development process. This function needs to get strong information upfront and reduce the fuzziness of the fuzzy front end of the new product development process.

Through this review it is also recommended to develop a metrics for voice of the customer which can be developed and measured at the start of the project. It is also recommended formal reviews should be conducted through the duration of the project to ensure the product specifications still meet the key functions identified in the voice of the customer activity. The formal reviews will allow the project team share results allow design optimisations and make decisions on product specifications. This system will allow quicker response to issues and allow quicker time to market.

5.2 Are there upfront targets for product yield and product cost?

To ensure commercial success the product must meet the customer requirements but it also needs to be financial viable develop and manufacture it. Capital costs are taken into consideration, development costs are also added to the model.

At the initial stage of the project identification and selection financial considerations are analysed. Part of the decision making process is to build a financial model to investigate the costs associated with the project. The return on investment is analysed and the time to profit is also analysed.

Summery of Results.

Review of the initial financial analysis for the projects showed there were financial and manufacturing model associated with the projects.

Review of the new product development process for products that are already in this cycle shows there are targets for product yield and cost built into the product specifications. These costs are developed based on various yield and manufacturing models. These models are built on solid financial analysis and are used as part of a product decision model to prioritise projects and development activities.

The review of the new product development projects in USCI Ireland indicated that the cost of the product and yield of the product are not measured through out the duration of the project.

Review of the initial product developed by USCI Ireland showed this product had design features which allowed the product perform better than competitor products. The desire to meet the design requirements over shadowed the manufacturing requirements until late in the project. As the project neared the end of the development phase and moved to the commercialisation phase, more focus was put on the product yield and cost. Resources that were being freed up from the design activities were deployed to yield improvement activities to increase the potential revenue return from the product.

While these yield improvement teams enjoyed considerable success and increased the yield they were constrained in their efforts as the product was tied into design and technology features which could not be changed.

To increase the efficiency and effectiveness of the product yield activity it is recommended to build this into the design requirements of the new product development process. The yield and product cost will be developed up front and built into the product specification. At formal stage reviews throughout the project life cycle yield and cost will be reviewed. This will allow earlier

identification of potential technology constraints early in the process and allow new alternative technologies to be reviewed before they are tied into the design.

Through the review of the new product design process it was identified that each development run produced developed a substantial amount of measurements. It is proposed to calculate the yield for each of these development runs and iterations to allow real time analysis of the yield at any point of the project. This would also allow the project team compare the current yields to the target yields and costs and deploy additional resources to refine process, technology or develop new technology if necessary.

5.3 Are there upfront targets set for process capabilities?

Developing robust products ensures customers are satisfied with the performance of the product and the company builds a good reputation for developing and manufacturing world class products. This reputation is important within the medical device industry as customers develop a strong sense of loyalty to brands.

Robust products perform well in the field and returns of defective products are substantially reduced. Robust products typically have process capability indices built into their specifications, e.g. Cp & Cpk. This drives the design engineer to examine the tolerances required for a specification, it also drives them to centre the process around the nominal and reduce the variation in the process. Completing these tasks gives the design engineer a good knowledge of the key inputs in the process which control the outputs.

Developing processes which are robust and repeatable, help reduce the cost, increase the quality and reduce the delivery time of the product. Using engineering tools such as design for six sigma, lean manufacturing and Taguchi design of experiments will help the company develop robust products.

Developing robust products reduces the variation seen in testing results and the variation seen in the manufacturing process.

Summery of Results.

Review of the new product development process indicated there were some robust engineering activities built into the process. Design of Experiments was conducted to analyze technical issues. The design of experiments activity identified the root causes and determined robust solutions. This helped reduce the overall duration of the project as it used a systematic approach.

Review of all the projects currently in the new product development process shows there are no targets determined up front in the project planning stage for process capabilities.

Adding process capability requirements to the design criteria of the project will help develop more robust products. It will also allow the project team assess technology capabilities very quickly and focus attention on the process which will cause problems.

Adding process capabilities requirements to the project metrics will drive the right activities while developing the product. The process capability requirements will drive the products and process towards six sigma capabilities and world class manufacturing. These capability requirements will be built into the project metrics. The project balanced scorecard will track the project teams efforts in reaching these capabilities. This will ensure the product being handed over to the manufacturing department will have high yields, low manufacturing costs, will meet the customer requirements and will be repeatable.

Review of the new product development process within USCI Ireland indicates there are up-skilling activities required to bring the design engineers to a strong level of understanding of the design for six sigma process.

Developing robust processes and projects and tracking them through the life cycle of the project will reduce the time to market as there will be substantial effort put into the design activity to ensure technical issues are resolved early in the design cycle.

5.4 Is there an ongoing measure of the project spend through the project?

Project spend overruns erode the potential profits. Project spend overrun may also occur due to the additional resources or equipment required to bring the project in on time.

The main root cause of project budget over run is lack of planning, poor product knowledge and not tracking the spend as it moves through the new product development process.

Summery of Results.

There are three main properties which must be delivered by the project leader, these are the quality of the product, the agreed delivery date and the project must come in within budget.

Within the medical device industry quality requirements are paramount, on some projects several years of clinical trials, animal trials and bench testing are required to ensure the product is safe for human use. Large portions of new product development budgets are spent on investing the safety and quality of the product. In some instances the product fails to meet these requirements and are killed off.

The projects undertaken by USCI Ireland are technology enhancements which due to advances in technology develop product which exceed the performance of products on the market.

Review of the new product development process within USCI Ireland shows budgets are developed for projects at the beginning of the concept phase. This financial analysis of the product under development takes into consideration the capital equipment required for the project, the product concepts required to meet the customer expectations, the development costs which will be incurred and the resources required to complete the project through to commercialisation.

The first project undertaken by USCI Ireland encountered technical issues, this required the project leader to conduct further development activities and deploy additional resources to the project. These additional resources and technical development activities.

The project team do not have access to the budget for the product in the new product development process. There is no monitoring of the actual spend against planned spend by the project team.

The budget for the new projects within the new product development process is controlled by the financial director and the research and development manager. As components, equipment or external testing is required quotes are obtained from the vendor and purchase orders are generated. These purchase orders are then approved by the research and development manager and the financial manager.

As the project leader gains more authority and control of their project teams, there are opportunities to give greater control of the budget to the project team. They will track their spend and monitor it against the planned spend.

The project team will report project spend as part of their project metrics on their balanced score card. As the metrics is a live document monitoring the actual spend can act as a reference document to identify opportunities to reduce spend on future projects.

Closely monitoring the project spend will allow the project team to anticipate spend on long lead items and can take necessary actions, thus offering opportunities to reduce the time to market by monitoring project spend in real time.

5.5 Is there a formal technology requirements assessment conducted?

Developing products which met and exceed the desires and requirements of the customer is the goal of every organisation. As medicine advances and more treatments are now made possible, customers the surgeons require product which help advance the medicine further.

Through the history there have been collaborations between surgeons and innovative companies which have advanced medicine through this partnership.

The advances in medicine has been helped through market pull, surgeons demanding products which push materials and technologies. There have been other incidents where technology advances

has developed products and technologies which allowed medical developments which advanced minimally invasive medical practices.

Summery of Results.

USCI Ireland have developed core competencies in their research and development department through the execution of the projects which have completed and the projects which are currently in their new product development process.

Technologies were identified which were necessary to develop the core competencies within this sector. The technologies and expertise were put place and several projects were initiated.

As new projects were assessed, financial assessments were conducted as well technology assessments. All projects are put through a formal review to examine if they fit into the companies core technologies.

This assessment gives the company a strong knowledge they will be successful in the project at they have a strong knowledge base developed.

The research also identified a purposeful stretch goal for the technology for each new project. This allowed the development engineers the opportunity to develop small incremental advances to the existing technology and develop more advance prototypes and products.

This technology development and monitoring expands the design team capabilities and offers potential customers opportunity to develop the features they require of dream about on their products.

This technology assessment is a continuous and ongoing activity with USCI Ireland.

As an outcome of the research it is recommended to develop a library database of technologies assessed and their potential capabilities for the company. This will not be a project specific metrics but a research and development department metrics. The sharing of this data will make advanced technology assessment and identification quicker and more efficient in the future. It will build on existing knowledge and help projects run more efficiently and reduce their time to market.

5.6 Are there formal “Stage Gate” reviews through out the project?

Review of the new product development process within USCI Ireland indicates there is a form of stage gate reviews conducted during the duration of the project. This stage gate review is in the form of a regulatory requirements review. The project stage reviews are coordinated by the project leader and completes a regulatory – quality check list to determine if all quality requirements are met at the different stages of the project.

There is no hold decisions associated with these reviews. Risk assessments are carried out to assess the challenges to the project if open action items are carried forward in the project.

Review of the new product development process indicates there are no formal stage gates for the design process within USCI. Stage gates have shown to significantly increase the success rate of projects and reduce the time to market.

There is a substantial opportunity to develop stage gates as part of the new product development process. The inclusion of the stage gate process will give a formulised structure to the new product development process. It will allow will team members fully understand the current position of the project.

Developing the stage gate process in combination with a balanced scorecard for the project metrics will offer significant organisation changes to the project development teams. It will also offer significant competitive advantages in the development and introduction new products into a competitive market.

5.7 How is the project leader selected?

The selection of the product which is put through the development process is based on putting the proposed projects through a mathematical model to determine how profitable the product will be , the type of technologies required to develop the product and the rate of return of investment.

The selection of the correct project will ensure commercial success and profitability for the company.

The role of the project leader within USCI Ireland is to help develop the schedule, identify resources, prioritise tasks and guide the team through the development process. The project leader reports to management on a regular basis informing them of updates in the project, requests additional resources if necessary and prioritises tasks in real time, and react to development issues as they arise.

The module notes (AUA 2004 p88) tell us a good project leader should have drive and a high level of effort, which facilitates a high desire for achievement. They should also have a desire to lead the team and influence others and take responsibility. They must practice honesty and integrity and develop trust within the team. They must have self-confidence in their ability and display self confidence in their decisions and goals.

Summery of Results.

Review of the new product development process within USCI Ireland shows that great care has been taken in selecting the project leaders for each of the development process. This is critical to the success of the new product development process as the project leader will be responsible for the execution of the project plan.

The project leaders appointed for each of the project have substantial experience within the medical device development and manufacturing fields. The project leaders are driven and have a desire to lead the team to reach their goals.

The review of the new product development process within USCI Ireland shows the project leaders have the process knowledge and maturity to assign additional resources to areas of concern.

As an output of this review it would be recommended the project leader have no other function on the team other than lead, complete and update the project metrics. This would allow the addition of additional metrics to the balanced score care and the opportunity to monitor the project more efficiently and reduce the time to market.

5.8 What is the make up of the team?

The efficiency of the project team determines how successfully the project will be executed. As with the project leader the project team is critical to the success of the of the product as it moves through the new product development process. Too few resources and the project will fail to meet the predetermined goals set out my management. Too many resources and the team will become disorganised and inefficient.

According to Larson and Gobeli (1988) there are three multi-functional team approaches which yield the best performance, these are Balanced Matrix, Project Matrix and Project Team. The Project Team is suited to complex projects and the Project Matrix works well for both complex and simple projects.

The module notes describe AUA(2004 p42) describes the principles of New Product Development teamwork, they are,

1. Select cohesive teams with synergies and mutual respect for each others expertise.
2. Engage specialists from major functional areas
3. Ensure a common vision of the process
4. Organise solutions that everybody understand
5. Encourage open-minded thinking
6. Maintain a good balance between individual and group work
7. Use systematic methods
8. Use both formal and informal communication
9. Select team members based on how suited they are to specific tasks
10. Provide leadership, emphasising and practicing processes to empower the team.

Summery of Results.

The review of the project team set up in USCI Ireland shows the project team formation is a mix of the project team and the project matrix. There is a core team made up of the project team leader (senior R&D resource) an R&D engineer manufacturing engineer and quality engineer. Additional resources are drawn into the project as required to help achieve goals and time lines.

The functional managers have a close connection with the project teams and mobilises resources quickly and efficiently to projects. This mobility of resources is seen as essential for the success of the projects running concurrently within the organisation. One of the major barriers to innovation within a small innovative organisation is the availability of skilled resources. This limiting factor is seen within the project structure within the USCI Ireland project organisation.

While the close involvement of the functional managers with the projects allows the movement of resources across the teams and has helped reduce the time to market, there are further opportunities available to further reduce the time to market and increase team efficiency.

As the project leaders role moves to a full time monitoring role there is an opportunity to identify training and development required by the project team and can be given through the duration of the project. This will help make the team operate more efficiently and expand team members knowledge. This will help reduce the time to market. The learning requirements can be tracked through the project metrics. This will also act as a motivation tool for the team members.

5.9 Does the team use metrics to track the progress of the project?

Developing a successful new product development process requires continuous monitoring of the new development process and making continuous improvements to the methodologies, tools and metrics used in the process. Keeping accurate data of the new product development process is necessary to allow retrospective analysis and improvements to take place.

Review of the new product development process within USCI Ireland indicated project metrics are not currently used in existing products. The only measurements currently used by the teams are the time lines developed through the project plan and the regulatory checklist to ensure the correct data is generated for the product submission.

As an outcome of this study there is an opportunity to develop additional project metrics which will drive the project team forward and through the ongoing monitoring activities will reduce the time to market.

5.10 What metrics are used to monitor the project?

As an outcome of the previous question it was observed there are no project metrics recorded by the project team. Project time lines are monitored and adjusted as the team manage project issues and delays. Senior management monitor and track budget spend and resource allocation. They also track project schedule clashes in projects.

As stated above there is an opportunity to develop project metrics.

Ledwith (2000) presents, that there are certain factors must be present for a firm to implement an efficient and successful new product development process.

Review if the new product development process within USCI was also investigated and classified as per research carried out by Ledwith (2000). The following represents a summery of the findings under the sections described in the previous chapters.

5.11 Organisational Factors.

USCI Ireland have good relations with external customers. This relationship has been developed through successful applications of new product development projects. Strong lines of communications are maintained between project managers and customers.

Internal relations within USCI Ireland are informal with open plan offices.

Internal communication is mainly conducted through project meetings. Information is shared through these meetings. There is no formal communication between project teams and senior management team. Meetings are the main source of dissipating project information

There is an opportunity for USCI Ireland to improve the efficient of their communication to reduce time to market and increase the knowledge and efficiency of the development teams.

5.12 Development Process Factors.

Senior management show strong support to new product development process by facilitating project team's requests and requirements. Senior management have strong experience in medical device manufacturing and development. They have gained several years experience and have launched several successful commercial products.

Senior management are available to facilitate technical discussions and share knowledge with the project teams

5.13 Skills and Capabilities.

USCI Ireland new product development team members have gained experience through development work within the company and in other Galway indigenous and large multinational companies. There is a vast and deep technical knowledge base.

USCI Irelands parent group in Japan specialises in the marketing and distribution of medical devices. USCI Ireland has access to marketing resources which feeds back information from surgeons. Having access to marketing is a large competitive advantage over other small indigenous medical device companies.

The company has a strong knowledge base internally. There are subject matter experts for polymers, polymer processing, metals processing, regulatory affairs six sigma and lean manufacturing.

USCI Irelands strategy is to develop and manufacture minimally invasive medical devices which met and exceed customer requirements. USCI achieve this through strong new product development process project teams quipped with strong cross functional teams processing strong process knowledge.

5.14 Marketing and New Product Characteristics.

Through the development process USCI use reverse engineering as a tool to investigate competitor products and develop product and process technologies to give the product competitive advantage in the market place.

USCI has its headquarter in Tokyo Japan. This presents the company with a strong marketing and competitive advantage as USCI has strong market knowledge. USCI also possesses a strong knowledge of Japanese requirements and information required to achieve product approval.

Through their OEM partnerships USCI Ireland has increased their market potential by increasing their product portfolio.

There is strong competitiveness in the minimally invasive medical device sector. Success is achieved through the development of innovative products which help advance the field of medicine.

5.15 Review and analysis of questionnaire.

The questionnaire discussed in chapter 4 was distributed to the research and development and the general manager within USCI Ireland. A total of seven people were surveyed in total within USCI Ireland. The survey was carried out in confidence, allowing the respondents to give unbiased, unpressurised honest responses.

The survey would gain an insight into perception of the new product development process from employees within the research and development department in USCI. As all research and development engineers spread across different development projects, which are at different stages of the new product development process, the perception of engineers would provide an interesting insight into the new development process in USCI Ireland.

The results of the survey would provide an opportunity to make the new product development process more efficient and reduce time to market.

The survey was also sent to two senior managers in 2 innovative indigenous Galway medical device companies within the Galway medical device cluster.

The purpose of this was to benchmark USCI new product development process against two innovative medical device companies operating within the medical device cluster in Galway.

Cappella Medical is a medical device company with research and development and clean rooms in Galway. Set up in 2005 by Israeli entrepreneur Ascher Shmulemitz. Cappella employs 15 people between Boston and Galway. Cappella develops drug coated stents for the treatment of side branches of the blood vessels (bifurcations)

Cappella are currently in the final stage of their clinical trials for their first medical product. They are also at the advanced stage of completing their TUV and FDA regulatory submissions.

Proxy Biomedical, located in Barna Galway, and is the manufacturer of tissue engineering biomaterials. The company is a leading innovator in the development of next generation soft tissue implants using absorbable and non-absorbable materials. Proxy Biomedical employees 15 people at its state of the art facilities in Barna. Proxy biomedical have successfully released products into the market and has established a mature manufacturing site.

The average results from the USCI respondents were plotted against the responses from Cappella and Proxy Biomedical.

The results are presented in the graph below.

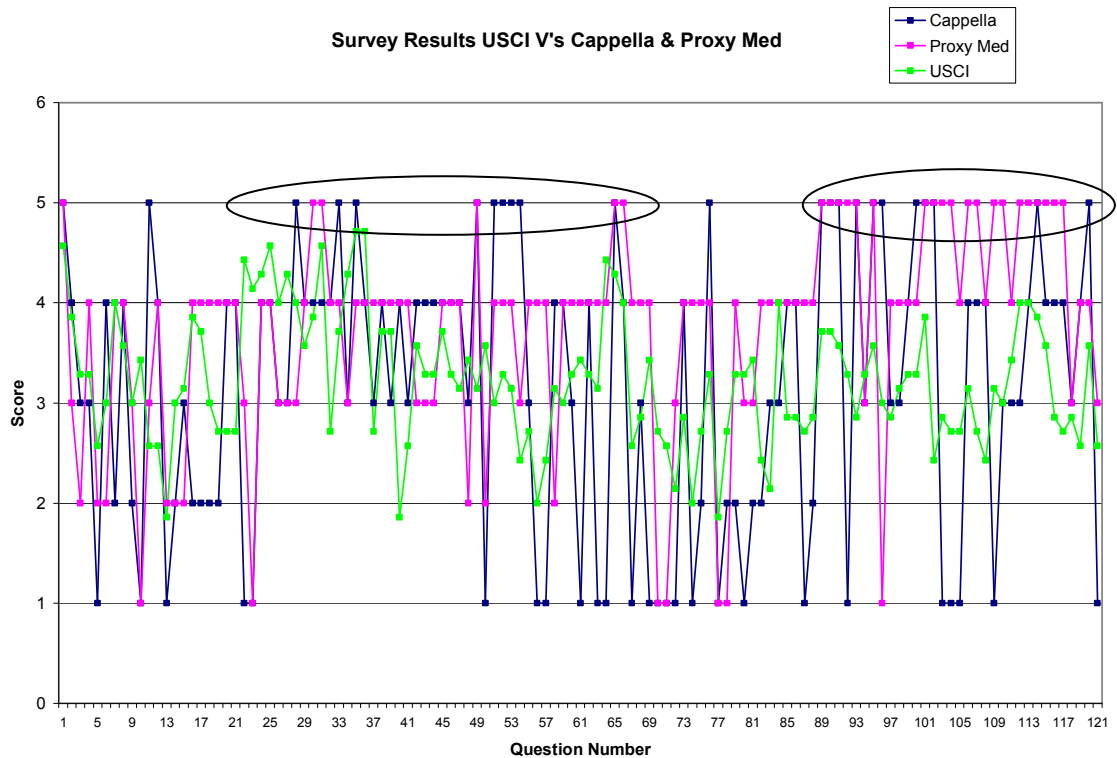


Figure 4: Survey Results; USCI V's Cappella & Proxy Biomedical.

The graph represents pictorial data comparing the response from all 3 companies. All answers are represented in the graph.

Further examination shows there are large clusters of responses which indicate USCI are not as efficient as the other companies in conducting some activities.

5.16 Assessing the difference in response between USCI & Cappella.

To assess the difference in practices between USCI Ireland and Cappella the average USCI response was subtracted from the responses from Cappella. Control limits were set up and drawn at plus 1.5 and minus 1.5 of the difference between the responses. This difference is deemed significant as it is far enough away to be significant enough to confirm a difference in the practices in both organisations. The survey results for the significant factors id presented in Appendix C.

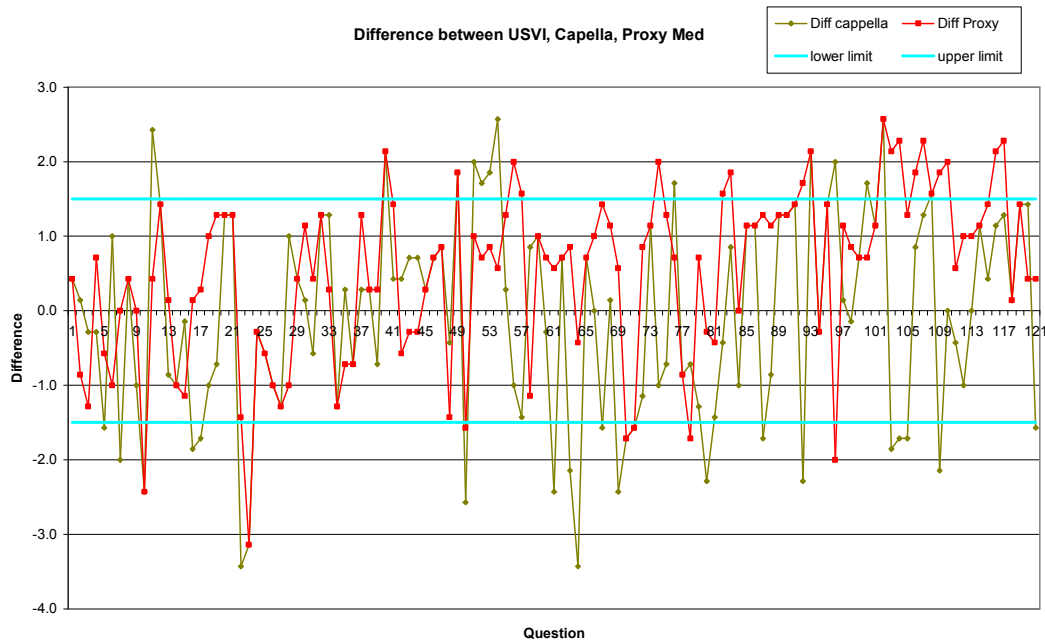


Figure 5: Difference between answers from USCI, Cappella & Proxy Biomedical

A significant negative answer indicates tasks USCI perform better than the other organisation.

A significant positive answer indicates better practices within the other organisations and offers USCI Ireland an opportunity to improve their practices.

The scope of the study is to identify opportunities to reduce time to market for the new product development process within USCI and the development of balanced scorecard of metrics to measure and track project efficiently. From this point of view we will analyse where in the process USCI Ireland fall down in the process and provide opportunity for new product development process improvements.

Q 11.Cappella use focus groups to a greater extent than USCI. Focus groups within the medical device industry consist of surgeons and medical professors who through their research are at the leading edge of medical research.

The use of focus groups can be very productive as cutting edge medical research can be combined with innovative products and lead to advances in medical surgery.

Focus groups can help speed up the time to market as they can offer constructive and efficient feedback on prototypes and development iterations.

There are opportunities for USCI Ireland to develop relationships with a focus group and help improve the efficiency of their development process. This offers insight into the testing required and details required in the regulatory submission.

Q 39. The feedback from Cappella versus USCI indicates they are significantly better at completing their projects on schedule compared to USCI Ireland. Combining this result with Q48 indicates Cappella have a closed loop system of “PLAN DO CHECK ACT” where they conduct their projects efficiently, review their performance and then adjust their process to improve it further.

There is an opportunity for USCI Ireland to develop a project review system to assess where slippage occur in the projects, adjust their new product development process and increase their efficiency and reduce time to market.

Q50, Q92. Review of these results indicates Cappella use a formal problem solving activity which mistake proofs processes. There are opportunities identified for USCI Ireland to implement formal problem solving/process improvement/ design for six sigma activities to improve project and process activities. Q51 also indicates while a continuous improvement mentality where new projects build new skills and core competencies thus developing a stronger business unit.

Q52. Careful identification and selection of projects ensure the development activities are linked to the strategic goals of the organisation. There is an opportunity for USCI to develop strong strategic goals, which will drive strategic project selection. Presenting company wide strategic goals in metrics form will clearly communicate the company’s intent and focus project activity towards achieving these goals.

Q53, Q75, Q95. Indicate the focus put on interdepartmental and cross functional cooperation to achieve new product development process success. This cross functional activity includes communication as a corner stone to efficient project execution.

The results of the study indicate an opportunity for USCI Ireland to develop cross functional communication and development activities. These will improve the efficiency of the development projects.

Q101, Q107 indicate Cappella develop their product concepts through collaboration with suppliers. These collaborations offer opportunities to use new innovative state of the art technologies to develop customer concepts.

The findings present opportunities for USCI Ireland to develop partnerships with innovative suppliers to help develop product concepts. To improve the project success criteria the development of several unconstrained project concepts is identified as a key success factor. Developing concurrent product concepts offers the development team the opportunity to select features from different concepts. Concurrent development of different concepts, no matter how off the wall they may be considered will improve the efficiency of the project development team.

As part of the new product development process metrics product concepts development activity can be recorded, monitored and tracked through the project duration.

5.17 Assessing the difference in response between USCI & Proxy.

The comparison between USCI and Proxy Biomedical indicates some common significant differences between USCI and Cappella. These common differences indicate the practices exercised by the other organisations can be classed as industry practice. These practices may be classed as common industrial practice but they may also be classed as best practice.

The results indicate an opportunity for USCI to benchmark these best practices and improve their new product development process and reduce product time to market. The survey results for the significant factors are presented in Appendix D.

Q39, Q48, Q92, Q101 & Q107 have been indicated as being significant for USCI and Cappella and Proxy Biomedical. These survey questions have been discussed earlier in the chapter.

Q55, Q56 & Q73 Proxy Biomedical show formal project planning activities. This activity at the front end of the project helps identify key projects and products which will meet the strategic goals of the organisation. The strategic review will also help identify resources, budgets and equipment required and available for the projects.

The results of this comparison indicate an opportunity for USCI to conduct deeper project analysis at the beginning of the project.

Development of formal project assessment activities would potentially resource and priority issues for the project team. These formal project determination activities could be built into a project selection metrics.

The development of these activities could highlight potential risks with products under consideration, the project development activities and resources.

Identifying key metrics, monitoring and recording them will present significant opportunities to reduce the time to market. The development of these formal project selection activities will also increase the success rate of projects selected to go through the new product development process.

Q81, Q82 Q116. Proxy Biomedical set process capability and yield activities early in the project to allow yield and process capabilities improvement activities take place over the duration of the process. This allows product and process development activities to take place concurrently. As the project moves through the process towards commercialisation phased the process is improved and ready for full scale up production.

Developing metrics for yield, cost and process capabilities can be tracked and measured during the duration of the project will reduce time to market as and develop more robust processed.

Developing targets at different stages of the projects give the project stretch goals and allow the process to mature and develop as processes as project team members gain experience in the process.

Q102, Q103 & Q105 Proxy Biomedical use multiple, explicit criteria to develop their prototypes and concepts. This gives Proxy Biomedical opportunities to develop several different concepts. Concepts are also developed and selected to meet predetermined requirements. This presents opportunities to gain an understanding of the product and development activities prior to selection. Conducting this activity gives more concrete information to develop project plans.

Implementing criteria for project concept selection at the front end of the process offers opportunities for USCI to identify higher potential concepts which will guarantee product success.

Developing project prototype selection criteria can be recorded into a metrics which will develop a leading prototype to pursue and develop through the new product development process.

Q106 Proxy Biomedical has developed a close relationship with their lead customers and includes them in their development review.

Including lead customers in design reviews offers USCI the opportunity to gain feedback in a quick manner. Questions can be answered quickly; technical decisions can be resolved quickly and clearly. This again will reduce the time to market as these efficiencies will reduce waist from the new development process.

Q91. Developing strong cross functional communication is critical to the success of the project. The sharing of data makes decision making easier, avoids costly mistakes and repeating work unnecessarily.

Q108 & Q109. Developing a good relationship with suppliers offers several opportunities for development companies. Within the medical device industry material repeatability and traceability is critical in customer safety. Proxy Biomedical have developed strong relationships with suppliers. Formal engineering analysis and supplier certification are conducted to ensure products are made to the customer requirements and are repeatable.

Developing formal supplier certification and material selection criteria is critical to the success of new development process as unrepeatability material will cause inconsistent processes and poor product yields. As USCI Ireland develops into a more mature company formal supplier procedures are being developed to ensure the purchased sub assemblies meet the desired requirements.

5.18 Assessing the difference in response within USCI.

Developing effective communications is a critical factor in developing a robust and continuously improving new product development process. Time lines can be reduced through continuous monitoring and feedback during the course of the project. The survey results for the significant factors are presented in Appendix E.

Developing measures is not enough to ensure monitoring of the new product development process. Effective measures which are defined as SMART measures are critical for the success of a project.

Through the survey, sent to the research and development department within USCI Ireland investigated the new product development process, including development activities, stage gates, design for six sigma and metrics to record and communicate project progress.

Through the analysis of the results returned it was observed some differences in the responses received. This response was analysed. A control limit developed by adding one standard deviation of the variation mean. Questions falling above this were analysed. Approximately 85% of the responses fell below this line.

Review of this variation indicates there are defecates in the method project information is dissipated through the organisation. The review also shows there are core team members who are present at meetings and have access to the information and there are extended team members who only attend meetings as deemed necessary. These members do not have access to all the information.

The difference in responses indicate there is an opportunity to develop stronger channels of communication which will reduce this variation as people will posses access to data and information.

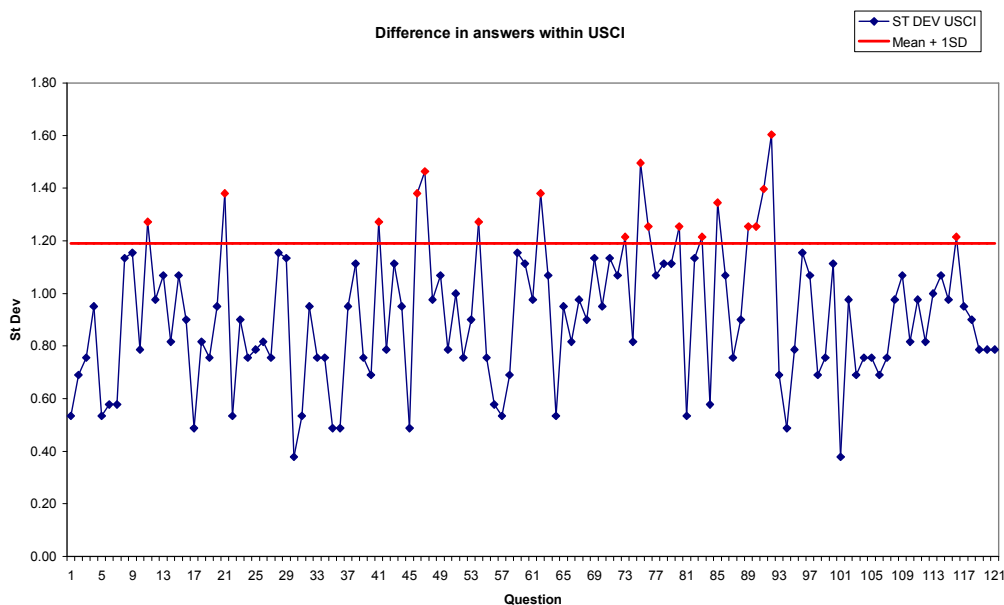


Figure 6: Difference in answers within USCI Ireland.

Chapter 6 Discussion.

This case study has examined aspects of the new product development process within a small indigenous Irish medical device organisation. The study investigates the system for developing innovations into commercially successful products.

The identification and understanding the difference in the new product development process between large multi-national organisations and small indigenous organisations is critical to the success of developing future economic success.

The study has shown there are advantages in developing a new product development process which is systematic. The development of key project indicators, used to measure and track the progress of the project will provide significant reductions in the time to market.

The study also shows USCI Ireland use a systematic new product development process which is focused regulatory requirements around staged development reviews.

The purpose of the study was to review the new product development process within USCI Ireland and investigate if there were additional systems and processes which could be added to the current new product development process to help reduce the time to market. The second purpose was to investigate through the literature review and the case study if the development of a set of metrics, used to track, monitor and introduce process improvements could reduce the time to market but introduce products that meet customer expectations.

The “fuzzy” front end of the project is where substantial reductions in time to market can be reduced the literature review shows with evidence there is substantial gains to be made by developing a systematic voice of the customer recording process.

Voice of the customer data can be systematically captured at the beginning of the project and monitored during the duration of the project.

The research into the new product development process within USCI shows there is no strong voice of the customer activities conducted. There is an opportunity for USCI Ireland to develop a strong

voice of the customer capturing process. This process could form the basis of the metrics and could be reviewed at the stage gates reviews. Through the review of the new product development process it is observed the introduction of a formal voice of the customer process would reduce the development cycle. The development of metrics to track the accuracy of meeting the customer requirements offers significant opportunities to flag issues early in the process.

Review of the new product development process within USCI shows costs and yields are identified as key components within the new product development process. These metrics are analysed at the project concept stage of the process. Review of the projects which have gone through the new product development process indicates the initial project did not conduct cost reduction or yield improvement activities until late in the project. Through the improvements in the new product development process cost and yield are tackled earlier in the future projects. Through the research carried out there are opportunities for USCI Ireland to build increasing production yields into the stage gate reviews for the duration of the project. This process can be repeated for the development of robust processes by setting process capability requirements.

Metrics will be developed within the project team to monitor and track the project spend, this is information that is currently not available to the project team.

Through the development of new products, technology assessments are continuously conducted. Technologies are advanced to meet development requirements. Review of the new product development indicates USCI Ireland conduct technology assessments. It is proposed to further develop this technology assessment by developing a database of technology assessed. This would be available as a reference for all new projects.

The new product development process employed by USCI Ireland is driven from a quality point of view. The reviews conducted use quality check lists to ensure regulatory requirements. Review of literature indicates significant advantages in developing a stage gate system into their new product development process. It is strongly recommended that the development of stage gates process be a high priority for the USCI Ireland senior management team.

Benchmarking the USCI Ireland new product development process against that of Cappella and Proxy Biomedical indicate there are opportunities for USCI Ireland to develop their new product development system further as the research indicates both companies conduct their project

management process significantly better than USCI Ireland. While it is recognised USCI Ireland execute several aspects of the new product development process better than the other companies the purpose of the survey was to identify opportunities for USCI Ireland to develop a world class new product development process.

Review of the results received from the research and development department within USCI Ireland indicated significant differences in the results received. Review of the data and demographics of the team members, (i.e. several engineers were involved in several projects others only one and some had only minor input into the projects).

Communication of key project data to all team members is critical to ensure the success of the project. The development of project metrics displayed centrally will increase the level of communication. The availability of project data will increase the efficiency of the project teams. It will also provide knowledge for other project teams.

The development of a balanced scorecard will offer a standard method of recording the metrics. It will offer a visual presentation of the metrics which will give a quick indication of the project status.

The aim of the study was to evaluate if the development of metrics within new product development process to reduce time to market. Review of the literature indicated the majority of the research was conducted in large organisations. The study found this knowledge can be transferred to small indigenous organisations. Developing a new product development process to increase the efficiency of the development cycle is essential to remain competitive in today's economic climate.

The one true way to ensure the new product development process is meeting the project requirements is to continuously measure the project outputs. Developing appropriate metrics will monitor the project output, indicating project risk, resource defecate and technology issues early in the process, allowing remedial actions and thus reducing the risk to project schedule.

The investigation into the research questions confirm the development of metrics for the new product development process reduces the time to market.

Chapter 7: Conclusions and further research.

USCI Ireland is an innovative company who have demonstrated they are capable of meeting the technical challenges associated with developing state of the art medical devices. They have shown they are capable of executing complex projects with cross functional teams.

USCI Ireland has a new product development system which is driven through project time lines (Gantt Charts) and the necessity to meet regulatory requirements through different stages of the project.

The research undertaken indicates there are large volumes of research carried out into the new product development process in large organisations. This research shows these learning are can be adapted into the new product development process in small organisations.

The research also indicates the development of a new product development process which incorporates review processes (Stage Gates) and process improvement tools (Design for Six Sigma) will develop more robust products which meet customer expectations and will reduce the time to market.

The research also indicates there are opportunities to reduce the time to market when new process development metrics are developed to capture the output of the new product development process. The research has shown there are opportunities for USCI Ireland to introduce metrics to their new product development process.

7.1 Further Research.

The purpose of this study was to evaluating the development of metrics within new product development process to reduce time to market. The research has conclusively shown there are opportunities for USCI Ireland to develop metrics which can monitor track and flag issues in the new product development process.

The research has met its objective in showing that the development of metrics will reduce the time to market. Further research is required to develop metrics which can be adapted into the new

product development process. The development of these metrics requires the input of senior management team, finance, research and development, quality and operations departments.

Training and up-skilling will be required to develop the team further in design for six sigma activities and the development of robust processes.

The development of metrics for the new product development processes within USCI will offer all resources the opportunity to review data for all projects. These metrics should be displayed centrally and will improve communication and transfer of knowledge.

The development of effective metrics will develop products which meet customer requirements, with acceptable costs and production yields in a shorter time. This will offer competitive advantage for USCI Ireland.

Chapter 8 Bibliography.

American Heart Association.

Accessed at: <http://www.americanheart.org/presenter.jhtml?identifier=1200000>

Atlantic University Alliance (AUA) (2004) “Manufacturing Improvement Methodologies” Masters in Technology Management.

Atlantic University Alliance (AUA) (2004) “Leadership, Change and Innovation Management” Masters in Technology Management.

Atlantic University Alliance (AUA) (2004) “Product Design and Development” Masters in Technology Management.

Booz Allen & Hamilton, “new product management for the 1980’s. New York: Booz Allen & Hamilton Inc., 192

Central Statistic Office (2004) EirStat Spreadsheet Service. Cork.

Cohen. M., A., Eliashberg. J., Ho., T-H., “New Product Development: The Performance and Time-to-Market Trade-off” *Management Science*, Vol. 42, No. 2, (Feb., 1996), pp. 173-186

Cooper, R.G. (2001a): “Doing it right – winning with new products”, *Ivey Business Journal*, July – August 2000

Cooper, R.G. (2001): *Winning at new products accelerating the process from idea to launch 3rd edition*, Basic Books/ Perseus Publishing, New York

Cooper, R.G., Edgett, S.J., Kleinschmidt, E.J. (2004) “Benchmarking best NPD Practices – 1”, *Research Technology Management*, January – February, 2004

Cooper, R.G., Edgett, S.J (2006) “Ten ways to make better portfolio and project selection decisions”, Product Development Institute Inc.

Accessed at: http://www.prod-dev.com/downloads/working_papers/wp_24.pdf

Cormican. K., O’Sullivan. D., “Auditing best practice for effective product innovation management” *Technovation* (2004) 819-829

Cuddy, J., (2004) “Towards an innovation culture?”. European Commission’s Enterprise DG, March 2004

Accessed at <http://cordis.europa.eu/itt/itt-en/04-2/dossier03.htm>

Curtis. A., Eatson-Hemphil. K., (2006) “Make better design decisions with VOC” accessed at <http://www.realinovation.com/content.c080602a.asp>

Dahan. E., Hauser J.R., (2001) *Product Development – Managing a dispersed Process*. The Handbook of Marketing. MIT Sloan School of Management.

Datar. S., Kekre. S., Rajiv. S, Rinivasan. K., (1997): “New Product Development Structures and Time-to-Market” *Management Science*, Vol. 43, No. 4, *Frontier Research in Manufacturing and Logistics*, (Apr., 1997), pp. 452-464

Dransfield, S.,B., Fisher, N.,I., Vogel N., J., “Using Statistics and Statistical Thinking to Improve Organisational Performance” *International Statistical Review / Revue Internationale de Statistique*, Vol. 67, No. 2, (Aug., 1999), pp. 99-122

EFGSN (2008) “Future Skills Needs of the Irish Medical Devices Sector” February 2008. Dublin

EMCC 2008. ECMM Case Study: Biomedical healthcare sector: Western cluster, Ireland. Dublin.

European Society of Cardiology.

Accessed at: <http://www.escardio.org/Pages/index.aspx>

Forfás (2006).Forfás Innovation Survey 2006. Dublin

Freeman-Bell, G & Balkwill, J. (1996) *Management in Engineering* 2nd Edition, Pearson Education Limited. Essex

<http://finance.google.com/> Accessed 5th July 2008.

Griffin. A., Hauser J.R., (1993); “The voice of the customer”, *Marketing Science*, Vol 12, No 1, Winter 1993

Hauser, J., R., (1998) “Research, Development, and Engineering Metrics” *Management Science*, Vol. 44, No. 12, Part 1 of 2, (Dec., 1998), pp. 1670-1689

Hinkle. G., C., (2008) “Five ways to improve your time to market” *Auxilium Product development excellence*.

Accessed at: <http://www.auxiliumtraining.com/FiveWaysToImproveTTM.htm>

Holt, K., (ed). 1973. *Innovation*, I.I.M.T

<http://www.isixsigma.com/library/content/c001211a.asp> Last accessed 30th August 2008

Ittner. C., D., Larcker. D., F., (1997) “Product Development Cycle Time and Organizational Performance” *Journal of Marketing Research*, Vol. 34, No. 1, *Special Issue on Innovation and New Products*, (Feb., 1997), pp. 13-23

Kaplan, R.S. & Norton, D.P. (1992) “The Balanced Scorecard-Measures that drive performance” *Harvard Business Review* January- February, page 71-19, 1992

Kaplan, R.S. & Norton, D.P. (1996) “The Balanced Scorecard” *Harvard Business School Pres.* Boston MA

Koen. P. Ajamian. G.P., Boyce. S., Clamen. A., Fisher. E., Fountoulakis. S., Johnson. A., Puri. P., & Rebecca Seibert “Fuzzy Front End: Effective Methods, Tools and Techniques”, *The PDMA Toolbox for New Product Development* (2002).

Accessed at: http://howe.stevens.edu/fileadmin/Files/publications/FuzzyFrontEnd_Old.pdf

Krishnan. V., Ulrich. K.T., (2001) "Product Development Decisions: A Review of the Literature" Management Science, Vol. 47, No. 1, Design and Development, (Jan., 2001), pp. 1-21

Larson, E.W. & Gobeli, D.H. (1988) "Organising for Product Development Projects" Journal of Product Innovation Management 5, pp.180-190

Ledwith. A., (2000) "Management of new product development n small electronics firms" Journal of European Industrial Training, 2/24/3/4 138-147

Lilien. G.L., Morrison. P.D., Searls. K., Sonnack. M., von Hippel. E., (2002): "Performance Assessment of the Lead User Idea-Generation Process for New Product Development", Management Science, Vol. 48, No. 8, pp. 1042-1059., Aug., 2002

Lipe. G., M., Salterio. S., E., (2000) "The Balanced Scorecard: Judgmental Effects of Common and Unique Performance Measures" The Accounting Review, Vol. 75, No. 3, (Jul., 2000), pp. 283-298

http://www.main-taunus-privatklinik.de/cgi-bin/mtkp/custom/pub/content.cgi?lang=1&oid=328&ticket=g_a_s_t. Last accessed 30th August 2008

http://architecture.mit.edu/house_n/documents/QuestionnaireToGuideCorporateResearch.pdf. (Questionnaire to Guide Corporate Research at MIT (2008)) Last accessed 30th August 2008

Meyer. M.H., Tertzakian. P., Utterback. J.M. (1997) "Metrics for Managing Research and Development in the Context of the Product Family" Management Science, Vol. 43, No. 1, (Jan., 1997), pp. 88-111

Munro-Faure, L., Munro-Faure, M., (1992) "Implementing Total quality management, Pitman Publishing London

Pessemier, E.A., Root H.P., (1973), "The Dimensions of new product planning" , Journal of Marketing 37, January 1973.

Phadnis . S., (2008) "Selection of Project Metrics"
Accessed at <http://www.isixsigma.com/library/content/c011008a.asp>

Rodengen. J., L., (2001) "The ship in the bottle The story of Boston Scientific and the development of less-invasive medicine" Write Stuff Enterprises, Inc. Florida

Smith., Reinersten., (1995) "Developing products in half the time", 2nd edition, John Wiley & Sons. Hoboken

Tidd, J., Besant, J., Pavitt, K, (2005) "Managing Innovation: Integrating Technological, Market and Organizational Change 3rd edition, John Wiley & Sons Ltd., Chichester

Tidd, J., (2006). Managing Innovation for Global Competitiveness, *Renaissance Project Symposium*, Tokyo, 16 March 2006,
Accessed at www.managinginnovation.com, 12th July 2008.

Tidd, J., & Hull F., M., (2005) Managing Innovation: Integrating technological, market and organizational change *Exercises and Resources*. Imperial College Press, London.

Ulrich, K.T. Eppinger S.D. (2003). Product Design and Development 3rd Edition. McGraw-Hill Education New York

USCI. Accessed at: www.usci.co.jp

Voss, C., (1998) “Made in Europe: Small companies” Business Strategy Review, Vol. 9 No 4, p1-19

Watson, G.H. (2005). Design for six sigma, Innovation for enhanced competitiveness. Goal/QPC Salem

Zirger. B., J., Maidique. M., A., “A Model of New Product Development: An Empirical Test”, Management Science, Vol. 36, No. 7, (Jul., 1990), pp. 867-883

Appendix.

Appendix A Statistics for Cardiovascular Disease Statistics

Statistics from the American Heart Association quote the following statistics.

- 80,700,000 people in the United States have one or more forms of cardiovascular disease (CVD).
- Claimed 869,724 lives in 2004 (final mortality) (36.3 percent of all deaths or 1 of every 2.8 deaths).
- Other final 2004 mortality: total cancer 553,888; accidents 112,012; HIV (AIDS) 13,063.
- Over 148,000 Americans killed by CVD in 2004 were under age 65.
- From 1994 to 2004, death rates from CVD declined 24.7 percent.
- In the same 10-year period the actual number of deaths declined 8 percent

The American Heart Association also tell us the following about Coronary heart disease

Coronary heart disease is caused by atherosclerosis, the narrowing of the coronary arteries due to fatty build ups of plaque. It's likely to produce angina pectoris (chest pain), heart attack or both.

- Coronary heart disease caused 451,326 deaths in 2004 and is the single leading cause of death in America today.
- 16,000,000 people alive today have a history of heart attack, angina pectoris or both. This is about 8,700,000 males and 7,300,000 females.
- This year an estimated 1.2 million Americans will have a new or recurrent coronary attack.
- About 310,000 people a year die of coronary attack in an Emergency Department or without being hospitalized. Most of these are sudden deaths caused by cardiac arrest, usually resulting from ventricular fibrillation.

The story in Europe is not any better, with the European Society of Cardiology quoting the following Statistics:

- Each year cardiovascular disease (CVD) causes over 4.3 million deaths in Europe and over 2.0 million deaths in the European Union (EU).
- CVD causes nearly half of all deaths in Europe (48%) and in the EU (42%).

- CVD is the main cause of death in women in all countries of Europe and is the main cause of death in men in all countries except France, the Netherlands and Spain.
- CVD is the main cause of the disease burden (illness and death) in Europe (23% of all the disease burden) and the second main cause of the disease burden in those EU countries with very low child and adult mortality (17%).
- Death rates from CHD are generally higher in Central and Eastern Europe than in Northern, Southern and Western Europe

Appendix B Questionnaire presented to Cappella, Proxy Biomedical & USCI.

A. How would you rate the challenges you faces when aligning products to customer needs?

		<i>Not Critical</i> → <i>Very Critical</i>				
		1	2	3	4	5
1	Gain a good understanding of customer needs.					
2	Trying to meet too many needs in single product or service.	1	2	3	4	5
3	Meeting too few needs in a product or service.	1	2	3	4	5
4	Trying to meet all needs rather than setting priorities.	1	2	3	4	5
5	Products are driven by “technology push” rather than a response to customer needs.	1	2	3	4	5
6	Products are not designed to meet a wide variety of customer needs	1	2	3	4	5
7	Marketing gives input product development strategy	1	2	3	4	5
8	Customers cannot articulate their needs.	1	2	3	4	5
9	Customers cannot imagine and/or evaluate possible new solutions.	1	2	3	4	5

B. Which of the following tools does your company use to discovers customer expectations and generate new product?

		<i>Not Used</i> → <i>Very Frequently Used</i>				
		1	2	3	4	5
10	Market surveys	1	2	3	4	5
11	Focus groups	1	2	3	4	5
12	One-on-one interviews	1	2	3	4	5
13	Ad hoc employee trials	1	2	3	4	5
14	Instinct	1	2	3	4	5
15	Observing behaviour and deducing needs	1	2	3	4	5
16	Reverse engineering successful products	1	2	3	4	5

C. During the product definition phase the following happens...

		<i>Not At All</i> → <i>Very Frequently</i>				
		1	2	3	4	5
17	Product requirements are refined and fed back to the customer.	1	2	3	4	5
18	Customers are involved continuously and interactively in product definition.	1	2	3	4	5
18	Project plans are most influenced by overall value to potential customers.	1	2	3	4	5
19	New product concepts are generated jointly by employees, customers and suppliers	1	2	3	4	5
20	Continuous product improvements occur because improvement ideas from customers are solicited.	1	2	3	4	5

D. How important are the following methods to get feedback on the market acceptance of your products?

		<i>Not Important</i> → <i>Very Important</i>				
		1	2	3	4	5
21	Sales reports	1	2	3	4	5
22	Customer satisfaction surveys	1	2	3	4	5
23	Salesperson feedback	1	2	3	4	5
24	Direct observation of customers using products in a hospital setting	1	2	3	4	5
25	Returned products	1	2	3	4	5

E. How critical are the following issues to the success of your organization?

			<i>Not Critical</i> → <i>Very Critical</i>				
26	Costs, make existing products for less.		1	2	3	4	5
27	Employee creativity; generating new products and product enhancements		1	2	3	4	5
28	Employee job satisfaction		1	2	3	4	5
29	Product design; fit form & function		1	2	3	4	5
30	Meeting Industry regulation		1	2	3	4	5
31	Securing intellectual property (e.g. patents)		1	2	3	4	5

E. How critical are the following to the success of your product?

			<i>Not Critical</i> → <i>Very Critical</i>				
32	Enhanced Features		1	2	3	4	5
33	Pricing		1	2	3	4	5
34	Reliability		1	2	3	4	5
35	Conformance with standards		1	2	3	4	5
36	Intellectual property to protect features		1	2	3	4	5
37	Being first-to-market advantages in the introduction of new <i>products</i>		1	2	3	4	5
38	Having new <i>product</i> innovations use the newest and best technologies available in our industry.		1	2	3	4	5

F. Rank how frequently (or not) the following happens

			<i>Not At All</i> → <i>Very Frequently</i>				
39	Our projects were completed on schedule		1	2	3	4	5
40	Our projects were completed within budget		1	2	3	4	5
41	Project outcomes agree with initial expectations		1	2	3	4	5
42	Project goals are supported by documented commitments (project contract)		1	2	3	4	5
43	These project objectives include quality cost and delivery of the new project.		1	2	3	4	5
44	Project goals are reviewed during the duration of the project.		1	2	3	4	5
45	Management communicates clearly-defined strategic objectives for our new product development projects		1	2	3	4	5

G. Rank how frequently (or not) the following lessons learned take place

			<i>Not At All</i> → <i>Very Frequently</i>				
46	Project performance is analysed against the best in class.		1	2	3	4	5
47	Improving the NPD process is the responsibility of all project teams		1	2	3	4	5
48	Improvement of the NPD process occurs through "Lessons Learned" activities held after the project.		1	2	3	4	5
49	Process learning occurs through exchange of process data and analyses of other projects		1	2	3	4	5
50	Problems are prevented from reoccurring.		1	2	3	4	5
51	NPD process goals help to build up new development competencies.		1	2	3	4	5
52	NPD process metrics are aligned with management strategic goals for the organisation.		1	2	3	4	5

H. Rank how frequently (or not) the following project selection activities take place

			<i>Not At All</i> → <i>Very Frequently</i>				
53	The projects initiation process involves all functional departments.		1	2	3	4	5
54	Project priorities are updated periodically through a systematic process.		1	2	3	4	5
55	All new opportunities are put through the formal process to determine viability and priorities.		1	2	3	4	5
56	NPD plans are most influenced by informed planning activities (e.g. SWOT, forecasting...).		1	2	3	4	5
57	Our strategy is a blend of what was planned and what emerges		1	2	3	4	5

I. Rank how frequently (or not) the following project measurement activities take place

			<i>Not At All</i> → <i>Very Frequently</i>				
58	Project schedule slippage is measured on a continuous basis.		1	2	3	4	5
59	Task duration times are tracked for specific project steps		1	2	3	4	5
60	Metrics are used to improve the NPD process		1	2	3	4	5
61	The NPD process is controlled through data on intermediate steps throughout the projects		1	2	3	4	5
62	Development process metrics are quantitative		1	2	3	4	5
63	Process data is collected.		1	2	3	4	5

J. Rank how frequently (or not) the following structured project activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
64	Product requirements are documented and subject to formal change control		1	2	3	4	5
65	Strategic reviews are held at the beginning of the project to outline goals and objectives		1	2	3	4	5
66	Reviews are conducted to select “the right project” rather than take on several projects?		1	2	3	4	5
67	Decisions on changes to product requirements are based on assessment of multiple predefined criteria		1	2	3	4	5
68	Concepts are documented and are subject to formal change control		1	2	3	4	5
69	We track the number of changes (of any type) in each project phase.		1	2	3	4	5
70	We benchmark best-in-class companies as well as competitors to assess how well we are doing in developing new products		1	2	3	4	5
71	We use structured methodologies like quality function deployment (QFD), or house of quality, to translate customer expectations into engineering requirements		1	2	3	4	5
72	Information on customer needs (i.e. external customers) and competitive conditions is disseminated throughout the company		1	2	3	4	5
73	We use decision models to prioritize projects		1	2	3	4	5
74	Structured problem-solving methods, such as cause-and-effect diagrams, are used to develop creative solutions to customer needs		1	2	3	4	5
75	Communications channels are open to all regardless of function or level in the organization		1	2	3	4	5

76	We use facilitators or 'process coaches' to help cross-functional teams to improve		1	2	3	4	5
77	Products are built using 'Design for Six Sigma'		1	2	3	4	5
78	Critical product parameters are systematically analysed (e.g. using design of experiments/Taguchi), imbedded in designs (e.g. robust methods).		1	2	3	4	5

K. Rank how frequently (or not) the following production review activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
79	Production processes are developed using off-line pilot production lines		1	2	3	4	5
80	Transition to production occurs through early product and process integration		1	2	3	4	5
81	Predetermined process capabilities are agreed early in the project		1	2	3	4	5
82	Predetermined process yields and costs are agreed early in the project		1	2	3	4	5
83	The process yields and product costs is measured and improved throughout the project		1	2	3	4	5

L. Rank how frequently (or not) the following project group activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
84	Accountability for managing a project is shared by everyone involved in the project		1	2	3	4	5
85	Project responsibilities are determined jointly by project members		1	2	3	4	5
86	Project planning emphasizes prevention of problems in projects		1	2	3	4	5
87	Project management activities emphasize proactively limiting schedule slippage		1	2	3	4	5
88	Project members communicate freely and continuously		1	2	3	4	5
89	Group achievements and individual achievements are equally important		1	2	3	4	5
90	Rewards are based on both individual and group achievements		1	2	3	4	5
91	Core project team members locate to be less than a one-minute walk away		1	2	3	4	5
92	People try to anticipate the needs of their internal customers and respond rapidly		1	2	3	4	5
93	Home department affiliations are unimportant when making product or process technology development decisions		1	2	3	4	5
94	Information related to product development & management is stored in a central database		1	2	3	4	5
95	Customer requirements are maintained in databases with multiple functions having online access to updated information		1	2	3	4	5

M. Rank how frequently (or not) the following technology activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
96	Technologies are proactively developed to gain competitive advantage		1	2	3	4	5
97	Technological changes in the industry are actively		1	2	3	4	5

	monitored and reviewed						
98	Project activities shows collaboration with external technology firms		1	2	3	4	5
99	Our company's core competencies are clearly defined and widely understood throughout the corporation		1	2	3	4	5

N. Rank how frequently (or not) the following technology activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
100	New product concepts are based on our current companies technological capabilities		1	2	3	4	5
101	New product concepts are explored in an unconstrained manner		1	2	3	4	5
102	Concepts are selected using multiple, explicit criteria		1	2	3	4	5
103	Concept selection is based on simultaneous evaluation of multiple concepts		1	2	3	4	5
104	Concept selection occurs after manufacturability issues have been assessed and addressed		1	2	3	4	5
105	Concepts are designed to optimize product performance and process performance		1	2	3	4	5
106	Lead customers/users participate in product development reviews		1	2	3	4	5
107	Suppliers help us to identify new ways of meeting customer needs.		1	2	3	4	5

O. Rank how frequently (or not) the following material selection activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
108	Suppliers are selected based on a formal supplier certification program		1	2	3	4	5
109	Materials are selected based on formal engineering analysis		1	2	3	4	5
110	Target specifications are set to minimize problems over the entire project life cycle		1	2	3	4	5

P. Rank how frequently (or not) the following project reviews activities take place.

			<i>Not At All</i> → <i>Very Frequently</i>				
111	The project is broken into development phases "stages"		1	2	3	4	5
112	A review is held at the end of each development phase "gates"		1	2	3	4	5
113	Senior Management attend these gate reviews.		1	2	3	4	5
114	Decisions about the product & project are made at these gate reviews		1	2	3	4	5
115	Project Go-Kill-Hold decisions are made at these gates		1	2	3	4	5
116	There are performance criteria (process capabilities, yield, cost, performance) that need to be met at stage.		1	2	3	4	5
117	The project remains in the current phase until the requirements are met		1	2	3	4	5
118	The "gate keeper" alters the resources on the project to meet targets		1	2	3	4	5
119	The deliverables at this gate review are examined to ensure the product meets customer requirements		1	2	3	4	5
120	Project success through these gates is measured and monitored to improve the NPD process		1	2	3	4	5

Questionnaire to Guide Corporate Research at MIT (2008)

Managing Innovation: Integrating technological, market and organizational change *Exercises and Resources (2005)*

Appendix C Cappella performs better than USCI Ireland in the following areas.

Q	Cappella Score	USCI Ireland Score	
11	5	2.6	Focus groups*
39	4	1.9	Our projects were completed on schedule
48	5	3.1	Improvement of the NPD process occurs through "Lessons Learned" activities held after the project.
50	5	3	Problems are prevented from reoccurring.
51	5	3.3	NPD process goals help to build up new development competencies.
52	5	3.1	NPD process metrics are aligned with management strategic goals for the organisation.
53	5	2.4	The projects initiation process involves all functional departments.
75	5	3.3	Communications channels are open to all regardless of function or level in the organization
92	5	2.9	People try to anticipate the needs of their internal customers and respond rapidly
95	5	3	Customer requirements are maintained in databases with multiple functions having online access to updated information
101	5	2.4	New product concepts are explored in an unconstrained manner
107	4	2.4	Suppliers help us to identify new ways of meeting customer needs.

* Cooper (2001 p181) describes focus groups as a handful of customers, either end users or industrial users as a fact and cost effective method of gaining insights into customers needs, wants and preferences.

Appendix D Proxy Biomedical performs better than USCI Ireland in the following areas.

Q	Proxy Biomedical Score	USCI Ireland Score	
55	4	2.0	All new opportunities are put through the formal process to determine viability and priorities.
56	4	2.4	NPD plans are most influenced by informed planning activities (e.g. SWOT, forecasting...).
73	4	2	We use decision models to prioritize projects
81	4	2.4	Predetermined process capabilities are agreed early in the project
82	4	2.1	Predetermined process yields and costs are agreed early in the project
91	5	3.3	Core project team members locate to be less than a one-minute walk away
102	5	2.9	Concepts are selected using multiple, explicit criteria
103	5	2.7	Concept selection is based on simultaneous evaluation of multiple concepts
105	5	3.1	Concepts are designed to optimize product performance and process performance
106	5	2.7	Lead customers/users participate in product development reviews
108	5	3.1	Suppliers are selected based on a formal supplier certification program
109	5	3	Materials are selected based on formal engineering analysis
115	5	2.9	Project Go-Kill-Hold decisions are made at these gates
116	5	2.7	There are performance criteria (process capabilities, yield, cost, performance) that need to be met at stage.

Appendix E Difference in results (low-high) within USCI Ireland.

Q	USCI LOW	USCI HIGH	
11	1	4	Focus groups (the use of focus group reviews)
20	1	5	Continuous product improvements occur because improvement ideas from customers are solicited.
40	1	4	Our projects were completed within budget
45	1	5	Management communicates clearly-defined strategic objectives for our new product development projects
46	1	5	Project performance is analysed against the best in class.
53	1	4	The projects initiation process involves all functional departments.
61	2	5	The NPD process is controlled through data on intermediate steps throughout the projects
72	1	4	Information on customer needs (i.e. external customers) and competitive conditions is disseminated throughout the company
74	1	5	Structured problem-solving methods, such as cause-and-effect diagrams, are used to develop creative solutions to customer needs
75	1	4	Communications channels are open to all regardless of function or level in the organization
79	1	5	Production processes are developed using off-line pilot production lines
82	2	4	Predetermined process yields and costs are agreed early in the project
84	1	4	Accountability for managing a project is shared by everyone involved in the project
88	1	5	Project members communicate freely and continuously
89	2	5	Group achievements and individual achievements are equally important
90	2	5	Rewards are based on both individual and group achievements
115	1	4	Project Go-Kill-Hold decisions are made at these gates