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A Study of Irish Medical Device Companies Best Practice New Product Development Tools and Methodologies

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A Research Dissertation submitted in partial fulfilment for
the Masters of Science in Technology Management in the
National University of Ireland, Galway,
College of Business, Public Policy and Law
School of Business & Economics

September 2009

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I Certificate of Authorship

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Signed: _____ Date: _____

II Acknowledgement

I would like to thank all the interviewees of this study for taking the time out of their busy schedules to allow me to meet with you and answer my study questions to form the bases of my findings and conclusions.

I would also like to thank my Research Supervisor, Dr. Ann Ledwith of the Department of Manufacturing & Operations Engineering, University College Limerick for her guidance, support and assistance over of the course of my study.

III Dedication

I dedicate this work to my wife Michelle for her support to me throughout this endeavour.

IV Abstract

The aim of this study is to investigate what New Product Development (NPD) process methodologies and what NPD tools are in use by Irish medical device companies, and to then recommend an adapted NPD process with the appropriate tools to deliver medical device companies a roadmap to choosing and bringing the right product to the market at the right time.

Case Studies were conducted on three medical device companies with their own varying characteristics. Face-to-face interviews were carried out using semi-structured questionnaires. Three R&D team members from each of the six R&D teams were interviewed across three medical device companies.

The findings found that Design for Six Sigma (DFSS) is used as an enhancement in all of the medical device companies, along with some Lean NPD initiatives, and a variety of NPD tools and methodologies and other varying characteristics.

DFSS phase methodology can be concluded as a must have for the Irish medical device company. Medical device companies must allow a feedback loop at the end of their process, which will feed lessons learned back in and allow R&D teams to continually tweak their NPD process for the best fit for them.

Lean NPD initiatives of value stream teams and reviewing the companies phase review usage should be followed. Cross functional team usage by the R&D team during NPD is a must. NPD tools and methodologies are a must have as part of the companies NPD process. Some are more than others.

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1 Introduction

1.1 Introduction

The aim of this study is to investigate what New Product Development (NPD) process methodologies and what NPD Tools are in use by Irish medical device companies. Every Research and Development (R&D) department will have some sort of NPD process already in existence. But what are the more successful medical device companies, in terms of new product sales, doing differently in their NPD process. The medical device industry is now a highly competitive industry, full of takeovers, buyouts and court cases. This study will recommend an adapted NPD process with the appropriate tools to deliver medical device companies a roadmap to choosing and bringing the right product to the market at the right time. Cooper says ‘it is estimated that only about 60% of new products launched in all industries are a success and about 45% of resources allocated to developing and commercialising new products go into products that are killed or fail’ (2001:25). This study will serve to address this generic industrial statistic, but in the case of the medical device industry in Ireland.

1.2 Rationale

The Irish Medical Devices Association (IMDA) is the business association within the Irish Business and Employers Confederation (IBEC) for the Medical Devices and Diagnostics sector.

The IMDA cites that there are over 140 companies in the medical device and diagnostic industry in Ireland. Some key facts and figure include: (Irish Medical Device Association, 2009)

- 140 medical technology companies in Ireland, exporting €6.2b worth of product annually and employing 24,000 people – The highest number of

people working in the industry in any country in Europe, per head of population

- Exports of medical devices and diagnostics products now represent close to 10% of Ireland's total exports
- The world's top medical technology companies have invested significantly in Ireland as well as indigenous companies that are emerging and competing internationally.
- The Irish government has identified the medical technology sector as one of the key drivers of industrial growth for the future

The US Food and Drug Administration (FDA) is an agency within the US Department of Health and Human Services which is 'responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation' (FDA, 2009).

FDA policies have increased the medical device company costs of research and development, product approval, and manufacturing. In an interesting article by Higgs, he cites references from various venture capitalists about how FDA policies have driven them to invest in companies in Europe. Quotes include 'don't screw around with the FDA; let's move these trails to Europe where there is a reasonable process' (Higgs, 1995). Higgs goes on to explain that even though companies move their trails to Europe, the FDA must still approve them to sell in the United States, but 'by the time we're approved in the U.S., that product will have been available in Europe on the free market for three to four years' (Higgs, 1995).

Medical devices are classified, following recommendations from FDA classification panels, into three regulatory categories: (Fries, 2006, p28)

- Class I contains devices for which general controls are sufficient. Fries describe them as non-life-sustaining. Their failure would cause no risk to life (for example: elastic bandages and examination gloves).

- Class II encompasses devices which cannot be classified in Class I, and for which special controls are required such as requiring special labelling requirements and post market surveillance (for example: X-ray devices). They are also not life-sustaining.
- Class III applies to devices that cannot be classified in Class I or II and that support life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury, [Example Catheters and cardiac pacemakers]. Fries describes them as ‘either sustaining or supporting life so that their failure is life threatening’ (2006:29).

According to the Irish Medicines board, Austria and Ireland are the European countries with the largest share of products classified into the higher risk category, Class III. ‘The result for Ireland is interesting and is associated with a large ownership of US based corporations of Irish manufacturers’ (Irish Medicines Board, 2006).

With Ireland producing one of the European’s largest share of high risk Class III medical devices, which can be grouped as high-tech products, comes the need to maintain this statistic and beyond, by having a smart and innovative New product Developed process that will turnover successful products to the market.

Considering that challenge along with a product environment that has costly and risky R&D, administration and regulatory standards, Irish medical industries must ensure they do not become complacent with their position.

1.3 Objectives

The challenge for Ireland according to the Irish Medical Devices Association ‘is to continue to develop and integrate the broad range of strategic competencies and support systems that will enable this island to compete as a mature, high value added economy, with innovation at its core’ (Irish Medical Device Association, 2009).

This study will review what current NPD processes, tools and methodologies are in use in the Irish medical device industry. What their advantages and disadvantages are, and review their performance at new product sales. These findings will form the basis in concluding what enhancements, tools and methodologies, high end Irish medical companies need to have to deliver the right products to the market at the right time.

Cooper and Edgett indicate that ‘a best-practices American productivity and quality center study reveals that almost no companies measure or report their NPD or R&D productivity as a business metric’ (2008:47).

Cooper and Edgett also cite a recent study from Arthur D.Little which ‘looked at output - measured by five-year sales from new products as a percentage of company sales – and input, measured by R&D spending, also as a percentage of company sales’ (2008:48). See Figure 1.1.

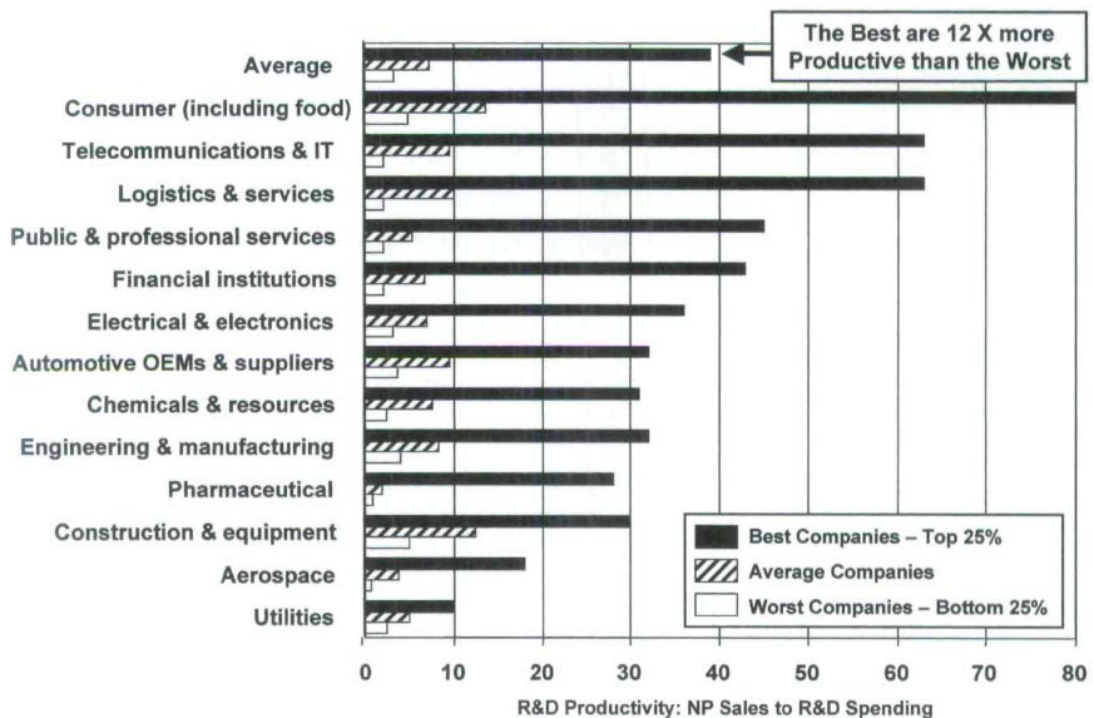


Figure 1.1 ‘NPD Productivity varies greatly among companies, with huge differences between the best and worst companies in each industry’ (Cooper and Edgett, 2008, p48)

There is no average for medical devices industries, but the average for both the Engineering and Manufacturing industries and for the Pharmaceutical industries have an approx best case performance of 30% of sales being from new products, indicating their best case productiveness in NPD. Similarly the worse performers are averaging approx 3 – 8% of sales from new products. A huge difference compared to the average best case of productiveness in NPD. This can lead to question what the difference between the best and worst performers are. And what is different in their NPD process.

1.4 Chapter Overview

The Literature review chapter introduces popular current NPD process tools and methodologies that are recommended by various specialist authors in the area. Design for Six Sigma (DFSS) is one methodology that is recommended as an enhancement to the NPD process. This methodology is summarised phase by phase through a NPD process. Through these phases various NPD tools are also recommended for use. Some of the popular NPD tools are summarised and discussed in this chapter also. The chapter also touches on the concept of lean and applying this to the NPD process as both a cost and time saving initiative. Lean also asks the company to challenge the usage of the various tools throughout the NPD process, ensuring they are really value add and not wasted effort for “ticking the box”.

The research methodology chapter firstly outlines the research question of this study. A range of research methods and their considerations are described around both the quantitative and qualitative range. The research method is chosen along with the reasons and its advantages. Finally a detailed description of the research method used is outlined followed by its limitations. The research methodology conclusions summarises the whole chapter’s main points and the resulting chosen research method.

The Findings chapter documents the finding of each of the R&D team members from each of the Irish medical device companies interviewed, about each of their

NPD process and the feedback of benefits and disadvantages they have come across. There are three Findings chapters for each of the three case studies of the three companies.

The Discussion chapter reviews the R&D team's findings and discusses whether they are as expected or not, when compared to the research completed in the literature review. It offers reasons for expected and unexpected findings by referring to both the literature review and the findings reviewed across all of the R&D teams.

The Conclusions chapter states the conclusions that can be taken for a best practice NPD process that an Irish medical device company should take based on the discussion and reasoning on NPD methodologies and tools advantages and disadvantages to a medical device R&D team.

2 Literature Review

2.1 Introduction

‘Most new product projects fail!’ (Cooper, 2001, p22). What action can be taken so as not to fall into this category? Cooper further breaks down the statistics of these failures where ‘for every four projects that enter development, only one becomes a commercial success. Even at launch, one project in three fails commercially’ (2001:22). Cooper also gives an analysis of the wasted effort to product projects that will eventually fail where ‘an estimated 46 percent of the resources’ that firms spend on the overall product development process, are ‘spent on products that either fail commercially in the marketplace or never make it to market’ (2001:22).

This overall analogy leads to the basis of the literature review where a relatively new product development process enhancement of Design for Six Sigma (DFSS) is introduced along with the theme of Lean product development. Some popular product development tools are also summarised as are advocated by both the DFSS process and the Lean product development process.

The literature review chapter will firstly review popular NPD methodologies. These are Design for Six Sigma (DFSS) in chapter 2.2 and Lean New Product Development (Lean NPD) in chapter 2.3. These methodologies direct an R&D team down a NPD process path and it recommends NPD tools that should be used along the way.

Therefore, following the completion of the DFSS and Lean NPD literature review, 13 of their NPD tools that are driven by their enhancements will be then be individually reviewed. These tools are described in chapters 2.4.1 to 2.4.13. These NPD tools are used at various phases of a company NPD process. The when and where of their use is detailed within the NPD methodologies of chapter 2.2 and 2.3.

2.2 Design for Six Sigma (DFSS)

2.2.1 Introduction

DFSS is a focused business process that can be used as an enhancement to a company's new product development process through the use of DFSS tools, management buy in and cross-functional teams. This business process hits the bottom line, improving profitability. DFSS properly applied 'generates the right product at the right time at the right cost' (Brue and Launsby, 2003, ix). Mader states that DFSS is not intended to replace a company's current design process, that 'instead DFSS methodology should be used as a framework at the macro level for deliverables and performance criteria for the design process already in place' (2003:88).

These DFSS tools, that according to Brue and Launsby generate the required predictable product, will be reviewed in the next sections. Mader also reiterates that DFSS is an enhancement to an existing new product development process and that it is 'the means to which we employ strategies, tactics and tools to enhance an existing design process to achieve entitlement performance' (2002:82).

Morgan comments that 'processes that exhibit six sigma performance are usually world class in performance level and that it is 'why the DFSS approach is becoming so popular and why it is critical to achieving customer satisfaction' (2005:106).

2.2.2 DFSS, its advantages

The probability that the customer will be satisfied with the product theoretically can be achieved to 'six sigma performance – a defect rate of 3.4 defects per million opportunities (DPMO), which is 99.9997% perfect' (Brue and Launsby, 2003, x). Table 2.1 demonstrates this defect rate and the effect on cost of poor quality. DFSS drives the user to follow a phased approach to projects many of which are similar. There are many models however the PIDOV method will be outlined as such an example in this section. The PIDOV approach applies to other versions such as:

- DMADV - Define, Measure, Analyze, Design and Verify
- DCCDI - Define, Customer, Concept, Design, and Implement
- DMADIC - Define, Measure Explore, Analyze, Design Implement and Control

Within each of these phases are many tools and methodologies through training and measurement, which can be used to guide the project to the DFSS success probability to meet the customer's expectations of the product.

Sigma	DPMO	Cost of Poor Quality
6	3.4	<10% of sales
5	230	10-15% of sales
4	6200	15-20% of sales
3	67000	20-30% of sales
2	310000	30-40% of sales
1	700000	>40% of sales

Table 2.1 An estimate of the cost of poor quality (as a percentage of sales) at each level and in terms of Defects per million opportunities (DPMO) (Brue and Launsby, 2003, p20)

As mentioned in Section 1.1, most product projects will fail with approximately 46% of resources wasted on products that are not profitable or killed (Cooper, 2001). So what does DFSS offer that can reverse this trend. It drives that organisational functions should work together through cross-functional teams to share information and born a product that has recognised the voice of the customer (further discussed in Section 2.4.4) and followed critical product requirements such quality, cost and schedule. This will ultimately positively hit a company's bottom line through successful product and launch to the required time to market, and through long term cost reductions through driving the six sigma approach to defects.

Today there is more pressure to develop products and services with greater value in less time at a lower cost. Time to develop new products and services is a critical success factor nowadays.

There are many benefits to organisations in long-term cost reduction such as development, manufacturing and service cost or product life cycle cost.

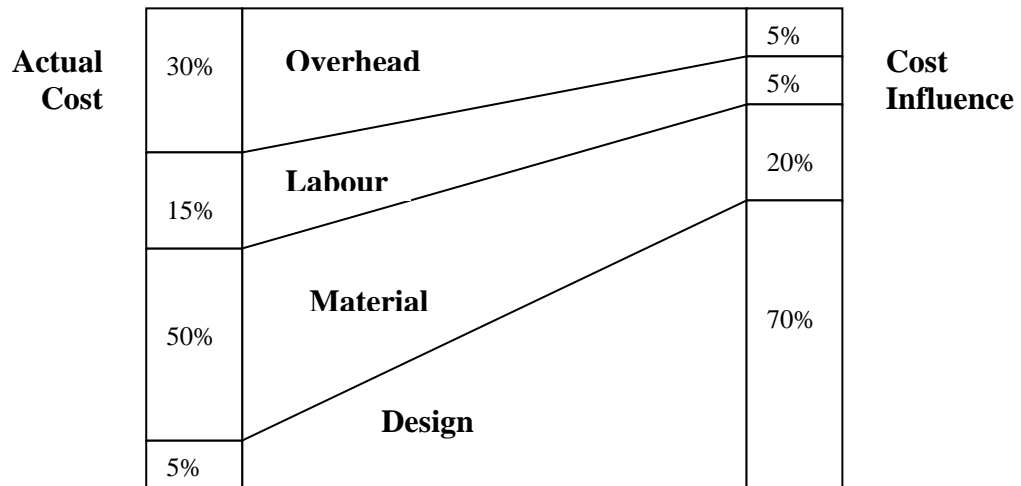


Figure 2.1 Impact of DFSS in product Design (Harry and Schroeder, 2000)

Figure 2.1 from Harry and Schroeder shows that design shows the smallest actual cost of a product but its influence is enormous on the overall cost. This drives the importance of upfront six sigma controls. It gives a great graphical representation to managers and employees to direct them to learn to think in cause and effect mode across the multi-functional team. Six sigma drives overall cost reduction but clearly cost increases such as in the design phase, are in fact a major investment in cost reduction. A simple analogy is analysing designs through for example modelling and simulation, which can prevent wasteful rework and poor quality, which may only be found at manufacturing level or worse, out with the customer. Defects cost in time and material such as scrap, rework, inspection, complaints and delays. Prevention in investing more at design level will save on these time and materials costs in the future and the company's status on delivering quality product will be held on high esteem. The better the design for the customer's requirements and their expectations, the easier it is to provide service and support.

Learning to think in terms of customers gives this new way of thinking and gives a new culture of responsibility throughout a cross functional team. Mader reminds us however that customers often ‘do not know what the next leap in development will or can be; therefore, an organization may be eternally destined to make only incremental improvements if it solely relies on the voice of the customer to dictate product development strategies’ (2003:88).

A note of caution added by Rosenau is to be aware that ‘Development teams can get so caught up in some elaborate development process protocol that they lose sight of the goal: getting the product to the market quickly’ (1996:350).

2.2.3 The IDOV Method

There are many approaches to DFSS all of which basically have similar steps. One such approach is the IDOV method (PIDOV abbreviated to IDOV). The five steps of the IDOV method as outlined by Brue and Launsby, 2003 are:

- Plan – Enable the team to succeed with the project by mapping all vital steps.
- Identify – Hear the voice of the customer to select the best product concept.
- Design – Build a thorough knowledge base about the product and its process
- Optimise – Achieve a balance of quality, cost and time to market.
- Validate – Demonstrate with data that the voice of the customer has been heard and that customer expectations have been satisfied

The DFSS approach may be structured into stages or phases as it is important for management oversight and control. The set up of a stage gate or phase gate review is often the mechanism of choice. The management team can review and assess the project at the end of each phase according to the plan initially set out. The timelines can be reviewed and key deliverables checked, so that a decision can be made whether or not the project is successful at that point and what then needs to be done. (Brue and Launsby, 2003)

As each organisation is different and their processes can vary, each NPD process approach for one organisation needs to be fine tuned over time to make a best fit. Below is an outline of a suggested approach to an organisation's process for new product development.

2.2.3.1 P – Plan Phase

This is where the team is set up to be successful in running the project. This involves selecting the project, managers to support it, choosing the people to form the team, establish a project charter and objectives, and drafting a timeline with full team input. Establishing what training is required and when it is required is also important. The work content of this phase will now be outlined. Suggested tools and methodologies will also be pointed out and these will be reviewed in the coming sections.

Project Selection can be from customer comments, customer surveys, input from R&D, Sales Marketing etc. Emphasis is on finding a highly visible project. A detailed project plan outlining timelines, milestones, and responsibilities should be defined. An important scheduling event is Phase gate reviews. They should also be scheduled in. These are reviewed in section 2.4.1.

The Project sponsor, or Champion, should be selected who is at the high management level who can break down barriers across functions, financial barriers and serves as a mentor.

The DFSS project lead should then be appointed. This person is a black belt who advocates being a change agent obviously with product development skills along with people skills. The black belt takes on the project lead role in the project.

The team itself should be cross functional (marketing, design, manufacturing, quality) who carry attributes such as highly skilled and open minded around change and in trying new things. Cooper and Edgett point out that 'in best performing businesses, effective cross-functional teams consist of key players drawn from different parts of the organisation, and players are assigned so it is clear who is on the team and who is not' (2008:53).

The detailed project plan should point to when certain areas of expertise are required and therefore when training is needed to fill these gaps (in the DFSS Tools) as the project requires it. As with any project, training is more fruitful when it is more relevant and practical, and where it is linked with real work. A training matrix should be developed based on schedule and on individual functional requirements.

A Project Charter should be drafted up and signed, the purpose of which is to set direction for the project team and define the parameters of the project. It ensures that management buy in to the project objectives, deliverables, inclusions and exclusions upfront. There are many variations of project charter. Examples of what the project charter should include are: (Brue and Launsby, 2003)

- Name of the project – give a title that describes it appropriately and sufficiently.
- Name the project leader and master black belt who will serve as a resource to the project lead.
- The scope should be defined outlining what the project is and is not.
- The starting and end point should be defined.
- The deliverables should be identified.
- The goals should be set.
- Identify the resources required.
- Identify and assess the risks to the project.
- Plan for organisational buy-in to the project.

Essentially the objective of this phase ‘is to rapidly evaluate new product ideas, answering the question, why is this a winning product?’ (Kumar and Frob, 2007, p286).

DFSS tools and methodologies which can and should be used in this phase include measurement system analysis (MSA), reviewed in section 2.4.3, Process capability data and mapping, and phase gate review (all phases). Other activities for consideration include lessons learned reviewed across all functions.

Finally, a Phase Gate project review should be carried out by management to review progress and assess whether the project merits continuing. A phase review is carried out at the end of every phase. Other criteria that should be included at the Phase gate review are metrics such as year 1 sales projections and time-to-market. These projected 'success criteria' and other data are 'a major input into the Go/Kill decision' for senior management [Cooper and Edgett, 2008, p54).

2.2.3.2 I – Identify Phase

This phase is used to identify and select the best product concept based on voice of the customer (VOC) analysis. Critical quality and technical requirements are specified through analysing the VOC results – Critical to Quality (CTQs). The work content of this phase will now be outlined. Suggested tools and methodologies will also be pointed out and these will be reviewed in the coming sections.

The customer should first be identified. Suggested tools can be to develop a prioritization matrix of customers, along with a SIPOC (Supplier-input-process-output-customer) map. See Figure 2.2 as an example.

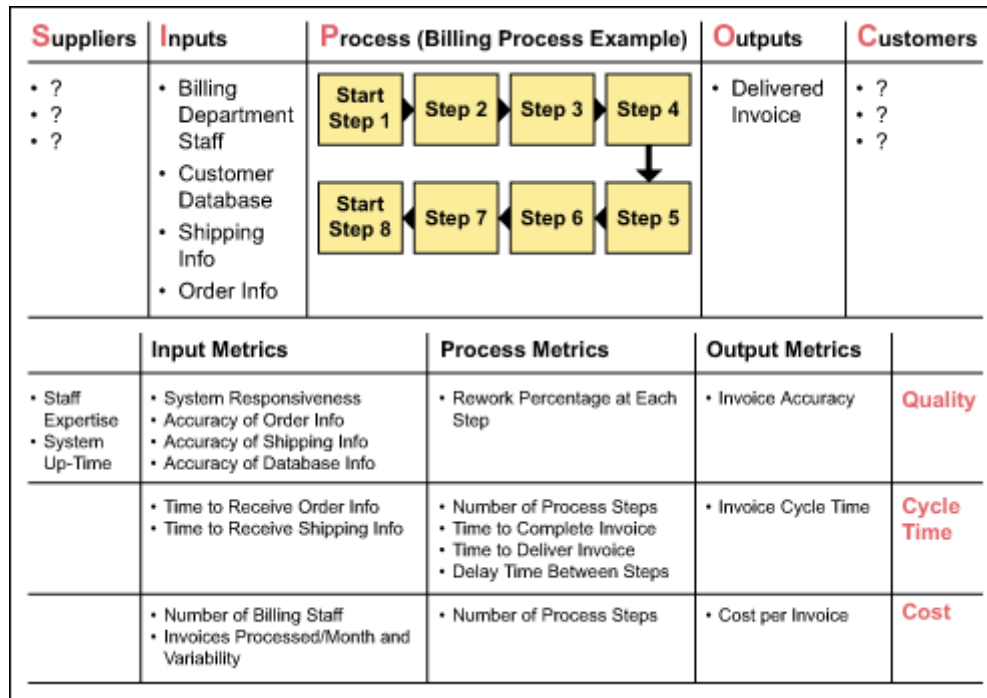


Figure 2.2 Example of a SIPOC Diagram. (Carey and Stroud, 2006)

In identifying and understanding the customer requirements, the VOC is dictated by DFSS as being essential. Methods for collecting VOC data are customer complaints, interviews (one-to-one, group discussion), customer specifications and conjoint analysis (ask the customer would they be willing to pay more for an additional feature; Is it nice to have or have to have?).

In the Identify phase, Quality function deployment (QFD) can be used to identify factors that are critical to customer satisfaction and critical to quality. QFD is discussed in section 2.4.5.

After obtaining customer feedback from the above tools, customer requirements should then be prioritised. This can be achieved by using Analytic Hierarchy Process (AHP) as a tool. Developed by Thomas Saaty, it allows the user to be subjective and at the same time apply a mathematical logic to help evaluate information and make decisions. Other requirements such as regulatory (medical devices are highly regulated) and environmental need to also be accounted for.

Another important analysis is Failure Modes and Effects Analysis (FMEA). This tool can be used to identify what are the critical success factors from the customer's point of view. FMEA is discussed in section 2.4.9. These factors can then be prioritised.

The next step would be to develop an all encompassing User Requirement Specification (URS) to capture these critical to success (or critical to quality (CTQ)) factors that have been identified. Benchmarking, discussed in section 2.4.2, can be used to set a target for performance and acceptability. From this, scorecards can be developed by the team, discussed in section 2.2.6, and used throughout the project to track progress against the design requirements and targets identified.

The next step in the Identify phase is to review potential design concepts from analysing the QFD. It is important to keep in mind components and sub-assemblies that can be reused for a particular product. This is especially true in the medical device industry. Where leveraging current components is not possible, Pugh matrix, discussed in section 2.4.7, is a useful tool to review the alternate options against what the design requirements are. The DFSS team can also conduct FMEA and possible design for X (DFx) tests for any concept that may be realised. DFx is discussed in Section 2.4.8. DFx will ensure that the actual process side of making the product is not lost when focusing the critical quality factors. Other factors such as equipment lead-time also need to be taken into account. The simple application of Poka Yoke, discussed in section 2.2.11, is very valuable to implement for mistake proofing down the line.

In aiding DFSS team concept innovation, brainstorming can be a simple tool to use. TRIZ is another problem solving methodology that can be used by the DFSS team, discussed in section 2.4.13.

The Pugh method can be used to evaluate the proposed concepts to allow the best direction to be identified. Finally the Identify phase-gate project review is carried out at management level. 'The return on investment for the company on this point forward compared with other uses for the resources is the sole basis for investing

in products at any phase despite the amount of previous investment' (Kumar and Krob, 2007, p286).

2.2.3.3 D – Design Phase

The design phase is where the functional requirements are identified through the CTQ customer factors that have been investigated. The functional requirements are then designed into concepts and solutions.

In selecting the best fit concept, again the Pugh selection matrix can be brought into play to aid in giving a first pass of selecting the best concept alternatives that should be worked on. The next pass is to use FMEA to identify what the potential failure modes might be, the key message of DFSS, being to remedy such potential problems at the early stages of the product cycle.

Tools such as Design of Experiments (DOE), discussed in section 2.4.12, simulation and modelling, should be used to identify and test the CTQ design parameters and their effects.

Again in this phase the scorecard is kept updated. Along with recording the CTQs, other data such as specifications, process capability and flags for unacceptable capabilities are recorded and followed up as appropriate.

Further testing and refinement of the Quality transfer functions, which are design functions which are influenced through CTQs, should then be tested through conducting design experiments, simulations or reviewed through benchmarking. The project scorecard records these quality transfer functions.

A word of caution from Mader here is 'a common mistake DFSS practitioners make, is to assume we are only referencing to hardware tests' where 'in fact, subjective tests such as choice modelling, focus groups and customer interviews are equally important' (2002:85).

A robust design is then created through standard design methodologies around tolerance design. It is important to realise that tolerances do influence quality, cost and time to market. The process capability indices should also be calculated. Gap analysis should be performed to identify any negative performance in the new design.

Design for X, should be worked into the design also for quality, time and cost savings further down the product life cycle.

Finally the scorecards are updated and the Design phase-gate project review is carried out. Kuber and Kron point out that lessons learned during the development of the new product should be shared across the relevant departments (2007).

2.2.3.4 O – Optimise Phase

The optimise phase purpose is the use of statistical tools and modelling to predict quality level, reliability and performance to achieve a balance of quality, cost and time to market.

FMEA and Anticipatory Failure Determination (AFD), discussed in section 2.4.10, should be used to help make predictions of failures later in the product cycle.

Again a review of the design to ensure robustness is carried out through DOE to optimise parameters and reduce variation improving the standard deviation. This optimisation addresses the CTQ factors ensuring their sensitivities are minimised and capability improvements can be identified.

Update the scorecards with the updated CTQ criteria and capability studies. Carry out the Optimise phase gate project review.

2.2.3.5 V – Verify/ Validate Phase

This phase seeks to demonstrate that the product or service satisfies the voice of the customer and that the design meets the customer CTQs.

The phase consists of validating the product, demonstrating process capabilities, checking tolerances and reliability by testing prototypes for example. Also an MSA can be carried out again to check process variation. A control plan should be set up to maintain the achieved process.

Finally the scorecards are updated and the Verify/ Validate phase-gate project review is carried out.

2.3 *Lean New Product Development*

Lean New Product Development (Lean NPD) can be described for the purposes of this study as strategies for eliminating wasted time and cost in terms of the time to market throughout the life cycle of a company's current product development process. Swink et al point out that attempts made to reduce the NPD lead-time, can raise costs, indicating that the 'probabilistic nature of NPD project activities contributes to costs increase under acceleration' (2006: 544).

Morgan and Liker indicate that Lean product development is a constantly evolving system where the 'basis of lean product development is the importance of appropriately integrating people, processes, tools and technology to add value to the customer and society' (2006:5). Morgan and Liker also reference that the lean product development system (LPDS) 'offers by far the greatest potential for a competitive advantage for any consumer-driven company' (2006:9).

The basis of Morgan and Liker's book is outlined in their LPDS model in Figure 2.3 below.

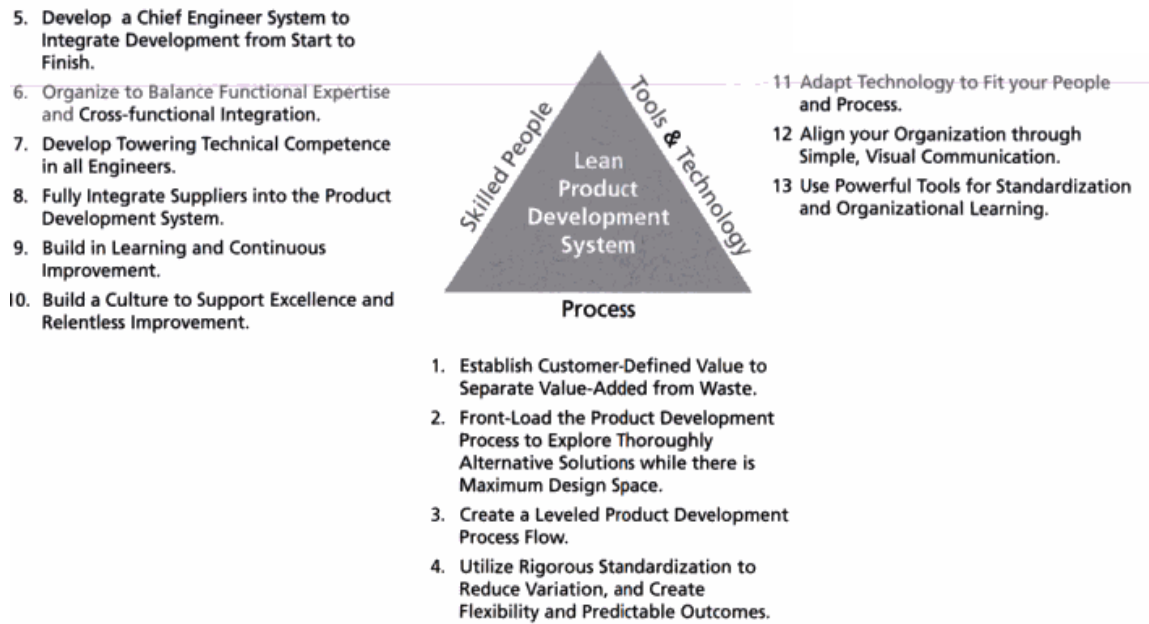


Figure 2.3 ‘LPDS Model and 13 principles’ (Morgan and Liker, 2006, p18)

Mascitelli states that there are ‘three distinct dimensions of product design and development that must be addressed’ for a firm to be competitive and ‘achieve excellence in lean product development’ (2007a:7). The first two dimensions, product achieving an acceptable high price and ‘cost optimization’ are outlined in the example enhancement process, Design for Six Sigma (Mascitelli, 2007a, p7). There are numerous tools that support this process, examples of which are described in section 2.4. Finally the third dimension is time to market. This is where lean product development comes in. Although DFSS boasts of its time to market process, lean drives from the strategic direction of time to market right down to the day-to-day activities of the design team such as email usage and meetings. It drives a lean thinking of the usage of the tools that for example are outlined in DFSS. As Mascitelli puts it ‘the market clock begins ticking when a new product becomes desirable by customers’ (2007a:9). Most time waste reduction is common sense and practical, changing the way people work every day, and improving the overall product development process.

Mascitelli has compiled a very interesting top ten list of sources of product development waste. These are: (2007a:18)

- Chaotic work environment – constant interruptions

- Lack of available resources – resource bottlenecks
- Lack of clear prioritization of projects / task
- Poor communication across functional barriers
- Poorly defined product requirements
- Disruptive changes to product requirements
- Lack of early consideration of manufacturability
- Overdesigning, analysis paralysis, gold-plating
- Too many meetings
- Email overload – the “email avalanche”

The lean methodology also touches on the voice of the customer (VOC). It however spells out what should and should not be worked on. From the VOC analysis the design team should know what adds value to the product, what is non added value but necessary for the product and what is non added value and not necessary for the product. To spell it out, the team should not be working on what is non added value and not necessary to the product. What adds value should be prioritised and more time spent on developing than what does not add value but is necessary. Again, common sense but is it happening? ‘All project value is embodied in its deliverables’ (For a task to be value-added, it must have a deliverable and a customer who needs it) (Mascitelli, 2007a, p96).

An example outlined by Mascitelli is of a Design engineer who happens to be working on a critical path item where 1 day slip is a project 1 day slip. Therefore if the design engineer is at the meeting, one could say it is a 1 hour project slip. Does the engineer need to be there? One should know the dollar value per day sensitivity of schedule slippage, even if for use as a wakeup call.

Another common sense approach is ensuring that priorities have been set by management for the design team. Setting the priorities can be achieved for example by ranking against factors such as retention of customers (or where the product is of strategic importance), market share, new markets and new technology with appropriate weighting factors. Where resourcing conflicts occur

where the resource is on critical path of both projects, management should know which project has the greater sensitivity to schedule delays.

In one of Mascitelli's articles, he suggests a simple 'three category prioritization language: must-haves, should have, and could-haves (M/S/C)' (2007b:38), in which he points out that 'this simple terminology can be applied to virtually every aspect of new product development and can have a significant impact on both time-to-market and design productivity' (2007b:38). The advantage is keeping team members focused on the most schedule challenging or technically challenging aspects of the project. It also allows scope reduction meeting the time to market goal. 'A general rule of thumb is that 80% of the profit in a company comes from 20% of the most profitable products' (Kumer and Krob, 2007, p280). Prioritising is therefore very important as by 'focusing on the few top profitable products will easily improve a company's bottom line while spending less money' ((Kumer and Krob, 2007, p280).

Other lean strategies include value stream team approach to organisational structure (which assumes the business unit has more than 100 employees). This allows team to be more focused. The grouping of the team depends on the current organisational structure and what the value stream should be formed around (product). This lean approach is 'key to avoiding resource conflicts and reducing barriers' (Mascitelli, 2007a, p76).

Cooper and Edgett advocate that 'many businesses idea-to-launch processes contain much bureaucracy, time wasting and make-work activities'. They continue by indicating that 'smart companies have made their NPD or stage gate process lean, by removing waste and in-efficiency at every opportunity' (2008:56).

Mascitelli gives interesting insight into the phase gate project process approach. He rails out the many advantages it has, especially over the "over the wall" approach just as described in section 2.4.1 later. But lean causes him to question if it is in fact best practice. He cites that many firms have adopted the phase gate structure to find that the time to market has got worse. 'It is not necessary to give

up time to market in return for managed risk and professional, high quality execution (Mascitelli, 2007a, p84). He suggests that once the phase gate structure has thought the engineer its values, the structure should be broken down to be more 'lean, efficient and natural' (2007a:84). Issues can include the lack of scaling and overkill on risk management for small projects limiting the time to market and causing loss of confidence when dealing with risk that is really low level. Suggestions can be to reduce the number of gates, allow work to continue through the gates, scale back tasks appropriately (are they redundant?). Mascitelli suggests that a company also uses the phase gates as a process for change control. A list of critical items that if changed, will change the duration of the project should be listed in these 'freeze gates' (2007a:90). See Figure 2.4. Morgan and Liker site that 'late engineering changes and the resulting expensive rework that they cause are the number one source of waste in every complex NPD process, regardless of industry' (2006:341). Ultimately the gate reviews should be finding errors, ensuring quality, and guaranteeing a successful and timely product launch.

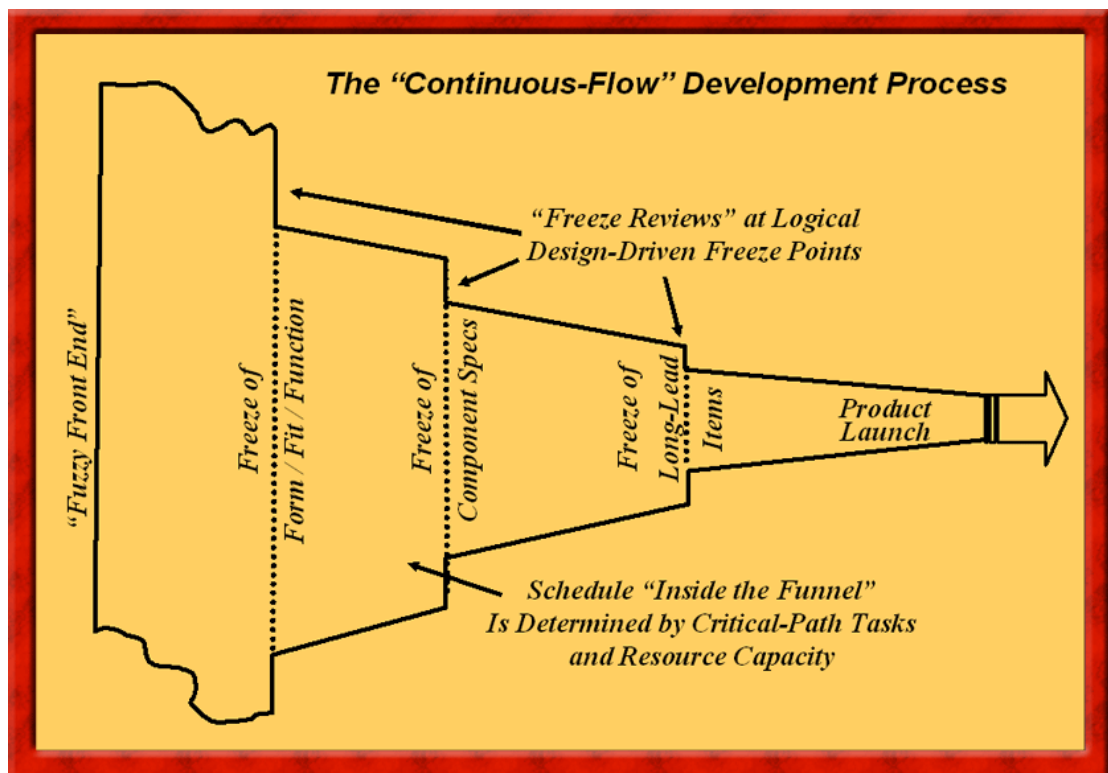


Figure 2.4 The 'Waste Free Design review' (Mascitelli, 2007a, p105)

Reviewing product manufacturing cost at the early stages of development is also important. Consider what the target manufacturing cost of the product is, can it be achieved through design for manufacturing. If not, can the price of the product be allowed to increase? If not the answer may be to kill the project and move on to a more profitable opportunity.

This also leads to the area of product value. Performance is not the only consideration. An interesting example Mascitelli cites is a paradox from Adam Smith in his book *The Wealth of Nations* where he noted ‘that if performance was the only consideration in determining the desirability of a product, then why it is that water is free and diamonds are extremely expensive?’ (2007a:145). Other product value considerations need to be taken into account such as esteem, scarcity and retained value.

Other simple Lean waste slashing methods and techniques include exception driven status reporting, Stand up meetings, time slicing, lean scheduling, email rules, and lean meetings.

It is key to realise that Lean NPD is not just about eliminating waste, as Lee-Mortimer says, ‘what managers have to recognise is that the real benefits of lean NPD come from creating flow’ (2007:48). He continues ‘It is only by focusing on flow – not wasted expenses – that they tap on the true potential of Lean NPD to simultaneously improve cycle time, quality and efficiency’ (2007:48). Examples Lee-Mortimer cites include flow improving the feedback loops of the design cycle, where they become much tighter in feeding information back such as test results and answers to key questions (2007). Lee-Mortimer recognises that ‘it would be virtually impossible to get an order of magnitude reduction in defects’ as even attempting this would ‘probably result in a dramatic reduction in creativity and innovation’ (2007:49).

The importance is of moving on and not be in a mode of waiting for the perfect information before moving forward. As Cooper and Edgett put it ‘the cost of delay should be weighed against the cost of being wrong’ (2008:56).

2.4 New Product Development Tools

Following on from the DFSS and Lean NPD chapters 2.2 and 2.3, are a list of 13 NPD tools that have been described and highlighted within these methodology chapters. Their uses, and the when and where to use them, have been documented in each of methodologies NPD process phases for use throughout a company's NPD process. Many NPD tools were described within the methodology phases, however, the 13 identified were the more popular NPD tools with in the phases that warranted further exploration. The 13 identified are not an exhaustive list as a company can apply as many tools as they like within their NPD process, but in terms of prioritising their resources and expediting time to market, these are identified as the main NPD tools of use.

The 13 NPD tools to be reviewed in chapters 2.4.1 to 2.4.13 are:

- Phase-Gate Project Reviews
- Benchmarking
- Measurement System Analysis (MSA)
- Voice of the Customer (VOC)
- Quality Functional Deployment (QFD)
- DFSS Scorecards
- Pugh Concept Selection Technique
- Design for X (DFx)
- Failure Mode and Effects Analysis (FMEA)
- Anticipatory Failure Determination (AFD)
- Poke-Yoke
- Design of Experiments (DOE)
- Triz

2.4.1 Phase – Gate project reviews

The phase gate project review is an important mechanism which provides management oversight and control. It is a management-oriented review that

occurs at the end of a project phase. The phase gate project review can also be referred to as a gate review, phase review or phase approval. Cooper says the 'process is a blueprint for managing the product innovation process to improve effectiveness and efficiency' with 'each stage consisting of a set of prescribed, cross-functional, and parallel activities' (2001:129).

The review assesses whether the project should be continued or not and that risks associated with continuation are manageable and can be mitigated. The resources to continue with the project are approved at this stage also. The same management team should be used across all projects so that consistency is maintained to the review process and that projects can in turn be compared allowing a greater ability to recognise good projects and also projects that may be in trouble. The team itself may consist of director level personnel and be the same as a product development steering team that may already be in place that manages the product development, screens the projects and recognises the priorities. There should be well-defined entry criteria, review objectives and an agenda for each phase review (Crow, 2005).

Hard and soft gates; when a company currently has an ill-defined process or if they lack any type of a phase-gate reviews, "hard" gates are best used whereby the review must be successfully completed before the project proceeds. However if a well-disciplined development process is already in place and gate reviews are a norm for development personnel, the company can use "soft" gates whereby the project is allowed to proceed in parallel with conducting the phase review. This allows a reduction of time-to-market (Crow, 2005)

Too summarise, project reviews are simply status checks which 'serve to evaluate the project plan or status relative to the initially set forth by the team in the project charter' (Waxer, 2001). Waxer points to phase review preparation such as, project progress monitoring, project guidance, breaking down barriers and displaying support, sharing of best practices and recognising and rewarding. Figure 2.5 demonstrates an example of different phase review prerequisites, timing and agendas.

Meeting Title	Program Approval Meeting	Design Approval Meeting	Pilot Approval Meeting
Timing	Prior to the Feasibility & Concept Phase	At the end of Feasibility & Concept Phase	At the end of the Prototype Phase
Stage Approved	The Program and the Feasibility & Concept Phase	Design Phase	Pilot Phase
Entry Criteria	Project Definition	Successful Concept Design Review	Successful Final Design Review
Meeting Required by	Resources can be applied to program	Quote Delivered to the Customer and Design Phase can begin	Pilot Phase can begin and production tooling ordered
Agenda	<ul style="list-style-type: none"> Program Overview Basic Customer Requirements Key Program milestone dates Product and tooling cost targets Quality targets Program risk issues Proposed NPD process deviations 	<ul style="list-style-type: none"> System Architecture Degree of new invention & technical development Manufacturing sourcing Concept Design review issues & proposed resolution Cost targets vs estimates Internal quality targets Program budget & preliminary investment requirements Program breakeven time Proposed customer quotation Updated program schedule Program staffing issues Program risk issues NPD process deviations 	<ul style="list-style-type: none"> Final Design Review issues & proposed resolution Customer satisfaction & issues Cost targets vs estimates Program budget Tooling & equipment investment & budget approval Program breakeven time Updated program schedule and status Program risk issues NPD process deviations

Figure 2.5 Phase Gate Definition (Crow, 2005).

‘The phase-gate reviews should have well-defined entry criteria, review objective and agenda for each review’ (Crow, 2005).

Of course at the end of a phase review, it is possible that the decision is to kill the project because of flaws that have surfaced. As Brue and Launsby state ‘many organisations have a very difficult time dropping projects. But killing a project early is smarter than putting a “dog” out in the marketplace’ (2003:122).

Kumar and Krob offer words of warning on phase reviews saying that researchers ‘warn against a process that puts too much of the approval and review effort onto the core team, not management’ (2007:280). They go on to say that companies that do use them often do ‘not include a feedback loop to improve future NPD projects by applying lessons learned in this project’ (2007:281).

Cooper also points to caution with use of the stage gate process, in that it should not be ‘a rigid system’ or not be ‘a bureaucratic system’ (2001:142), that it is a roadmap and not a template. This briefly overlaps with the ethos of lean product

development system regarding the use of the gate reviews and the watch out for their disadvantages.

2.4.2 Benchmarking

Benchmarking is a tool used for establishing and evaluating performance metrics and producing data and statistics based on those metrics. It is essential for use in continuous improvement and for product design. As Ulrich and Eppinger put it, ‘unless the team expects to enjoy a total monopoly, the relationship of the new product to competitive products is paramount in determining commercial success’ (2003:79).

Types of benchmarking include the following: Process benchmarking for identifying best practices both internally and externally, evaluating them and implementing the one with the best competitive advantage. Product performance benchmarking compares competing products performance, features and customer acceptance for quality improvement. Strategic benchmarking compares competing companies for marketplace competitiveness examination and use certain ideas discovered from the benchmarking studies (Bogan, 1994).

Brue and Launsby outline three types of benchmarking. The first, internal, being to determine what the best business practices are within the organisation.

Competitive to research best in class products and processes of the organisations competitors. The third, functional, is to examine product and processes that do not compete directly with the organisation. Benchmarking should allow the organisation to figure out where they want to go with its processes.

Benchmark Focus	Benchmark What?	Example Performance Metrics
Strategic Planning	Products	Average profit per unit sold
		Average sales volume per period Market share
	Services	Customer complaints per 1000 products sold
		Liability litigations per 1000 products sold
		Replacement part orders per 1000 products sold
	Business processes	Accuracy of forecast assumptions
		Customer satisfaction rating
		Defect rates
		Employee retention rate
		Training hours per employee-year
Products	Competing products	Comparative performance
		Ease of assembly
		Number of innovative features
		Number of manufacturing processes
		Number of problems found in design review
Customer Satisfaction	Customer service	Customer complaints per 1000 products sold
		Customer satisfaction rating
		Number of billing errors per period
		Percent of first-time fixes on service calls
		Percent of on-time deliveries
Internal processes	Current practices & Capabilities	Comparative cost per part
		Comparative cycle time
		Competitor capabilities
		Cost per selected result
		Mean time between repairs
		Number of problem free machines
		Percent of process performance improvement
		Project completion cycle times
Inputs	Suppliers, parts	Defects per 1000 parts delivered
		Downtime due to shortages (JIT)
		Number of quality improvement programs
		Percent of parts meeting specifications

Table 2.2 Example Benchmarking focuses and examples of their possible metrics (Hiam, 1992, p296)

From the Table 2.2 above, the process of benchmarking should be adapted to the objectives of the organization. Customer expectations should be covered through a list of the benchmarking metrics generated.

Brue and Launsby offer a note of caution where ‘benchmarking best practices may not help in developing a design, and may actually hurt, since sometimes

comparisons - even with the best - can hinder creativity' as 'knowing something is the best can be intimidating' (2003:123). Another note of caution is from Cooper where he identifies problems such as 'getting the cooperation and the truth from participating firms' (2001:70).

2.4.3 Measurement System Analysis (MSA)

Measurement is an important factor in the DFSS process. MSA should be used 'when the project team identifies channels for process capability on the means of measuring process capability' (Brue and Launsby, 2003, p123).

MSA generally involves factors such as repeatability, reproducibility, stability, linearity, bias and discrimination. 'When appraisers/operators do not measure a part consistently, the expense to a company can be great: satisfactory parts are rejected and unsatisfactory ones are accepted' (Breyfogle, 2003, p307). Breyfogle also points out that a poor measurement system can cause loss of sales and unnecessary expense in trying to fix a product of manufacturing problem where the source of the problem is the measuring system (2003:307). In MSA you should firstly consider if you are addressing the right thing. Gauge repeatability and reproducibility (R&R) study is one example of a MSA tool used to evaluate measuring instruments. This kind of activity ensures that during the NPD process, engineers can make confident analyses and conclusions throughout the process and not be based on assumptions or inadequate considerations.

2.4.4 Voice of the Customer (VOC)

The Voice of the Customer (VOC) is used to describe both the stated and the unstated customer needs or customer requirements. 'Capturing the voice of the customer early within the DFSS process is essential to creating a successful design' (Breyfogle, 2003 p909). This is further challenged when a company may have to listen to the needs of multiple stakeholders which 'requires a company to be able to conduct manifold market research and to consolidate opposing needs' (Bamforth and Brookes, 2002, p809). Bamforth and Brookes go on to say that

‘manufacturers have a key role to play in improving quality via customer input into the product design process’ (2002:809).

Breyfogle references some market place phenomena of customer behaviour. For example ‘on problems with a loss of over \$100 and where a complaint has been resolved, only 45% of customers will purchase again’, also ‘word of mouth is significant’ where 16 people will be told if a customer is not satisfied with a compliant resolution (2003:53). Customer satisfaction, retention and loyalty are an important business factor.

There are a number of ways to capture the VOC: interviews, surveys, focus groups, customer specifications, observation, warranty data, field reports, etc. Once the target market and subsequent customers have been identified, the next step is to plan how to capture these customer's needs or requirements for a specific project. This plan includes specifying how to identify target customers, what customers to contact to capture their needs, how one would collect their needs, and a schedule and estimate of resources to capture the voice of the customer. The ‘VOC must be heard accurately and interpreted accurately if high quality products are to be designed and marketed successfully’ (Urban and Hauser, 1993, p336).

Appropriate techniques are used to capture the voice of the customer, as opportunities arise. The nature of the customer relationship will dictate the appropriate technique. This is illustrated in Table 2.3 below. Cooper and Edgett also list six different methods of undertaking VOC work. These are: (2008:51)

- Customer visits with in-depth interviews
- “Camping out” or ethnography
- Lead user analysis
- Focus group problem detection sessions
- Brainstorming group events with customers
- Crowd sourcing using online or IT-based approaches

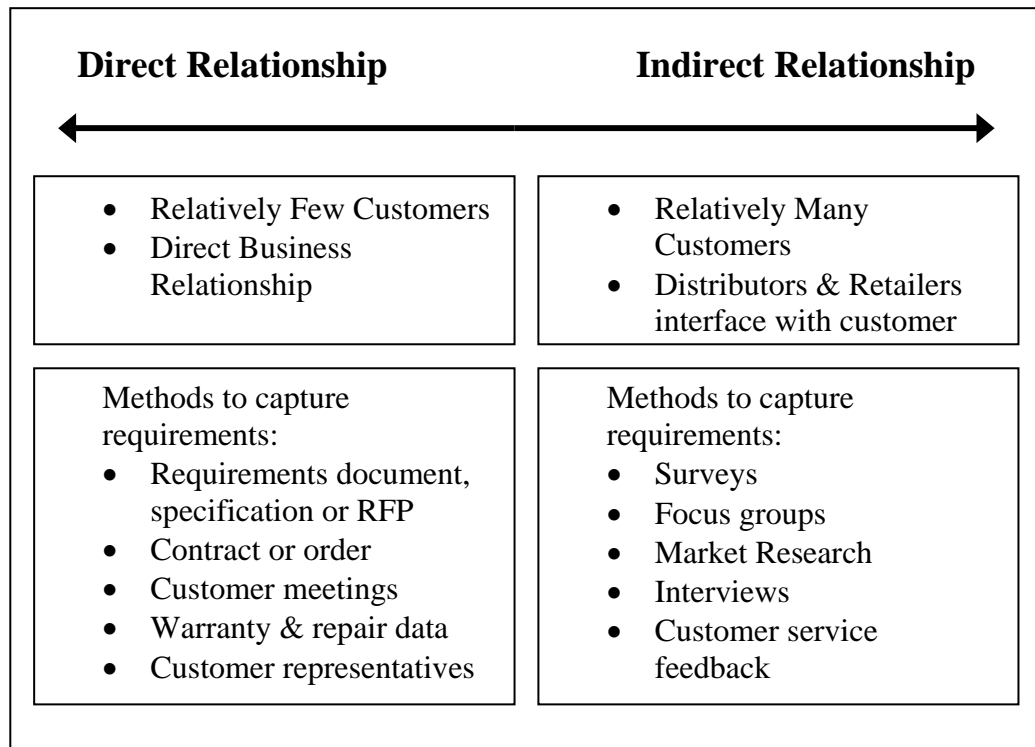


Table 2.3 The Customer Relationship – the appropriate technique (Crow, 2002c)

The traditional scenario of marketing having the responsibility for defining customer needs and product requirements tends to isolate R&D and Product development personnel from the customer and from gaining a first hand understanding of customer needs. Product development personnel need to be directly involved with marketing in understanding customer needs. It aids to minimize hidden knowledge, overcome technical arrogance and provide more openness for development decisions.

The number of customers that should be captured depends on the product complexity, market diversity, product use, and the sophistication of customers. Research for a range of products indicates that, 20 customers on average would fulfil the goal to get to the 90-95% level of capturing customer needs (Crow, 2002c).

There are different types of customers where needs can be captured. They can be current customers, potential customers, competitor's customers, and lead customers.

After identifying the basic customer needs, priorities related to each need should be addressed as not all customer needs are equally important. Ranking and comparisons can be used to aid in prioritizing these customer needs and understand how satisfying the need will influence the customers purchase decision.

The customer's perspective on the proposed product relative to the competition should be obtained once the concept for the product has been determined or when a prototype has been developed. This will allow ranking of the proposed product or prototype against competitor products.

In addition to 'stated' customer needs are the 'unstated' needs or opportunities. These needs are assumed by customers and do not become stated or verbalised during discussions.

2.4.5 Quality Function Deployment (QFD)

Quality Function Deployment (QFD) is a structured approach to translating defined customer needs into specific plans to produce products to meet those needs. QFD is a 'useful customer driven product development tool for translating the needs of the customer into efficient communication' through the various NPD phases to 'achieve customer satisfaction' (Chen and Ko, 2009, p2620). Fries describes QFD as 'a process in which the voice of the customer is first heard and then deployed through an orderly, four phase process in which a product is planned, designed, made, and then made consistently' (2006:124). As described above, the voice of the customer is used to capture both the stated and unstated customer requirements and needs, through interview, surveys, focus groups, customer specification and observation etc.

The process of QFD involves building matrices, the first being the House of Quality (HOQ) matrix. The HOQ displays the customer's needs and wants along the left hand side and the design team's response to these needs and wants along the top. HOQ is an important tool for QFD activities, 'containing information on

the “what”, “how”, relationship between “what” and “how”, and the relationship between the “how” factors themselves’ (Chen and Ko, 2009, p2621). Cohen gives an example of a QFD house of quality template in Figure 2.6.

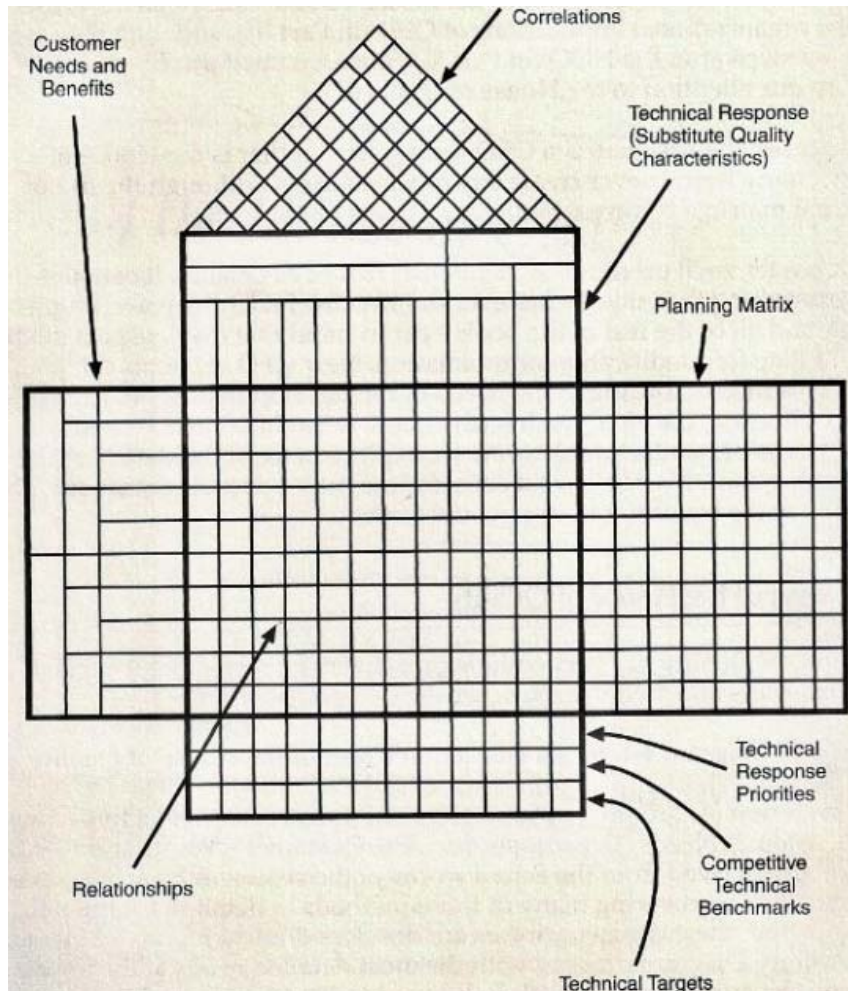


Figure 2.6 The QFD House of Quality (Cohen, 1995, p70)

The QFD matrixes are a great communication tool for competitive analysis and to allow the real value of decision making through the involvement of various functional departments (Marketing, R&D, Manufacturing, Customer Support, Finance etc). This allows essential requirements, constraints and hidden knowledge to be communicated for the ultimate outcome of a satisfied customer.

Cohen indicates that ‘QFD optionally involves constructing additional matrices which further guide the detailed discussions which must be made throughout the

product development process' (1995:13). Matrices can be prepared at each of the four phases indicated by Fries above. For example a new product concept selection matrix can also be drafted to help with the evaluation process of analysing and evaluating through cost studies and trade studies. See Figure 2.7 below for an example of a concept selection matrix.

Criteria	Importance Rating	Concept A	Concept B	Concept C
Low APU Weight	4	⊙ 20	○ 12	○ 12
Low turbine wheel weight	4	⊙ 20	○ 12	⊙ 20
Controlled turbine inlet temperature	6	○ 18	⊙ 30	△ 6
Acceptable turbine assembly life	5	○ 15	⊙ 25	○ 15
Turbine assy tri-hub containment	5	⊙ 25	⊙ 25	○ 15
High equivalent shaft horsepower	4	△ 4	⊙ 20	⊙ 20
Strong internal containment ring	4	○ 12	⊙ 20	○ 12
Total		114	144	100

Figure 2.7 Concept selection matrix (Crow, 2002a)

Another example of a QFD matrix is the deployment matrix. The product requirements are translated into critical part characteristics. Product requirements and the critical part characteristics relationships are established and important ratings calculated along with the target values for each part characteristic. A part/assembly deployment matrix example is shown in Figure 2.8 below.

Product Design Requirements	Priority	Critical Part Char. Targ. Value	Turbine wheel					Combustor		
			Balanced	Surface finish	Backface geometry	Grain refinement	Airfoil geo. & thickness	Material	Linear pattern factor	Nozzle throat area
Low APU Weight	4	158lb					⊙	○		
Low turbine wheel weight	5	<4lb			○	⊙	○			
Controlled turbine inlet temperature	6	1850° max				○			⊙	⊙
Acceptable turbine assembly life	3	3,000 hrs	⊙		⊙	⊙	⊙	⊙	⊙	
Turbine easy tri-hub containment	4	2.5lb ⊙ PW		⊙	⊙	⊙		○		○
High equivalent shaft horsepower	4	350 hp		⊙		○				⊙
Importance Rating			15	40	35	90	50	39	⊙ Strong relationship ○ Mild relationship	

Figure 2.8 Part/Assembly Deployment Matrix (Crow, 2002a)

To sum up, QFD begins with product planning; continues with product and process design and finishes with process control, quality control, testing, support and training. Multiple functional disciplines are therefore required to address these ranges of activities adequately. QFD provides the structured process required for these teams to begin communicating, making decisions and planning the product before plunging into actual design activities before a consensus has been reached giving greater overall commitment.

A cautionary note from Fries is that QFD ‘should be viewed from a very global perspective as a methodology that will link a company with its customers and assist the organisation in its planning process’. Fries points that organisations often just build matrices in doing QFD where the result is that ‘building the matrix becomes the objective of the process’ (2006:125).

2.4.6 DFSS Scorecards

The development team use scorecards to record design requirements, capture information, estimate performance, track results and make any gaps obvious and actionable. Brue and Launsby define it as a ‘systematic way for the project team to set goals, predict results, calculate capability, identify gaps and track

- Aim for a world-class concept, settle for nothing less
- Start with the best current concept, even if it's the competition's
- Either beat the best current concept or use it

Frey et al sets the goals of the Pugh selection process as a 'controlled convergence on a strong concept' and a 'shared understanding of the reasons for the choice' (2009:42). Frey cites that most engineers use informal concept review meetings to which he says he thinks is 'somewhat too little structure in engineering practice today' (2009:45).

Brue and Launsby recommend that two passes be made in evaluating design alternatives. The first using the Pugh concept selection technique and the second using FMEA along with the Pugh selection matrix. There are a number of steps to follow in completing the Pugh selection matrix. A basic example of a completed Pugh selection matrix is included in Table 2.4 below.

Concepts						
Criteria	A	B	C	D	E	F
Ease of use	0	–	0	–	–	0
Ease of transport	0	–	–	0	+	0
Reliability	+	+	0	+	0	+
Accuracy	0	0	0	0	–	0
Durability	0	0	0	0	0	+
Aesthetics	+	–	–	0	–	0
Sum of +	2	1	0	1	1	2
Sum of 0	5	2	5	4	2	4
Sum of –	0	3	2	1	3	0
Score of	2	–2	–2	0	–2	2
Rank	1	3	3	2	3	1
Continue	Yes	No	No	Yes	No	Yes

Table 2.4 Pugh matrix (Brue and Launsby, 2003, p137)

2.4.8 Design for X (DFx)

DFx is an important part of DFSS, both in the identify phase in selecting the product concept and in the design phase to mitigate and manage risks. This mitigates against the age old problem of manufacturing and assembly problems found at the optimisation phase. Thus early design reviews will improve quality. Lower costs and reduce time to market. Breyfogle describes DFx as a strategy where ‘the design is continually reviewed for the purpose of finding ways to improve production and other non-functional aspects of the process (2003:910). ‘Design for X is the value-added service of using best practices in the design stage to improve X, where X is one of the proliferations of purposes or concerns’ (Brue and Launsby, 2003, p138). There are a number of DFx purposes or concerns. For example, Design for Assembly (DFA) focuses on the assembly part of the manufacturing process. DFA techniques ‘simplify the product by focusing on parts count reduction through elimination or integration of parts’ (Selvaraj et al, 2009, p14). Huang outlines factors DFA considers related to the subject product, ‘including part symmetry, size, weight, fits, orientation, form features’ and also factors relating to the assembly process ‘such as inserting, handling, gripping, orienting, special tooling’ (1996:1). Examining such potential issues carefully, brings better teamwork cooperation, resulting in better design decisions and assembly efficiency down the line. Design for Manufacturing (DFM) is another popular DFx function. ‘DFM methodology involves considering design goals and manufacturing constraints simultaneously in order to identify and alleviate manufacturing problems while the product is being designed’ (Selvaraj et al, 2009, p14)

DFA is one such example. Brue and Launsby list a number of DFx families: (2003:138)

- DFM – Design for Manufacture
- DFMA- Design for Manufacture and Assembly
- DFR – Design for Reliability
- DFT – Design for Testability
- DFC – Design for Cost

- DFS – Design for Serviceability
- DFQ – Design for Quality
- DFF – Design for Fabrication
- DFD – Design for Disassembly
- DFD – Design for Diagnosis
- DFI – Design for Inspection
- DFG – Design for Green

Haung points that the use of DFx is ‘both encouraging and disappointing’ as ‘the number of companies who are using DFx is small relative compared to the manufacturing population’ even though many companies would like to introduce it (1996:13).

Using DFx early in the design process may require additional effort, however, these approaches bring along improved business practices, management philosophies and technology tools that result in a product that is more producible and transitions to manufacturing quickly with a low life cycle cost.

2.4.9 Failure Mode and Effects Analysis (FMEA)

‘The failure mode and effects analysis (FMEA) is a method of reliability analysis intended to identify failures which have significant consequences affecting the system performance in the application considered’ (Fries, 2006, p169). It is a methodology used for analyzing potential reliability problems in the development cycle at the early stages where issues can be more easily overcome. As outlined in the Pugh selection technique, it can be used in evaluating a design concept for failure modes so that they can be addressed there and then. Breyfogle maintains that for companies to remain competitive they must continually improve. The benefits he draws from executing FMEA include: (2003:360)

- Improved product functionality and robustness
- Reduced warranty costs
- Reduced day-to-day manufacturing problems

onto a risk outlined by Segismundo and Miguel that ‘one of the biggest risks that occur in projects currently using FMEA is when the team finishes working on a certain phase’ and ‘moves on to the next’ responsibility for implementing improvement actions are delegated to the quality group instead of finished out properly (2008:900).

2.4.10 Anticipatory Failure Determination (AFD)

Anticipatory Failure Determination (AFD) is a methodology used for failure analysis like FMEA. However it identifies and mitigates failures from a different perspective. It asks the developer to study the failure as the intended consequence and come up with ways to allow it to happen reliably. ‘Anticipatory Failure Determination (AFD) is used to reverse the problem and view a failure as something intended – and the project team tries to devise ways to ensure that the failure always happens reliably’ (Brue and Launsby, 2003, p147).

AFD avoids this risk of the denial phenomenon where people would rather not think about the worse case scenarios and possibilities. As FMEA gives results from knowledge of the team members and their experiences, the theory is they may not want to think about some worse case scenarios.

Brue and Launsby reference an insight into AFD from a fellow colleague where he says ‘the psychological effect of switching the question from “What could go wrong?” to “How can I make it go wrong” is simply amazing’ (2003:148).

2.4.11 Poka-Yoke

‘Products that go together only one way require less worker training, perform more reliably, and repair more quickly. Then the advantages kick in’ (Dvorak, 1998, p181).

The name Poka Yoke is Japanese for mistaken-proofing. It was developed by Shigeo Shingo, a Toyota engineer. Shingo defines a poke-yoke system of

possessing two functions: ‘it can carry out 100 percent inspections and, if abnormalities occur, it can carry out immediate feedback and action’ (1986:99). A poke-yoke can be of various types. These include a control method, a warning method, a contact method, fixed-value method or a motion-step method (Shino, 1986)

Shingo maintained that ‘mistakes will not turn into defects if worker errors are discovered and eliminated beforehand’ (Shingo, 1986, p50). Shingo outlines that people say it is impossible to eliminate defects from any human task, but he points out that this is because there is no separation between errors and defects. As he puts it ‘defects arise because errors are made; the two have a cause and effect relationship (1986:82).

A simple example that Shingo shared was how poke yoke can be used to find mistakes at a glance. If a worker has to assemble a device with two push buttons and two springs for each one, a worker can sometimes forget to put a spring under one of the buttons and a defect then occurs. Here a simple poke yoke device consisting of a small dish that the worker uses to count out two springs before each assemble. After the assembly is complete, if a spring remains in the dish, an error is occurred. The assembly can be immediately remedied. Here the cost of this inspection is negligible, looking at the dish, and the rework at this point is minimal compared to being discovered at a later stage. In these simple cases, poke yoke is an effective device compared to demands from management for greater worker diligence and calls for being more careful. (Shingo, 1986)

The goal of Poke-Yoke is to engineer the process so that mistakes are prevented or that there is an ability to immediately detect and correct the mistake, by being a cheap introduction to the process itself, at the source of where mistakes are made. The best poka-yoke ideas are ‘simple, inexpensive, and fail-safe’ (Dvorak, 1998, p183).

2.4.12 Design of Experiments (DOE)

DOE is an effective method for solving complex problems with many variables, as the project team needs to identify cause-and-effect relationships (Brue and Launsby, 2003). A robust product is achieved when it works as it has been intended to, even if the product's manufacturing process varies or if there is variation from product deterioration or if there is variation in its use. The product designer must understand what the sources of variation could potentially be and use this knowledge to make the product less sensitive to variation, therefore giving a robust design. Breyfogle directs that 'DOE techniques are useful when a practitioner needs to "kick" a process so it can give us insight into the possible improvements' (2003:549). DOE techniques offer a structured approach for changing many factor settings at the same time, interfering with the process, while observing for any improvements or degradation made. The effects of several factors can be considered at the same time in one experiment, without the need to evaluate each possible combination of factors (Breyfogle, 2003).

Wang and Liu eludes to this also when they refer to researchers starting on measuring and obtaining results before they start work on modelling, instead of planning proper experimental designs to 'reduce the empirical loading as well as simplify the analysis of decisive variables' (2004:220).

The designer must understand which design parameters are critical to the achievement of a robust design and use this knowledge to intelligently design the product. Standard techniques include adding design margins or tighter tolerances. Optimum product design parameters can be calculated when a performance characteristic can be mathematically related to design parameters. Design of Experiments (DOE) comes in to play when these relationships are unknown.

The approach of Design of Experiments techniques is to design industrial experiments to further improve the understanding of the desired performance characteristic and of the relationship between product and process parameters. Only a small number of all the possible experimental combinations of parameter values are conducted (Breyfogle, 2003). Experiments using orthogonal arrays can

be used ‘to experiment over a wide variety of factor settings, while keeping the effects of each factor separate’ (Brue and Launsby, 2003, p154).

Traditional one-at-a-time approaches can miss interactions due to the number of experiments required. For example, the number of trials required to assess all the combinations of seven two level factors would be 128 trails. However, wisely applying DOE techniques would reduce the trails required, and cost, by applying a small subset of possible combinations instead (Breyfogle, 2003).

2.4.13 Triz

As problems can be grouped generally in known and unknown solutions, Breyfogle points out that known solutions can be solved by current available information, while ‘those with no known solution are called inventive problems’ (2003:913).

Triz is an acronym for a Russian phrase meaning “theory of inventive problem-solving”, developed by a Russian mechanical engineer Genrich Altsshuller.

Altsshuller standardised solutions into 5 levels: (Breyfogle, 2003, p912)

- Standard: Uses methods well known in the profession
- Improvement: Uses methods from inventors own history and technology
- Within existing paradigm: Uses methods from other fields and technologies
- Outside existing paradigm: Uses little known and understood physical effects
- Discovery: Goes beyond contemporary scientific knowledge

Altsshuller found that problems requiring inventive problem solving could be solved by using one of 40 fundamental inventive principles (e.g. do in reverse, self-service) which are listed in Table 2.7. A feature or parameter would be selected and changed to improve the feature of the problem. Using Triz directs the problem solver’s thought process to start with a list of 39 features/parameters, list in Table 2.6, such as waste of time, force, speed and shape. The problems are stated in terms of a conflict between two attributes [e.g. part, features, and

characteristics]. The theory being that this will allow generic solutions to be realised that already have used and documented in other industries (Breyfogle, 2003).

1. Weight of moving object	2. Weight of nonmoving object	3. Length of moving object
4. Length of nonmoving object	5. Area of moving object	6. Area of nonmoving object
7. Volume of moving object	8. Volume of nonmoving object	9. Speed
10. Force	11. Tension, pressure	12. Shape
13. Stability of object	14. Strength	15. Durability of moving object
16. Durability of nonmoving object	17. Temperature	18. Brightness
19. Energy spent by moving object	20. Energy spent by nonmoving object	21. Power
22. Waste of energy	23. Waste of substance	24. Loss of information
25. Waste of time	26. Amount of substance	27. Reliability
28. Accuracy of measurement	29. Accuracy of manufacturing	30. Harmful factors acting on object
31. Harmful side effects	32. Manufacturability	33. Convenience of use
34. Repairability	35. Adaptability	36. Complexity of device
37. Complexity of control	38. Level of automation	39. Productivity

Table 2.6 The 39 Engineering Parameters from Altshuller (Mazur, 1995)

1. Segmentation	2. Extraction	3. Local Quality
4. Asymmetry	5. Combining	6. Universality
7. Nesting	8. Counterweight	9. Prior counter-action
10. Prior action	11. Cushion in advance	12. Equipotentiality
13. Inversion	14. Spheroidality	15. Dynamicity
16. Partial or overdone action	17. Moving to a new dimension	18. Mechanical vibration
19. Periodic action	20. Continuity of a useful action	21. Rushing through
22. Convert harm into benefit	23. Feedback	24. Mediator
25. Self-service	26. Copying	27. Inexpensive, short-lived object for expensive, durable one
28. Replacement of a mechanical system	29. Pneumatic or hydraulic construction	30. Flexible membranes or thin film
31. Use of porous material	32. Changing the color	33. Homogeneity
34. Rejecting and regenerating parts	35. Transformation of the physical and chemical states of an object	36. Phase transformation
37. Thermal expansion	38. Use strong oxidizers	39. Inert environment
40. Composite materials		

Table 2.7 The 40 Inventive Principles from Altshuller (Mazur, 1995)

For using Triz, the engineer ‘needs to first find the corresponding contradictions for the problem’ and ‘match the meaning of each contradiction with two appropriate parameters’ from Table 2.6, then the engineer can find inventive

principles from table 2.7 when the ‘parameters of contradiction for an engineering system’ are found (Li and Huang, 2009, p8303).

Brue and Launsby however offer caution to the use of Triz in DFSS as they believe that potential solutions it generates may take years to prove out (2003). However, there is no denying that Triz is a powerful physiological tool that enables designers to think outside the box opening up ideas and generating great products.

2.5 Conclusion

NPD methodologies and their NPD tools, properly applied to a company’s current NPD process, can turn the tide on coopers ‘most new product projects fail’ statistic (2001:22). A focused enhanced lean NPD process using the correct tools will generate Brue and Launsby objective of generating ‘the right product at the right time at the right cost’ (2003, ix). The challenge now is to realise what NPD process methodologies and tools are the best mix for optimum NPD results. In this chapter, the DFSS and Lean NPD methodologies have been reviewed. A list of their more popular NPD tools has also been individually reviewed. This is the bases of the theory of what is best practice NPD for a company. But what is the reality. This study will investigate what NPD methodologies, enhancement and tools Irish medical device companies are actually using within their NPD processes. The findings along with the learning’s from this literature review will recommend what is the best practice NPD process for an Irish medical device company.

3 Research Methodology

3.1 Introduction

The research methodology chapter firstly outlines the research question of this study. A range of research methods and their considerations are described around both the quantitative and qualitative range. The research method is chosen along with the reasons and its advantages. Finally a detailed description of the research method used is outlined followed by its limitations. The research methodology conclusions summarises the whole chapters main points and resulting chosen research method.

3.2 Research Question

This research is aimed at Medical Device Companies in Ireland to study their New Product Development (NPD) process. Its aims at researching what enhancements (if any) they are using on their NPD process and also what tools and methodologies they are using. The data generated around these medical device companies NPD process, will be used to generate what could be described as the best practice new product development process for the Irish medical device industry in terms of company performance with introducing new products to the market.

In the literature review, DFSS and Lean product development are the main current popular enhancements discussed. Their recommended and popular tools for NPD are also outlined.

The research question is what the best practice NPD process is for an R&D department of an Irish medical device company. The research objective is to take a cross section of R&D teams with successful Irish medical device companies and find out what are the main drivers behind their NPD processes in terms of methodologies and tools used. These findings, along with the literature review theories, will be discussed, and finally, used to conclude what enhancements, tools and methodologies, high end Irish medical companies need to have to deliver the right products to the market at the right time.

3.3 Appropriate Research Methods

Appropriate research strategies for the application of research methods can be classed as quantitative or qualitative. Their differences will be summarized below under the role of theory to research, epistemological orientation and ontological orientation.

Gelo et al cite that ‘quantitative research is concerned with counting occurrences, volumes, or the size of the associations between entities’ and the ‘qualitative research aims to provide rich descriptive accounts’ (2008:267). Gelo et al direct that ‘quantitative approaches are usually deductive and theory driven’ while ‘qualitative ones are inductive and data drive’ (2008:272).

As stated, quantitative research in relation to the role of theory to research can be described as deductive theory. The researcher takes what is known about a particular subject area and subjects the ideas to the rigours of testing before confirming or rejecting them as knowledge. The process of deduction is outlined below in Figure 3.1. The deductive process is very linear, as below, one step follows the other in a clear sequence (Bryman and Bell, 2003).

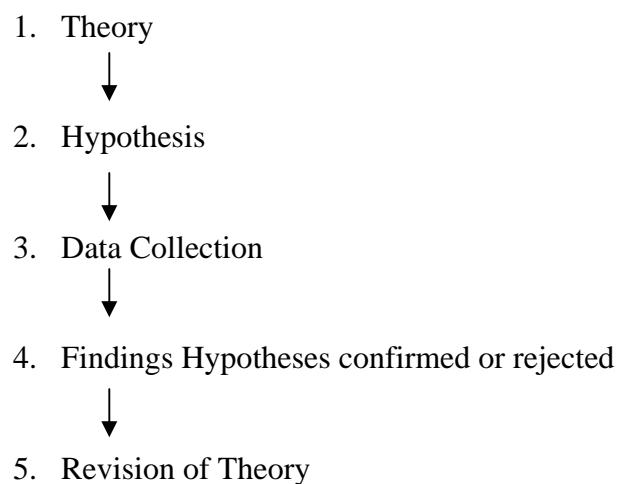


Figure 3.1 The process of deduction (Bryman and Bell, 2003, p11)

However, a researcher's view of the theory may change when they analyse the data collected. Several reasons may cause the researcher to move away from the deductive method and change to a more qualitative strategy. For example, new theoretical findings may be published, the relevance of certain data may change the view of a theory after it has been collected or data collected may not fit with the original hypotheses.

Qualitative research takes an inductive approach to the role of theory. Gelo et al describe that in qualitative research, 'data interpretation is based on a process of inductive inference' by creating explanations, understanding and theories from the data (2008:277). The researcher generates the research theory from feeding their findings back into the theory. The inductive approach reverses the deductive approach from theory first and observations/findings second to observations/findings first and theory second. However, deductive and inductive strategies should be thought of as tendencies between the relationship of theory and research rather than as a distinction between the two (Bryman and Bell, 2003).

3.3.1 Case Studies

Case Studies explore the subjects and issues through detailed and intensive analysis of a single case. 'Consider that most case studies seek to elucidate the features of a broader population' (Seawright and Gerring, 2008, p294). The approach to research is through trying to attribute causal relationships unlike descriptive surveys which only describe the situation. Multiple sources of data must be collected but in a somewhat focused way. The case study approach may be useful in this thesis research in determining the relationship between an organisation's enhancements to their new product development (NPD) process and its specific characteristics such as profile, products, and performance. This approach can be described as deductive as the case study would require the prior development of a theoretical position in NPD to aid in directing the data collection and analysis process. Data collection for case studies can involve direct observations and interviewing as well as using existing documentation available.

Interviewing ‘provides access to the context of people’s behaviour and thereby provides a way for researchers to understand the meaning of that behaviour’ (Dilley, 2004, p128). However the danger in case studies is that the researcher may generalise from a specific case which can question the case study reliability, replicability and validity. ‘Chosen cases must also achieve variation on relevant dimensions, a requirement that is often unrecognised’ (Seawright and Gerring, 2008, p294). It begs the question as to how a single case can possibly contain findings that are representative to other cases. The researcher must not delude themselves into thinking typical cases can be used to represent for example all organisations, managers, events etc. The case study may be used to generate concepts and meanings within for example an organisation, which position can then be tested in other case studies to other organisations to achieve a degree of theoretical generalisation. This can be described as a confirmatory or deductive approach. Another type of case study is exploratory or an inductive approach where the theoretical position is generated from case to case but each case cannot then be compared. See Figure 3.2 below for this illustration. One other criticism of case studies is the amount of time they can take as well as the volume of documentation that has to be dealt with (Bryman and Bell, 2003). Interviews ‘allow us to investigate, in critical ways, our respondent’s comprehensions of their experiences and beliefs – as well as our own’ (Dilley, 2004, p128).

Research Methodology

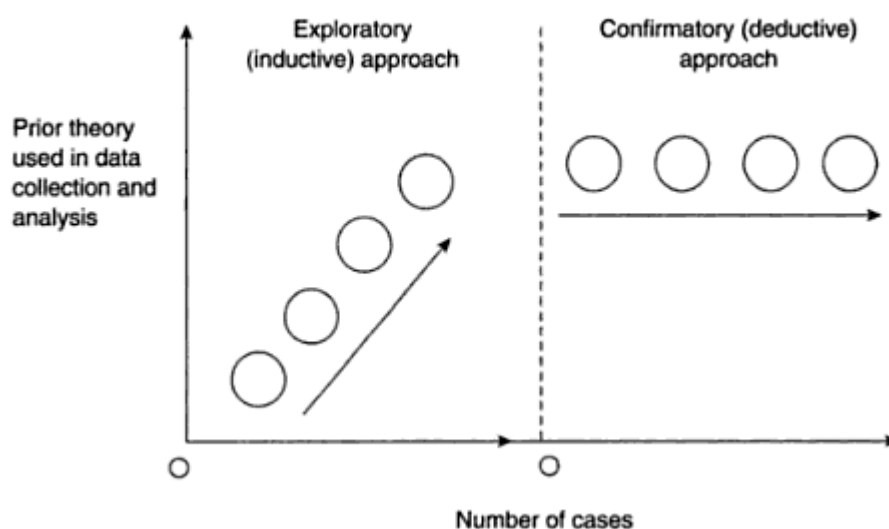


Figure 3.2 A comparison of two case study positions; inductive and deductive (Sage, 2004, p126)

3.3.2 Questionnaires

Questionnaires can be described as a research tool in which individuals are asked to respond to the same set of carefully constructed questions that are set out in a predetermined order. The constructed questionnaires must be valid, reliable and objective. One avenue to deliver such questionnaires would be web surveys. Couper describes them as a double-edged sword referring to the power of web surveys is that they make 'survey data collection available to the masses' at 'dramatically lower costs than traditional methods' (Couper, 2000, p464). When the objectives of the research are set, this will dictate whether the use of a questionnaire will fit. For example, in a case study that would typically look for in-depth analysis of opinions and perspectives of a small number of individuals, it may be unsuitable to use a questionnaire that is highly structured. But in a situation where the audience is very large and questions need to be standardised, the questionnaire is a very good research method. The questionnaire has many advantages such as low cost both in terms of time and money, the return of data can be very quick, the time and place for completing the questionnaire is up to the respondent, their anonymity can be assured and finally, with questionnaires, interviewer bias is greatly reduced. However in terms of disadvantages, respondents could give misleading or inaccurate answers in which the researcher will not be able to detect. The face-to-face interview however should reveal such misleading areas through observation and probe this area gently for a more accurate reply (Bryman and Bell, 2003). During such semi-structured or unstructured interview settings, the interviewer must consider how to 'gain access to the setting and participants', 'gain trust' and 'establish rapport', (Matteson and Lincoln, 2009, p660). Matteson and Lincoln continue with the opportunity of probing during interviews using semi structured or unstructured questionnaires indicating that 'the strongest justification for the more probe-based paradigm is that it generates verbal material' that 'may not emerge unless a cognitive interviewer specifically asks for it' (2009:662).

3.4 *Choosing a Research Method*

The research method chosen, to generate a best practice NPD approach, is through using a semi-structured questionnaire which will be used during a face-to-face interview to allow a build up of a number of case studies, taking a confirmatory or deductive approach in comparing each case. It is felt that a large audience is required through standardised questions in order to give comparisons to aid in generating a best practice NPD. This would be a huge challenge in the highly competitive medical device industry and take a long time. Therefore three non-competing Irish medical device companies will be targeted and a number of case studies will be built up from each company through a semi-structured interview process.

Using a case study approach with a prepared semi-structured questionnaire during face-to-face interview, would allow a number of case studies to be compared and contrasted more easily. The danger here, as outlined in section 3.3.1 above, is that the best practice NPD process that would be generated may only be generalised from these two cases, which questions its reliability, replicability and validity. In addressing this, multiple case studies within each of the three companies will be used.

Also the reality of the medical device industry is one of fierce competition and security in knowledge transfer between organisations which is why only non-competing companies are targeted.

‘When you study your NPD process, you should choose experienced people from your core product development groups as your task force leaders because they will provide valuable insights into the current state of your product development value stream’ (Morgan and Liker, 2006, p343). Morgan and Liker also point out to be aware that ‘their stories will often contradict each other’ which should not come as a surprise (2006:343).

3.5 Description of Research Method used

Three Irish medical device companies were used with a number of R&D teams within each company. As the basis of identifying each company and team throughout the remaining chapters, they will be identified as follows:

- Company A, Team 1
- Company A, Team 2
- Company A, Team 3
- Company B Site A, Team 1
- Company B Site B, Team 2
- Company C, Team 1

Company A has a large sized R&D Department within their medical device company.

Company B has a number of medical device and pharmaceutical sites in Ireland. Two of their medical device sites were targeted. Company B Site A has a medium sized R&D department within their medical device company. Company B Site B has a small sized R&D department within their medical device company. Company C medium sized R&D department within their medical device company.

The target was to interview the team lead, a senior R&D engineer and an associate engineer from each team. Table 3.1 illustrates the actual R&D engineer levels interviewed from each company.

Company	Team	R&D Interviewee #1	R&D Interviewee #2	R&D Interviewee #3
A	1	Project Eng 1 [A1]	Senior R&D #1 [A1]	Associate #1 [A1]
A	2	Project Eng 2 [A2]	Senior R&D #2 [A2]	Associate #2 [A2]
A	3	Project Eng 3 [A3]	Senior R&D #3 [A3]	Associate #3 [A3]
B	1	R&D Director [B1]	Project Lead [B1]	Associate #1 [B1]
B	2	R&D Manager[B2]	Senior R&D #2 [B2]	Associate #2 [B2]
C	1	Project Lead 1[C1]	Senior R&D #1 [C1]	Associate #1 [C1]

Table 3.1 Interview structures completed

Each of the R&D team members in Table 3.1 were interviewed using a semi-structured interview. This allowed the interviewer to explore topics of interest which arose during the conversation.

3.6 Limitations

Scandura and Williams state that ‘any research method chosen will have inherent flaws, and the choice of that method will limit the conclusions that can be drawn’ (200:1249). The limitations of this study may be directed to the decision not to target direct competing medical device companies to directly compare their NPD process. As I would have to be honest to each company as to what other company types I would be interviewing and documenting results against, it would be unreasonable to believe that direct competing companies would allow their team members to be interviewed with resulting NPD process information directly compared to competitors. However, on the other hand, comparing three Irish medical device companies, each with a different line of medical products, should give an interesting line up of results.

Also, interviewer bias, although being a concern, is not thought an issue through the interviewing of multiple engineers within each team, any bias would be nullified over this range.

3.7 Conclusions

The chosen means of research methodology has delivered a broad range of findings across different lines of Irish medical device companies. It can be described as a quantitative research approach where the researcher takes what is known in theory about NPD methodologies and NPD Tools and challenges it's usage against what is really used in Irish medical device companies. Face-to-face interviews were the chosen means of gathering the study findings. Semi-structured questionnaires were prepared in advance of the face-to-face interview. This semi-structured questionnaire was then used to step through the interview and at the same time allow the both parties to probe a particular area or elaborate in particular areas. The semi-structured questionnaire aim was to allow the same level of in-depth analysis of opinions and perspectives as case studies.

Three non-competing Irish medical device companies with different product lines were chosen for the study. R&D teams within each of the companies were interviewed through three levels of engineer; Lead, Senior and Associate. As well as allowing gathering of additional findings, it mitigated against interviewer bias. There was also a good spread of medical device company sizes and of R&D department company sizes. As stated above by Seawright and Gerring, 'chosen cases must also achieve variation on relevant dimensions, a requirement that is often unrecognised' (2008:294). This is certainly addressed with the various different dimensions of the company's chosen, in their sizes, R&D department sizes, and their product offerings. This is important as the conclusion will recommend a best practice NPD process that can be used for all Irish medical device companies.

These three companies will be outlined next, each as a case study, under the main headings of the literature review and of the semi-structured questionnaire. Note Table 3.1, which can also act as a guide to the format of the findings.

4 Findings – Company A Case Study

4.1 Company A Profile

Company A is a large medical device company with a large R&D department. It is 15 years in Ireland and has approximately 2800 employees on site. 200 of the employees work in the company's R&D department, which was established 12 years ago. It is one of the world's largest medical device company dedicated to the development of less invasive therapies. These procedures provide effective alternatives to traditional surgery by reducing procedural trauma, complexity, and risk to the patient, cost and recovery time. The devices are generally inserted into the human body through natural openings or small incisions in the skin and can be guided to most areas of the body to diagnose and treat a wide range of medical problems.

Company A's products are mainly used in the areas of cardiology, neuroradiology, gastroenterology, pulmonary medicine, radiology, urology and vascular surgery.

Company A manufactures products for the organisation's main product ranges using a full array of on-site technologies, rendering it virtually self-sufficient in the supply of its own sub assemblies. Company A's products span 60 categories and include more than 14,500 product variants. The main three product areas are Interventional Cardiology, Peripheral Interventions and Endosurgery.

The findings for the three R&D teams within Company A will be outlined next.

4.2 Company A, Team 1 (A1)

4.2.1 Team Profile [A1]

Company A Team 1 interviewees consisted of a R&D Project Engineer, a Senior R&D Engineer and an Associate R&D Engineer.

Project R&D Engineer 1 has 9 years experience in the medical device industry. The Senior R&D Engineer 1 has just over 13 years experience in the medical device industry. The Associate R&D Engineer 1 has 3 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

4.2.2 New Product Information [A1]

When each team member was asked when they last introduced a new product, they point to the current project where they are launching a new product in November 2009, or in two months time.

When asked how many projects they introduced per year, again each team member pointed to the current project which has been going for approximately 18 months to date. So one product is introduced in approximately 18 months. The team concluded that Company A exceeded goals in their Market Share performance, and exceeded goals in their Profit Performance.

When asked what percentage of turnover was spent on NPD, the Project Eng and the Senior Eng indicated between 10%-12%. They pointed that 45% of turnover comes from new products, less than 3 years old. The Associate Engineer did not know.

Each team member was then asked to categorise the current product project they were working on; Derivative, Platform or Breakthrough. They each agreed that it was Platform. The new product in development has new materials and a new drug, and is based off a current product on the market.

4.2.3 NPD Process [A1]

Company A Team 1 NPD process enhancements

Team 1 members were asked if they used any enhancements to compliment their current NPD process. They all indicated that Design for Six Sigma (DFSS) was being heavily advocated. I probed about the use of other enhancements such as Lean product development. Both the R&D Project Eng 1 and the Senior R&D Eng 1 concluded that it was not formally in use. They both however indicated that some lean approaches were driven on an individual basis, but it was not through company direction. The senior R&D eng 1 indicated he came across other R&D project engineers driven everyday lean approaches such as stand up meetings and email rules, but that it was not really taken seriously. The associate Engineer did not come across any lean approaches.

The team members were asked if they came across any other enhancement. The senior R&D Eng 1 did indicate that company A was driving an approach he titled Knowledge Driven Product Development (KBPD). It had not been rolled out across the R&D department, but he indicated that it had come up through company A's acquisition of another company that was using it.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Very helpful

Lean Product Development – Currently using & Very helpful

Other [KBPD] – Not used

The team indicated that upper management were very helpful in supporting enhancement implementation and its usage. The R&D project engineer indicated that he found that DFSS showed problems up front, allowing them to be solved before they become an issue, essential front loading the process and causing less or no fire fighting.

Company A's Team 1 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process.

Each team member duly pointed to the company's established Product Development Process or PDP. Company A PDP consists of five main headline activities related to the NPD team, spread across five phases of the PDP process. The main headline activities were Integrated Business plan development, Product Development, Packaging and Label development, Design control reviews and Intellectual Property (IP) Management. These were carried out throughout the PDP five phases of Proposal, Definition, Development, Validation and scale-up, and Commercialization.

Team 1 relayed the following outline of Company A's established formal PDP process

The Proposal Phase

The team pointed to the first functional activity band, Integrated Business Plan (IBP). At the proposal phase of the PDP process, the business rationale and objective for the project is established through a Preliminary IBP, which is presented to company A's Project Investment Board (PIB) to gain project approval and assignment of a full Core Team. The IBP at this stage can be described as an assumption based business plan.

The Definition Phase

The purpose of the Definition Phase is to refine the business opportunity, define the technical and product performance requirements, and establish a work plan for the balance of the project. The Core Team is established at the start of this phase. Critical project elements must be understood in sufficient detail for the Core Team to determine project risk, resource requirements, and commit to a final schedule. Approval of the Integrated Business Plan (IBP) by the PIB at the end of the Definition Phase begins full development of the product.

The Development Phase

The purpose of the Development Phase is to develop and document the design and to verify that it meets the product specification. This phase includes technical development, verification of the product design, development of the production process, and release of engineering documentation to formal change control. This phase concludes with the testing of the product to verify that performance requirements have been achieved. Global launch and support planning begins during this phase.

Validation & Scale-up Phase

The purpose of the Validation & Scale-up Phase is to prepare all aspects of the product and process for efficient manufacturing and launch. During the phase, manufacturing process validation is completed, as well as all documentation needed to begin volume product delivery. Design Validation, to ensure that the product meets the customer needs, is also conducted during this phase. This phase may include market evaluations and clinical studies. PIB approval at the end of the phase authorizes commercial launch of the product.

The Commercialization Phase

In Commercialization Phase, the product is launched and all activities required for general release of the product are concluded. Requirements for completing this phase include achievement of efficiency and effectiveness of manufacturing and marketing activities. Establishing Post Market Surveillance is a key part of this phase. PIB approval at the end of this phase closes the project.

Company A's Team 1 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. All team members immediately indicated that they do follow the company's PDP process and that it does not hinder their goal of developing a great product. The project Eng 1 and senior eng 1 indicated that that the company's PDP process was a roadmap for achieving the goals and that it is flexible across its five phases.

The team members were asked if management set product project priorities where some team members may be working on more than one project. They indicated that priorities were agreed by the company's PIB. Only the R&D project eng 1 seemed to be aware of priorities, the senior R&D eng 1 and associate R&D eng 1 did not appear to be concerned, they just took direction from the R&D project engineer.

When asked if the value stream approach around NPD teams was used, all team members agreed that it was. Each team member reported to a functional Manager mostly dedicated to a related family of products. The R&D project engineer also reported to a functional manger.

The team were then challenged on phase review usage which came up throughout their company's NPD description. The team members indicated that team based phase reviews did not occur. Only the FDA directed product specification, design freeze, design verification, first human use and design transfer phases. These were seen as additional activities to comply with FDA guidelines more than a time of project review. The project R&D eng 1 indicated that he was responsible for preparing phase review presentations to the company's PIB. These phase reviews occurred at upper management level and did not involve the senior R&D engineer and Associate Engineer. The project engineer concluded that the phase reviews were business driven not product driven.

The team were asked if they knew the product target cost price when they started working on their current NPD project. Both the R&D project engineer and the senior R&D engineer indicated that they did. The associate engineer did not know.

Company A's Team 1 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process. The following functional areas were indicated by team 1 members:

- Finance
- Customers (Doctors)

- Equipment Engineering
- Manufacturing
- Upper management
- Marketing
- Packaging / Sterilization
- Suppliers (Drugs)
- Design Assurance

When probed about sales, this was indicated to be relayed through marketing. All team members indicated that cross development team usage was very helpful in developing the new product. When pushed for an example, the senior R&D engineer indicated that feedback loops through the cross functional team around product specifications did occur, but that they were informal. They only formally occurred at the PIB. The associate engineer said he rarely came across cross functional team members.

4.2.4 NPD Tools and Methodologies [A1]

The following list of NPD Tool and methodologies in Table 4.1 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews				X				
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment				X				
DFSS Scorecards		X					X	
Pugh Concept Selection Matrix	X							X
Design for X (DFx)	X							X
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination	X						X	
Poke Yoke				X				
Process Capability studies	X							X
Multi- Vari Analysis	X							X
Design of Experiments	X							X

Table 4.1 Company A Team 1 NPD Tools and Methodology usage

Some highlighted high usage tools by team 1 were Measurement System Analysis and Design of Experiments. These are used numerous times throughout the NPD process.

Competitive testing or Benchmarking is used by team 1 early in the project and was checked again later in the project.

Voice of the customer is used by team 1. The R&D project eng 1 did point out however that as the current product project they are working on was a platform product, they only deviate from two product characteristics, but that these were from feedback from the customer.

DFSS scorecards were stated as not used by the team 1 or even that they came across the term, yet it is an important part of the DFSS process as outlined in the literature review. However, after probing the R&D project eng 1, he stated that he does track the product project through regular meetings, meeting minutes and is implementing metrics on progress. This is related to the DFSS scorecards purpose. Another observation was Anticipatory Failure Determination (AFD) whereby team 1 stated they did not use. However, senior R&D eng 1 did understand the term and indicated that this failure testing was done more informally, and recorded on lab books and technical reports.

4.3 Company A, Team 2 (A2)

4.3.1 Team Profile [A2]

Company A Team 2 interviewees consisted of a R&D Project Engineer, a Senior R&D Engineer and an Associate R&D Engineer.

The Project Engineer 2 has 7 years experience in the medical device industry. The Senior R&D Engineer 2 has 9 years experience in the medical device industry. The Associate R&D Engineer 2 has 4 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

4.3.2 New Product Information [A2]

Each team member was asked when they last introduced a new product. The associate eng 2 actually worked with team 1 up to 6 months prior so he indicated that that product was due to launch in November, which is an 18 month duration, per team 1 indications. The current product project is expected to take 12 months. The R&D project eng 2 and senior R&D eng 2 also indicated the same 12 month duration.

When asked what percentage of turnover was spent on NPD, the Project Eng and the Senior Eng indicated between 10%-12%. They pointed that 45% of turnover comes from new products, less than 3 years old. This is the same information as team 1.

The team concluded that Company A exceeded goals in their Market Share performance, and exceeded goals in their Profit Performance.

Each team member was then asked to categorise the current product project they were working on; Derivative, Platform or Breakthrough. They each agreed that it was Platform. The new product in development was to be an improvement of a current product.

4.3.3 NPD Process [A2]

Company A Team 2 NPD process enhancements

Team 2 members were asked if they used any enhancements to compliment their current NPD process. They all indicated that Design for Six Sigma (DFSS) was being heavily advocated. When probed about the use of other enhancements such as Lean product development, it was not used by any of the team members. No other enhancements were used by the team. Knowledge Driven Product Development (KDPD) was not used nor had they come across it.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Very helpful

Lean Product Development – Not used

Other [example: KBPD] – Not used

They indicated that upper management are very helpful in supporting DFSS enhancement implementation and its usage. Benefits cited by team 2 were that it was a mature process where lessons learned had been constantly fed back into the process through the R&D project engineer so that management can update as appropriate.

Company A's Team 2 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process. Per NPD Process [A1] for team 1, the company's current process is the same for team 2. Company A has a PDP process with Proposal phase, Definition phase, Development phase, Validation and Scale-up phase and Commercialization phase.

Company A's Team 2 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. Again, as per team 1, all team 2 members indicated that they do follow the company's PDP process and that it does not hinder their goal of developing a great product. Team 2 did agree that their company's PDP process is flexible and is fed with lessons learned keeping it up to date and more real to the team members.

The team members were asked if management set product project priorities where some team members may be working on more than one project. They indicated that priorities were agreed by the company's PIB.

When asked if the value stream approach around NPD teams was used, all team members agreed that it was. Like team 1, each team 2 member reports to a

functional manager mostly dedicated to a related family of products. The R&D project engineer also reported to a functional manager.

The team were then challenged on phase review usage which comes up throughout the company's PDP process. Team 2 like team 1 pointed to the FDA directed product specification, design freeze, design verification, first human use and design transfer phases. The team members saw the phase reviews as formal upper management level and not for advantageous use for them.

The team were asked if they knew the product target cost price when they started working on their current NPD project. None of the team members knew the target price. The R&D project engineer did indicate that because it was a product improvement project, the product price would probable increase from its original price.

Company A's Team 2 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process.

The following functional areas were indicated by team 2 members:

- Finance
- Equipment Engineering
- Manufacturing
- Upper management
- Marketing
- Design Assurance

Some interesting notes from the functional areas indicated were that customers were not part of the cross functional team as it was a "straight forward" improvement product project from already noted customer feedback. One other interesting point the senior R&D eng 2 made is that he would prefer if upper management were not part of the team (referring to team member functional managers), as he felt that the R&D project engineers in general can get intimidated by them and bias the team.

4.3.4 NPD Tools and Methodologies [A2]

The following list of NPD Tool and methodologies in Table 4.2 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews				X				
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment				X				
DFSS Scorecards				X				
Pugh Concept Selection Matrix				X				
Design for X (DFx)				X				
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination				X				
Poke Yoke	X							X
Process Capability studies	X							X
Multi- Vari Analysis				X				
Design of Experiments	X							X

Table 4.2 Company A Team 2 NPD Tools and Methodology usage

Team 2 like team 1 also indicated high usage of Measurement System Analysis and Design of Experiments. Team 2 also highlighted although they are indicating VOC usage, it is minimum as the project is platform product improvement.

Again, DFSS scorecards were not used. After probing team 2, they did indicate that meeting minutes and actions were developed and tracked, but not to the level advocated by DFSS scorecards.

4.4 Company A, Team 3 (A3)

4.4.1 Team Profile [A3]

Company A Team 3 interviewees consisted of a R&D Project Engineer, a Senior R&D Engineer and an Associate R&D Engineer.

The R&D Project Engineer 3 has 7 years experience in the medical device industry. The Senior R&D Engineer 3 has 6 years experience in the medical device industry. The Associate R&D Engineer 3 has 2 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

4.4.2 New Product Information [A3]

Each team member was asked about the duration of the last time they introduced a new product. The team indicated that it was between 8 months and 18 months. The current product project they are working on is also platform whereby the new product although new will be mostly driven to use current product characteristics of numerous products with current available in house technologies for its manufacture. The duration as indicated by team 3 is targeted at approximately 14 months including equipment readiness.

Team 3 also gave the same responses for percentage of turnover spent on NPD, of 10%-12% and a 45% turnover coming from new products, less than 3 years old.

The team concluded that Company A exceeded goals in their Market Share performance, and exceeded goals in their Profit Performance.

4.4.3 NPD Process [A3]

Company A Team 3 NPD process enhancements

Team 3 members were asked if they used any enhancements to compliment their current NPD process. Each team member agreed that Design for Six Sigma (DFSS) was used and is a major talking point around management.

Again Lean product development was not used by team 3 either, nor did they come across Knowledge Driven Product Development (KDPP). The senior R&D engineer 3 did indicate that he came across Effective Product Development but it was just a term not a direction or process to follow for him.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Very helpful

Lean Product Development – Not used

Other [example: KBPD] – Not used

Team 3 also indicated that upper management are very helpful in supporting DFSS enhancement implementation and its usage.

Company A's Team 3 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process. Per NPD Process [A1] for team 1, the company's current process is the same for team 3. Company A has a PDP process with Proposal phase, Definition phase, Development phase, Validation and Scale-up phase and Commercialization phase.

Company A's Team 3 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. The team 3 members indicated that they do follow the company's PDP process and that it does not hinder their goal of developing a great product. They agreed with Team 2's observation that the PDP process is flexible and that it does change based on feedback given by the team to upper management.

The team members were asked if management set product project priorities where some team members may be working on more than one project. They indicated that priorities were agreed by the company's PIB and that these were followed.

When asked if the value stream approach around NPD teams was used, all team members agreed that it was. Like team 1 and 2, each team 3 member reports to a functional Manager mostly dedicated to a related family of products. The R&D project engineer also reported to a functional manager.

The team were then challenged on phase review usage which comes up throughout the company's PDP process. Team 3 also pointed to the FDA directed product specification, design freeze, design verification, first human use and design transfer phases. These FDA phase reviews were seen as part of the product project plan of activities to get through. Team 3 sees the phase review as not a team project review activity but rather an activity step.

All the team 3 members all knew the product target cost price of the product project they are currently working on. This can be plainly seen as the members are driving to leverage characteristics of other established in house products and current in house technologies for its manufacture.

Company A's Team 3 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process.

The following functional areas were indicated by team 3 members:

- Finance
- Equipment Engineering
- Customers
- Suppliers
- Manufacturing
- Upper management
- Marketing
- Design Assurance

Team 3 pointed to heavy usage of Equipment engineering and manufacturing engineering with the R&D team to leverage available processes and technology and drive the product design in that direction. However the senior R&D engineer pointed to his experience where sometimes the cross functional team members slow the product development process as their department goal will not be the same as the R&D department goal.

4.4.4 NPD Tools and Methodologies [A3]

The following list of NPD Tool and methodologies in Table 4.3 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews				X				
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment				X				
DFSS Scorecards				X				
Pugh Concept Selection Matrix	X							X
Design for X (DFx)	X							X
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination				X				
Poke Yoke	X							X
Process Capability studies	X							X
Multi- Vari Analysis				X				
Design of Experiments	X							X

Table 4.3 Company A Team 3 NPD Tools and Methodology usage

High usage of Measurement System Analysis and Design of Experiments was again indicated by Team 3. Competitive testing (or benchmarking) was also of high usage.

Design for X was used around current available products and technologies. Again, DFSS scorecards were not used. Team 3 R&D project engineer held responsibility for tracking the project through usual methods of regular meetings, minutes and action items.

5 Findings – Company B Case Study

5.1 Company Profile

Company B is a large multinational healthcare company that spans medical devices, imaging solutions, pharmaceuticals and medical supplies. It has a number of medical device company sites in Ireland. Two of these company site's R&D department teams were interviewed.

Company B site A is a medium sized medical device company with a medium sized R&D department. It is 24 years in Ireland and has 630 employees on site. 17 of its employees work in the R&D department, which was established 20 years ago.

Company B site A manufactures a range of respiratory aid devices and services that facilitate the monitoring, diagnoses and treatment of respiratory related conditions.

Team 1 were interviewed from this site.

Company B site B is a medium sized medical device company with a small sized R&D department. It is 27 years in Ireland and has 650 employees on site. 3 of its employees work in the R&D department, which was established 6 years ago.

Company B site B manufactures a range of surgical devices and energy-based devices. Team 2 were interviewed from this site.

The findings for the two R&D teams within Company B will be outlined next.

5.2 Company B, Team 1 (B1)

5.2.1 Team Profile [B1]

Company B Team 1 interviewees consisted of the R&D director, R&D project lead and an Associate R&D engineer

The R&D director has 16yrs experience in the medical device industry. The R&D project lead has 5yrs experience in the medical device industry. The associate R&D engineer has 2 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

5.2.2 New Product Information [B1]

When each team member was asked when they last introduced a new product, they each indicated 6 months ago. When asked how many new products a year were introduced they all indicated less than one. Indications from the team are 1 product every 18 – 24 months.

When asked what percentage of turnover was spent on NPD, the R&D director indicated between 2.5 to 3%, with 25% of turnover coming from new products less than 3 years old (in site A). The R&D director concluded that Company B site A met their goals in Market Share performance, and met their goals in Profit Performance.

Each team member was then asked to categorise the most recently introduced new product in terms of newness: Derivative, Platform or Breakthrough. They each agreed that it was Platform.

5.2.3 NPD Process [B1]

Company B Team 1 NPD process enhancements

Team 1 members were asked if they used any enhancements to compliment their current NPD process. They all indicated that Design for Six Sigma (DFSS) was the main driving enhancement within their PDP process. The team indicated that no other enhancement was applied to their PDP process.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Very helpful

Lean Product Development – Not used

Other – Not used

The team indicated that upper management were very helpful in supporting enhancement implementation and its usage. In fact DFSS implementation was driven corporate wide.

Company B's Team 1 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process. The R&D director indicated that they do have a structured NPD process which they call Product Development Process or PDP, which was recently introduced with the aid of a professional leadership consultancy company. Company B's PDP consists of 5 phases. These are concept, feasibility, development, qualification and Launch.

Team 1 relayed the following outline of Company B's established formal PDP process.

The Concept Phase

Voice of customer analysis directs the company's R&D department to take on opportunities. A project objective is outlined which addresses such opportunities and approval is gained at director level and across sites. Approval is gained for finance and resourcing is then obtained and the core team is identified.

The Feasibility Phase

Here the core team works on the Voice of customer analysis and researches the critical to quality factors. The project itself is further refined so that its feasibility becomes clear. A project contract is developed consisting of a project plan, resourcing requirements and a project risk analysis.

The Development Phase

Concept development to the project contract is the focus of this phase. Also included in this phase is product verification through various product testing and documentation development. The design is frozen and is ready for qualification. Launch planning activities are kicked off.

The Qualification Phase

Product process validation is carried out, documented and approved. The product and process is prepared for scale up for the Launch phase.

The Launch phase

The product is launched on the market. The project team monitors the products progress and feedback. The product is tweaked if there is sufficient reason to do so.

Company B's Team 1 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. All team members indicated that they do follow the company's PDP process. The R&D director indicated that the process does not cause them to lose site of the goal, but did indicate that it is a formal process that is not flexible and not scalable by product. The R&D project lead indicated that there actually is a PDP light version, but that it has never been used. He pointed that this was because the core team wanted to ensure that they were covered from a regulatory and IP point of view at all times even if it meant possible overkill within the PDP process. However he felt that the Company's PDP DFSS approach has of great benefit in terms of the designing the right product through upfront planning around voice of the customer and risk analysis. The associate engineer indicated that the PDP process was formal and was followed through as set out by the company.

The team members were asked if management set product project priorities where some team members may be working on more than one project. All team members indicated that project product priorities are set, communicated and followed. The

R&D project lead gave an example where the previous year 3 projects were running concurrently and it was imperative that priorities were set, so that if resource conflicts arose, team members knew which project to prioritise.

When asked if the value stream approach around product development teams was used, team members indicated that it was not. Team members reported to a functional Manager and were not dedicated to a family of products.

Each team member was asked about phase review usage. The R&D director indicated a figure of up to 10 phase reviews or more and that it was a highly used and important activity throughout each project. The team indicated that phase reviews were carried out at the end of each PDP process stage, at each regulatory or FDA directed stages and even throughout the launch stage until the project is closed. The R&D project lead was asked about project activity during the actual phase reviews. He indicated that work continued in parallel and that there was no start stop activity.

The team were asked if they knew the product target cost price when they started working on their current NPD project. All the team members said they know the product target cost price at the start. The R&D project lead did indicate that marketing always kept on top of this as historically they know that the cost price can creep up. He indicated that the sale price is only increased if an additional feature adds value.

Company B's Team 1 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process. The following functional areas were indicated by team 1 members:

- Finance
- Customers
- Engineering
- Manufacturing
- Upper management

- Marketing & Sales
- Packaging
- Suppliers
- Regulatory Affairs
- Clinical Affairs
- IP and Legal

All team members concluded the cross-functional team was somewhat helpful in developing new products. When queried why not very helpful, the R&D director indicated that there is currently an initiative in progress to change the new product development team structure to pull greater support from other functional areas.

The R&D project lead agreed with this. He indicated that at present on new project team organisation charts, he has dotted lines to the various functions which is not good enough in leveraging support for high priority projects as support is required throughout a project. The R&D director and R&D project lead indicated that a higher level lead which will be titled new product development lead will have direct reports in each function, where R&D will be treated as one function. The associate R&D lead did hear about this initiative but is unaffected by it.

5.2.4 NPD Tools and Methodologies [B1]

The following list of NPD Tool and methodologies in Table 4.4 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews	X							X
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment	X							X
DFSS Scorecards	X							X
Pugh Concept Selection Matrix	X							X
Design for X (DFx)		X						X
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination								X
Poke Yoke	X						X	
Process Capability studies	X							X
Multi- Vari Analysis		X					X	
Design of Experiments (DOE)	X							X

Table 5.1 Company B Team 1 NPD Tools and Methodology usage

Some highlighted high usage tools by team 1 were VOC, Measurement System Analysis, FMEA and DOE. These are used numerous times throughout the NPD process. The R&D director interestingly commented that DOE is dangerous if

used incorrectly, so caution must be taken in using correctly. She also commented that benchmarking although used was often not completed due to resourcing. The R&D project lead indicated that benchmarking was not used enough and mostly completed against the company's own products and not competitors. But he did indicate that this was often by design so as to not influence designers towards competitor's products due to IP issues.

5.3 Company B, Team 2 (B2)

5.3.1 Team Profile [B2]

Company B Team 2 interviewees consisted of the R&D Manager, a Senior R&D Engineer and an Associate R&D Engineer. In site B this consists of the whole R&D department.

The R&D Manager has 23 years experience in the medical device industry. The senior R&D engineer has 15 years experience in the medical device industry. The associate R&D engineer has 4 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

5.3.2 New Product Information [B2]

Each team member was asked when they last introduced a new product. The team stated November 2008 with an average of 1 product introduced per year. When asked what percentage of turnover was spent on NPD, the R&D manager indicated 4%, with 20% of turnover coming from new products less than 3 years old. The R&D manager concluded that Company B site B met their goals in Market Share performance, and met their goals in Profit Performance.

Each team member was then asked to categorise the current product project they were working on; Derivative, Platform or Breakthrough. They each agreed that it was Derivative.

5.3.3 NPD Process [B2]

Company B Team 2 NPD process enhancements

Team 2 members were asked if they used any enhancements to compliment their current NPD process. They all indicated that Design for Six Sigma (DFSS) was the only enhancement enforced on their PDP process.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Very helpful

Lean Product Development – Not used

Other – Not used

The team indicated that upper management were very helpful in supporting enhancement implementation and its usage. All management sectors were well versed in its usage.

Company B's Team 2 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process. Per NPD Process [B1] for team 1, the company's current process is the same for team 2. Company B has a PDP process with Concept phase, Feasibility phase, Development phase, Qualification phase and Launch phase.

Company B's Team 2 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. All team members indicated that they do follow the company's PDP process. The R&D manager indicated that

it did not cause them to lose site of the project goal but that their PDP process is a formal procedure where the actual tool usage is flexible over each product project. The R&D manager gave some insight into the introduction of DFSS into their process in 2003 to 2004. Previous to its introduction he witnessed various issues and mistakes that should have been caught upfront. He advocates that DFSS drives the engineer to capture potential issues upfront, right up to a final qualification evaluation with the customer before launching the product.

The team members were asked if management set product project priorities where some team members may be working on more than one project. All team members indicated that project product priorities are set but that in their small R&D team resourcing conflicts were rare. The team were not asked if they used the value stream team approach as it would be not applicable in a R&D department of 3.

Each team member was asked about phase review usage. The R&D manager quoted a figure of approximately 10 phase reviews. The senior R&D engineer indicated that the phase reviews were a part of the process and did not stop the flow of project activities around each review period.

The team were asked if they knew the product target cost price when they started working on their current NPD project. All the team members said they know the product target cost price. The R&D manager elaborated saying that the target cost price was related to the design input document from their customer requirements.

Company B's Team 2 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process. The following functional areas were indicated by team 2 members:

- Customers
- Engineering
- Manufacturing
- Upper management
- Marketing & Sales

- Packaging
- Suppliers
- Regulatory Affairs
- Clinical Affairs

All team members concluded the cross-functional team was very helpful in developing new products. The R&D manager concluded that weekly upper management meetings occurred to review project progress and ensure cross functional support.

5.3.4 NPD Tools and Methodologies [B2]

The following list of NPD Tool and methodologies in Table 4.5 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews	X							X
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment	X						X	
DFSS Scorecards	X							X
Pugh Concept Selection Matrix	X							X
Design for X (DFx)	X							X
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination		X					X	
Poke Yoke		X					X	
Process Capability studies	X							X
Multi- Vari Analysis								X
Design of Experiments (DOE)	X							X

Table 5.2 Company B Team 2 NPD Tools and Methodology usage

Some highlighted high usage tools by team 2 were VOC, Measurement System Analysis and DOE. These are used numerous times throughout the NPD process. The R&D manager indicated that there are always more learning opportunities and that these get fed back into the process.

6 Findings – Company C Case Study

6.1 *Company Profile*

Company C is a medium sized medical device company with a medium sized R&D department. It designs and manufactures a range of medical devices including angioplasty hypotubes and stents, and can facilitate design and manufacturer of complete catheter assemblies.

It is 29 years in Ireland with the last 9 years dedicated to medical devices. It has approximately 500 employees. 60 of the employees work in the company's R&D department.

1 R&D team was identified in company C R&D department for interviewing

6.2 *Company C, Team 1 (C1)*

6.2.1 Team Profile [C1]

Company C Team interviewees consisted of an R&D project lead, a senior R&D engineer and an Associate R&D engineer.

The R&D project lead has 8yrs experience in the medical device industry. The senior R&D engineer has 5yrs experience in the medical device industry. The associate R&D engineer has 5 years experience in the medical device industry.

Each Engineer was interviewed separately using a pre-prepared semi-structured questionnaire.

6.2.2 New Product Information [C1]

When each team member was asked when they last introduced a new product, they each indicated 4 months ago. When asked how many new products a year were introduced they all indicated between 6 and 10.

When asked what percentage of turnover was spent on NPD, the R&D project lead and senior R&D engineer indicated between 25 to 30%, with approximately 40% of turnover coming from new products less than 3 years old. The team concluded Company C met their goals in Market Share performance, and exceeded their goals in Profit Performance.

Each team member was then asked to categorise the most recently introduced new product in terms of newness: Derivative, Platform or Breakthrough. The team indicated that new products were mostly Derivative and Platform.

6.2.3 NPD Process [C1]

Company C Team 1 NPD process enhancements

Team members were asked if they used any enhancements to compliment their current NPD process. They all indicated that Design for Six Sigma (DFSS) was the only enhancement within their NPD process. The R&D project lead indicated that DFSS benefited the company through faster product to market.

In summarising the enhancement usage for statistic comparison, the team response was:

DFSS – Currently Using & Somewhat Helpful

Lean Product Development – Not used

Other – Not used

The team indicated that upper management were very helpful in supporting enhancement implementation and its usage.

Company C's Team 1 NPD Process

Each team member was asked about the company's NPD process and if they have a structured NPD process. The team indicated that they do have a structured NPD process. Their process consists of 5 phases which are; Evaluation, Screening, Development, Testing and Launch.

Team 1 relayed the following outline of Company C's established formal PDP process

The Evaluation Phase

Voice of customer analysis is reviewed and ideas are gathered to be evaluated as potential product options. The customer, who is often a medical device manufacturer themselves, is kept involved in the initial evaluation phase to ensure the project is steered down the correct path of what the customer wants. Approval is often gained from the customer themselves to proceed with the project.

The Screening Phase

Here the ideas generated in the evaluation phase are critically evaluated, often using concepts and product prototypes. A final concept is selected. The finance side of things is also reviewed; cost to produce, sale price, potential sales and profit potential. Final approval is gained to proceed with the project to the development phase (Or indeed the decision may be to kill the project based in this information).

The Development Phase

The selected product concept is fully developed, including product testing as the development phase progresses. Finally the design is frozen and ready for formal qualification testing.

The Testing Phase

Product process validation is carried out, documented and approved. This is an important deliverable to the medical device manufacturer customer, and also a must have if sending the product to the market directly. The product and process is prepared for scale up for the Launch phase.

The Launch phase

Production is ramped up and the product is launched on the market. Again the market may be other medical device manufacturers or for full product assemblies, the final customer themselves. The project team monitors the products progress and feedback.

Company C's Team 1 PDP process probed & challenged

The team members were then challenged if they actually did follow the company's PDP process. They were also asked if they felt that elaborate company NPD processes cause them to lose sight of the goal. All team members indicated that they do follow the company's PDP process, but that it is a flexible process. The R&D project lead indicated that because management drove the NPD process within the company, and no other company influences arise around follow a formal process, this allows the process to be flexible and scalable around whatever product development project is in progress.

The team members were asked if management set product project priorities where some team members may be working on more than one project. All team members indicated that project product priorities are set through management and reviewed at weekly update meetings. The R&D lead engineer indicated that project priorities often change as the customer and market changes.

When asked if the value stream approach around product development teams was used, team members indicated that it was not. Team members reported to a functional Manager and were not dedicated to a family of products. The senior R&D engineer indicated that as there were multiple product variants, separating resources by products or product groups was not feasible. Priority setting was using to flow the resources.

Each team member was asked about phase review usage. The R&D engineer indicated that informal phase reviews were conducted within the development team. Business reviews or milestone reviews were conducted at scheduled management meetings for review.

The team were asked if they knew the product target cost price when they started working on their current NPD project. All the team members indicated that they know the product target cost price and that it was reviewed within the team continually.

Company C's Team 1 – Cross Functional Team usage

Each team member was asked about cross functional teams. They all agreed that they use cross functional team members throughout the company's PDP process.

The following functional areas were indicated by team members:

- Finance
- Customers
- Engineering
- Manufacturing
- Marketing & Sales
- Packaging
- Suppliers
- IP and Legal

All team members concluded the cross-functional team was very helpful in developing new products. The R&D project lead was asked why Upper management was not listed. He indicated that they were involved at the higher review stage only during meeting progress updates and did not interact with the NPD team itself.

6.2.4 NPD Tools and Methodologies [C1]

The following list of NPD Tool and methodologies in Table 4.6 were reviewed with each team member and asked if they were used and how helpful it was.

NPD Tools and Methodologies	Currently Using	Currently implementing	Currently Training	Not Used	Not at all helpful	Not very helpful	Somewhat helpful	Very helpful
Phase-Gate Project Reviews	X							X
Measurement System Analysis (MSA)	X							X
Benchmarking	X							X
Voice of the customer (VOC)	X							X
Quality functional Deployment	X							X
DFSS Scorecards				X				
Pugh Concept Selection Matrix				X				
Design for X (DFx)				X				
Failure Modes and Effects Analysis (FMEA)	X							X
Anticipatory Failure Determination				X				
Poke Yoke	X						X	
Process Capability studies	X							X
Multi- Vari Analysis	X						X	
Design of Experiments (DOE)	X							X

Table 6.1 Company C Team 1 NPD Tools and Methodology usage

Some highlighted high usage tools by team 1 were VOC, FMEA and DOE. These are used numerous times throughout the NPD process. DFSS scorecards were not used as all projects were monitored by their respective R&D leads.

7 Discussion

7.1 Company Profiles

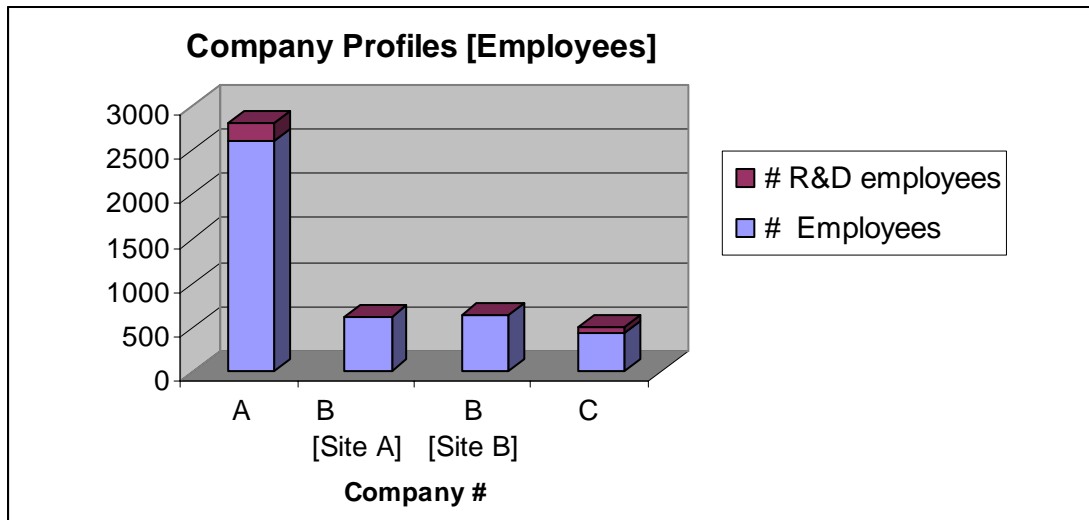


Figure 7.1 Interviewed Companies Employee Statistics – R&D portion of employees

Figure 5.1 demonstrates the size of the companies interviewed and to their respective R&D departments. Company A has a large sized R&D department. The department is well established in Ireland. Company B Site A has a small to medium sized R&D department. The department is also well established in Ireland.

Company B Site B has a small sized R&D department. The R&D department was only setup in recent years. Site A and Site B were historically separate companies, but were bought out by Company B.

Company C has a medium sized R&D department, but it is in high proportion to the total employee level at 12% as demonstrated in Figure 5.2. This can also be explained as the company does not necessarily produce everything it designs through the R&D department. The R&D department itself is open for business in contracting out a full medical device design service to other medical device companies who do not have the necessary skills and resources.

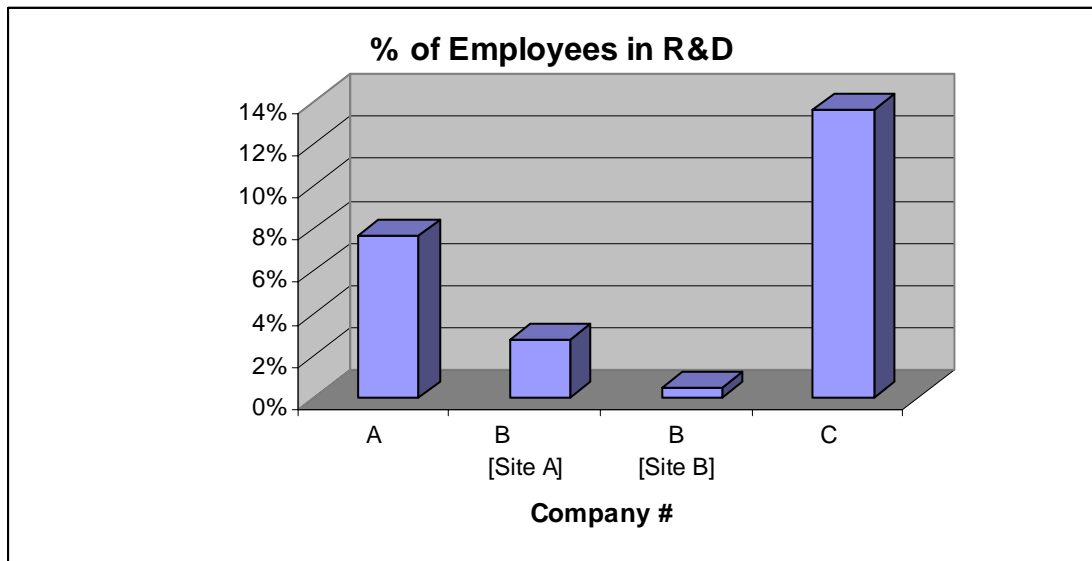


Figure 7.2 R&D employees as a percentage of total Company Employees

The range of company sizes and characteristics act as a good spread in the comparison and the study of each of the team's findings and results, addressing the research methodology concern around case studies where it points to Seawright and Gerring's statement that 'chosen cases must also achieve variation on relevant dimensions, a requirement that is often unrecognised' (2008:294).

7.2 Team Profiles

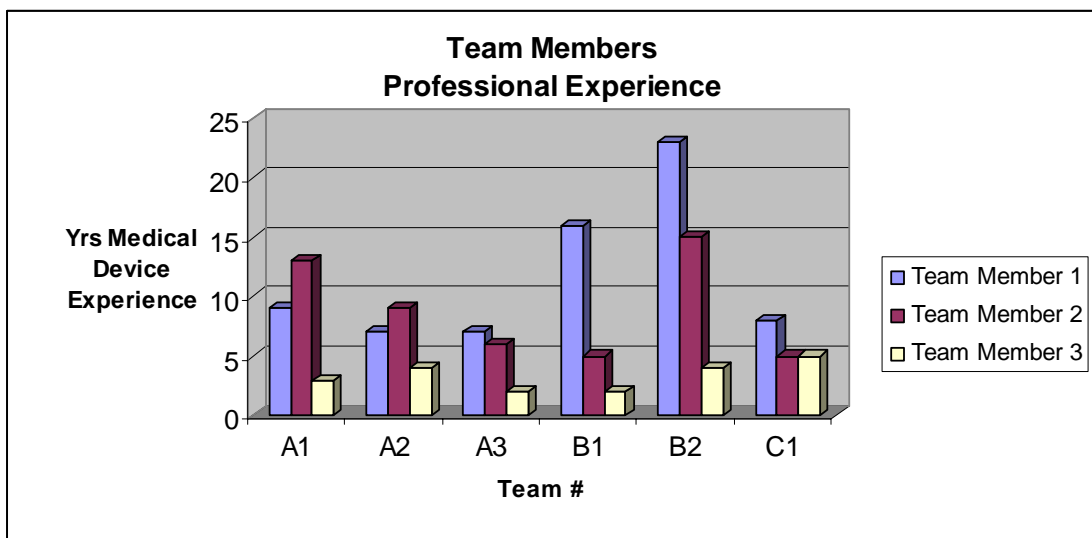


Figure 7.3 Team members number of years R&D medical device experience

Figure 5.3 demonstrates that each team interviewed has at least one, if not two members, with a high level of medical device experience to draw from in answering interviewer questions. This reinforces the validity of the findings. Company A has a large R&D department and has separate R&D teams. Hence, a clean cut of Engineer levels of project R&D engineer, senior R&D engineer and Associate R&D engineer could be taken.

Company B is a different set-up. The R&D director is director of both Site A and Site B. She was interviewed with respect to Site A only (where she is based). A R&D project lead and associate engineer level were allowed to be interviewed with permission from the R&D director. For Site B, all 3 R&D employees were interviewed. This included the R&D manager, who reported to Company B R&D director.

Company C R&D department team interviewees were similar levels to that of company A. This demonstrates that the experience of the teams interviewed addresses Morgan and Liker's recommendation in the methodology chapter where they state that experience people from the core PD team should be chosen as 'they will provide valuable insights into the current state of your product development value stream' (2006:343).

7.3 New Product Information

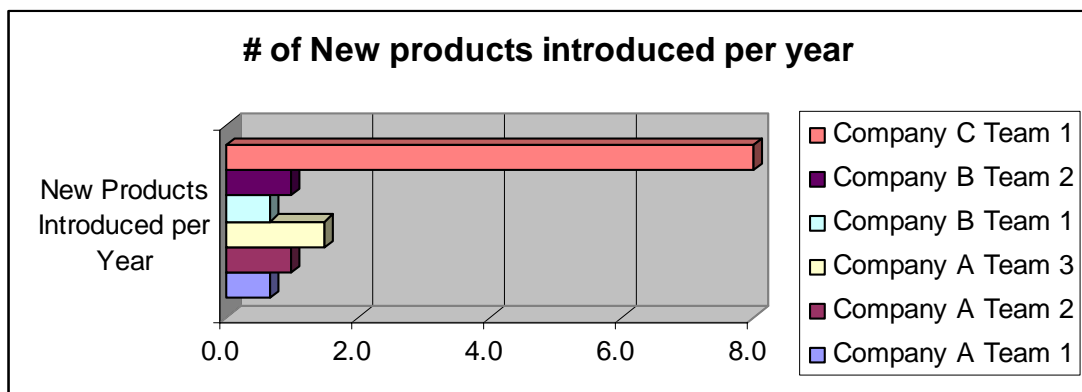


Figure 7.4 Number of New products introduced per year per R&D team

From Figure 5.4, it is demonstrated that company A averages approximately 1 new product per year across the three teams. This can be viewed as a very low new product turnover for a company with 200 employees in their R&D department. However, this may be explained due to the nature of their products. They are Class III per the FDA medical device categories classifications, as outlined by Fries in the Introduction. Company A design and build fully assembled catheter devices, often with drug coated stents. Although being platform, these are highly complex medical device assemblies requiring high levels of testing and documentation. This can explain the seemingly low level of new product turnover, but for a high value product (See Figure 5.5; 45% turnover in new products for company A).

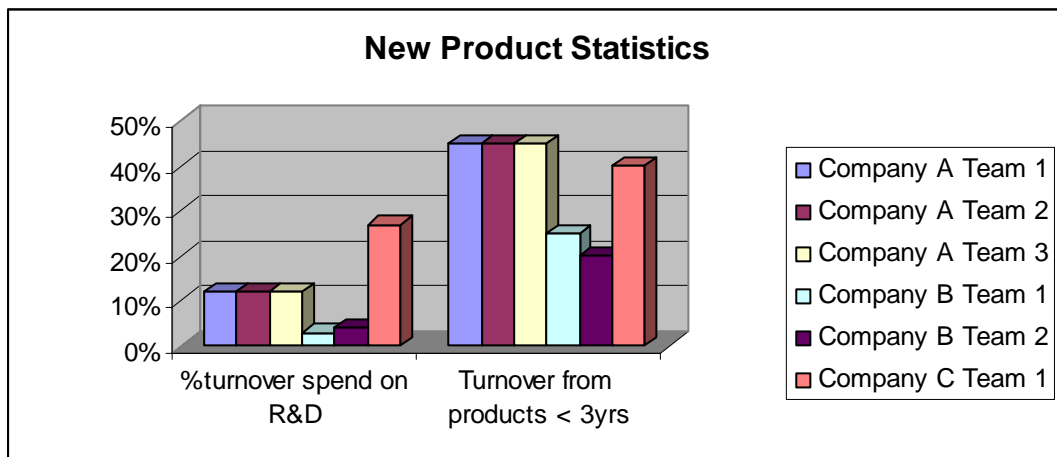


Figure 7.5 New Product Statistics – Percentage turnover spend in R&D and percentage turnover from New Products

Company B, Site A and Site B, average 1 new product per 1.5 years across the two sites, as demonstrated in Figure 5.4. As Company B has a much lower percentage of turnover spent on R&D and a much lower number and percentage of employees working in R&D when compared to Company A, it can seem like a much better result. However, Company B new products are platform and are Class II per the FDA medical device categories classifications, a lower classification than Company A, and hence a lower value (20-25% turnover in new products per Figure 5.5) and not as specialised.

From Figure 5.4, Company C averages 8 new products per year. Its new products are Class III per the FDA medical device categories classifications, the same high level classification as Company A. The company has a high turnover spend on R&D compared to Company A. Figure 5.5 demonstrates that it has a similar success rate of 40% turnover from new products to Company A also, with less than a third the number of R&D employees as demonstrated in Figure 5.1. The best case average turnover flagged in the Introduction from figure 1.1 for both the Engineering and Manufacturing industries and for the Pharmaceutical industries is 30% of sales being from new products. Company A and Company C are over this industrial average for the high achievers.

However, although Company C new products are class III, they typically are catheter assembly parts and not the fully assembly product ready for use by a doctor (which Company A is), but parts ready for shipment to other medical device companies for finishing the final assembled product.

As outlined in the introduction, Ireland produces one of the Europe's largest share of high risk Class III medical device products. The 3 companies interviewed are all involved in the R&D of high Class FDA rated medical devices, which is critical for their survival in this niche market in Ireland, and hence this study has chosen a good cross section of R&D medical device companies.

7.4 NPD Process

Design for six sigma methodology is a relevantly new initiative of enhancing a company's current new product development process and it is therefore surprising that all of the company's interviewed all use DFSS as the driving methodology behind their NPD process. This is demonstrated in Figure 5.6.

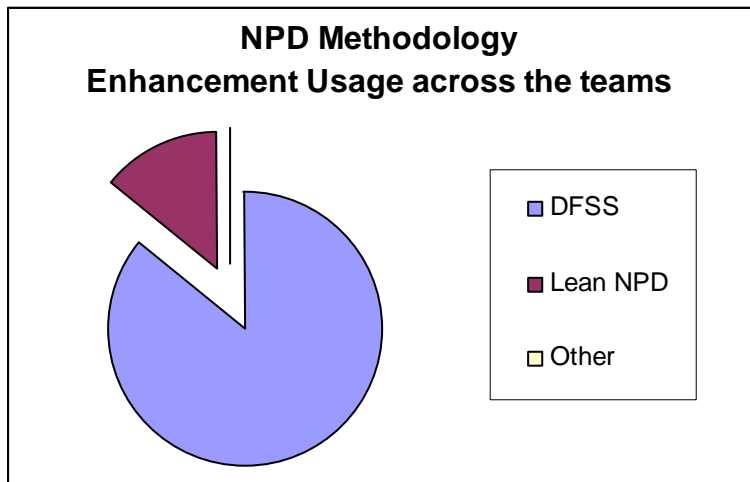


Figure 7.6 NPD Methodology enhancement usage across the 6 teams

Company interviews cited advantages and benefits such as, front loading the NPD process by showing problems up front solving them before they become an issue, roadmap for achieving goals and in some cases flexibility across phases.

In Company A's case, team 2 felt it was a mature process where lessons learned had been constantly fed back in to the process. These advantages match the ones cited in the literature review for DFSS. The cost of poor quality to sales is reduced by frontloading and routing out issues upfront and not after the product hits the market. This is iterated again in the literature review in Figure 2.1 where upfront six sigma control at the design phase is demonstrated through cause and effect; 5% cost to design can have up to 70% effect on cost influence. The DFSS mantra is to design the right product which is just what an interviewee in Company B Team 1 cited, through upfront planning around the voice of the customer. The R&D manager in Company B Team 2, who has 23 years experience, himself stated that he witnessed product issues and mistakes previous to the companies introduction of DFSS in 2003/2004 that would now have been caught through DFSS upfront. Again this concurs with the advantages in the literature review where it is noted that DFSS can prevent wasteful rework and poor quality, instead of finding it at the manufacturing level or worse, out at the customer.

In the literature review, a word of caution offered from Rosenau was that elaborate company NPD processes cause teams to 'lose sight of the goal: getting product to the market quickly' (1996: 350). I put this theory to each team member. All interviewees disagreed. I also asked if they actually really did follow their formal NPD process. These questions allowed some interesting observations to be followed up.

Company A interviewees mostly indicated that they do follow their in house PDP process and that it does not hinder goals. They indicated that the process is flexible across the NPD phases. The process seemed to work well for all team members. The main reason was answered in Team 2 where an interviewee indicated that their PDP process is flexible and is fed with lessons learned keeping it up to date and more real for team members. Company A's NPD process is therefore a matured process that has allowed itself to evolve to make it a better and better fit for each team that use it. This concurs with the literature review around DFSS IDOV method where it indicates that each organisation must fine tune their NPD process over time. Clearly Company A does this by implementing lessons learned back into their NPD process.

Company B interviews also mostly indicated that they do follow their in house PDP process and that it does not hinder goals. However, since their process was only recently introduced, it was plain to see that it had some more maturing to do. The interviewees indicated that it was a formal process, with most interviewees indicating it was not flexible. There was a light version, but nobody would risk using it in case they missed something and would put themselves on the line. Some frustration did come across from the project lead from Company B team 1 where he felt sometimes there was overkill in the activities of some projects. He also mentioned the process being corporate driven. There was no mention of a feedback loop from any interviewees from Company B to allow for continuous improvement such as mentioned in Company A. This contradicts the literature review, but the effects of this contradiction are plain to see. DFSS should be an enhancement to the current process and allow flexibility around the product in question being developed. It was felt that the company should drive its DFSS process to match its own company and not that of the corporation.

Company C interviews again also mostly indicated that they do follow their in house PDP process and that it does not hinder goals. They indicated that their process is flexible across products. It was interesting to note that company management drove the process and allowed flexibility. This may be easier for management to do this as there are no corporate reports, they are the top of the company and obviously have no qualms about making these calls. For the company to average 8 new products per year, this flexibility is a must for each product. This is a clear lesson for Company B to follow, when compared to the flexibility demonstrated by Company A and Company C. Company B's challenge is to work with corporate in allowing their company their own individuality to be tuned over time through lessons learned for their NPD process.

Lean product development is another initiative reviewed in the literature review. All teams dismissed its use in their NPD process. Only some lean suggestions such as stand-up meetings and email rules were followed, but only on an individual bases and not a company roll out. The literature review states the potential for competitive advantage. It describes Lean NPD as a strategy for eliminating wasted time and cost in terms of the time to market throughout the life cycle of a company's NPD process. However, since these medical device companies are on the high end medical device design and manufacture, competitiveness on price is not necessarily the driving factor.

However, there were some observations of Lean product development approaches that interviewees may not have been aware of such. Company A was the only company to follow the value stream approach of creating teams around products, a lean initiative. Company B team members reported to functional managers, and did not segregate per product. Company C did not either. Although Company C is explainable, due to the number of new products they go through, it would be unreasonable to reshuffle for every product. For Company B Site A, as it produces an average of 1 product per 1.5yrs could implement this initiative. Again the issue of corporate driven comes up. Company B, Site B, has 3 R&D employees so is not applicable to product team aligning. This value stream approach concurs with Mascitelli in the literature review where he highlights the advantages of

developing teams around products, where there are enough employees in the business unit, to avoid resource conflicts and reduce barriers.

Another Lean product development initiative is the smart usage of phase reviews. This may have been unknown to interviewees, but observations to their usage were made. Company B cited up to 10 phase reviews per product, which from previous information are assumed to be formal phase reviews (corporate driven). This compared to the other two companies is a high level of team soaking time, which is exactly the watch out relayed in the literature review, when Mascitelli cites that the time to market can often get worse. Company A and Company C mentioned most phase reviews taking place at upper management level with little or no team involvement except the R&D team lead or project engineer. In the literature review, the true potential of lean NPD is cited as focusing on flow and not wasted expenses.

	Phase 1	Phase 2	Phase 3		Phase 4	Phase 5
DFSS	Plan	Identify	Design	Optimise	Validate	Implementation
Company A	Proposal	Definition	Development		Validation & Scale-up	Commercialization
Company B Site A	Concept	Feasibility	Development		Qualification	Launch
Company B Site B	Concept	Feasibility	Development		Qualification	Launch
Company C	Evaluation	Screening	Development		Testing	Launch

Figure 7.7 DFSS phases contrasted against each interviewed company's NPD phases

Figure 5.7 outlines each of the companies 5 main phases. As indicated above, each company uses the DFSS enhancement. This is evident as you read each of the company's NPD phases they match the mantra of the DFSS 5 step IDOV method phases, with an additional phase of Implementation capturing the company's launch or commercialisation phase in every company interviewed.

7.5 Cross Functional Team usage

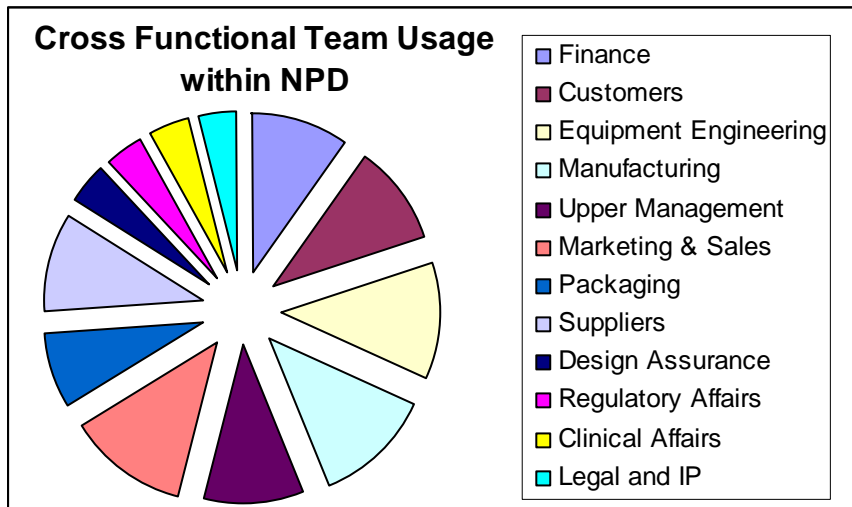


Figure 7.8 Cross Functional team usage during the NPD process across the 6 teams

As shown in Figure 5.8, all of the teams interviewed used cross functional teams throughout their NPD process. The literature review also confirms this trend with DFSS usage where it indicates that cross functional teams should work together to born a product that has recognised the VOC and follows critical product requirements.

During the interviews, some interesting feedback was received around the cross functional teams. Notable examples are where the senior R&D engineer from Company A Team 2, noted that he would prefer if upper management were not part of the NPD team itself as they can cause intimidation and bias the team. It is therefore interesting when comparing to Company C, that upper management is not listed on the cross functional team. The R&D lead interviewed in Company C indicated that upper management were involved during high level reviews and update meetings only, and were not part of the NPD team.

It is interesting that Company B, although using cross functional teams have come up with problems where the R&D project lead has a dotted line to the functional

area, and therefore no pull in making things happen when they need to in the particular functional area during the NPD process. The R&D director indicated that they were changing the NPD structure to address this problem, which is a good indication that the company can be flexible in this regard and make the necessary changes to address NPD as a whole.

7.6 NPD Tools and Methodologies

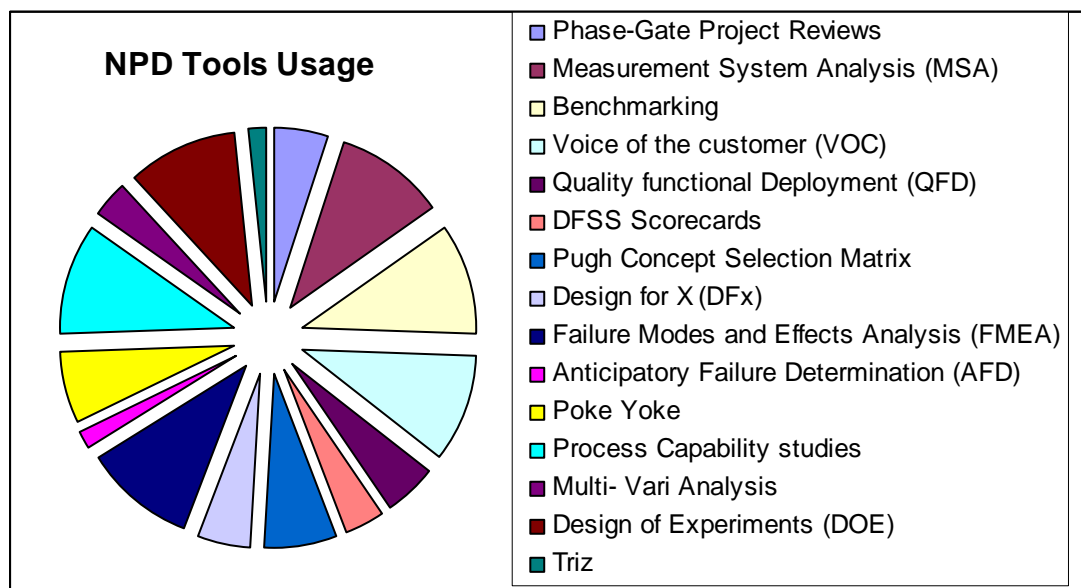


Figure 7.9 NPD Tool usage across the 6 teams

Figure 5.9 outlines the main tools advocated by the DFSS methodology as outlined in the literature review, some more popular than others. Each team noted different tools they used, along with their usefulness during each teams NPD process.

Notable observations include tools of high usage such as MSA, DOE, FMEA and process capability studies. VOC although used by all teams, was of low usage by Company A teams 1 and 2 as they were deviating approximately 2 product characteristics from a platform product. Also, benchmarking, although used across all teams, was of low usage in Company B teams as they felt that they did

not want to influence designers towards or around competitor products due to potential IP issues it may inadvertently cause. Internal benchmarking was more common across most of the teams.

Another point of note is the use of DFSS scorecards. Company A and Company C do not use them at all. Standard project management tools such as meeting minutes and project tracking are used instead. This is interesting as this tool is a major highlight in the DFSS process in the literature review, where the DFSS scorecard is developed and updated throughout the whole NPD process. Company B team 1 and 2 on the other hand do use DFSS scorecards, finding them very helpful. This questions the value of using these if Company A and Company C can both manage sufficiently without them, especially with Company A's matured NPD process. It is also interesting that the R&D director commented on a desire to use some of the tools more often, but was restricted due to resourcing. Maybe, the time spent continually drafting and updating scorecards could be better spent. One must question its value as the literature review shows it to contain a lot of work in tracking through the NPD process. Garcia-Valderrama et al point that these scorecards are a method of 'evaluating R&D projects in different stages of their product life cycle' (2009:1179), however, Company A and Company C are clearly managing without them and evaluating their projects through the project lead project meetings, minutes and phase review usages.

Other tools of little or low usage such as AFD are really down to the new product being developed. They are not must have tools in the eyes of the teams interviewed. Both Company A and Company B teams point out that there will always have to be manufacturing line quality checks at all points along a product manufacturing line due to the high risk nature of medical device Class II and III products. Triz was only used by one team. This seems to confirm what was cautioned in the literature review where it may only be suited to breakthrough products where potential solutions it generates may take years to prove out. Another cautionary note on DFSS was the over dependence on VOC, as customers did not know the next leap in development. However, VOC was heavily used across all teams. No teams indicated that they were working on breakthrough products.

7.7 Discussion summary

The Company Profile section confirms that the range of company sizes and characteristics act as a good spread in the comparison and the study of each of their team's findings and results, addressing the research methodology concern around case studies where it points to Seawright and Gerring's statement that 'chosen cases must also achieve variation on relevant dimensions, a requirement that is often unrecognised' (2008:294).

The New Product Information section confirms that the product classes of the case studies come under the top two high end classes, Class II and Class III medical devices, which hits the market flagged in the Introduction where it indicates that Ireland has one of Europe's largest share of high risk Class III medical device products.

The NPD Process section confirms the usage of DFSS across all companies. It outlines some advantages of its use which concurs with the advantages in the literature review where it is noted that DFSS can prevent wasteful rework and poor quality, instead of finding it at the manufacturing level or worse, out at the customer.

The NPD Process section also contains, Figure 5.7 which outlines each of the companies 5 main phases. This further matches the DFSS methodology where each of the company's NPD phases match the mantra of the DFSS 5 step IDOV method phases, with an additional phase of Implementation capturing the company's launch or commercialisation phase.

The NPD Process section also outlines the importance of flexibility in the NPD process where the process is fined tuned through feedback loops incorporating lessons learned. This is a clear lesson for Company B to follow, when compared to the flexibility demonstrated by Company A and Company C. Company B's challenge is to work with corporate in allowing their company their own individuality to be tuned over time through lessons learned from their NPD process.

In the NPD Process section, Lean NPD section initiatives are outlined. The value stream approach and phase review usage were highlighted as main findings.

The value stream initiative of matching teams to products worked well for Company A. Company B Site A however mentioned resourcing restrictions, which would be overcome if they aligned teams to new products, with 1 product per 1.5yrs, this could easily be done. It was directed that this value stream approach concurs with Mascitelli in the literature review where he highlights the advantages of developing teams around products, where there are enough employees in the business unit, to avoid resource conflicts and reduce barriers.

The second lean NPD initiative of smart phase review usage is demonstrated by minimally involving the whole R&D team in every phase review, and by using management instead. This lead to where management should not be used.

In the Cross Functional Team Usage section it was concluded that Cross functional team usage by the R&D teams during NPD is also a must, which concurs with the DFSS methodology outlined in the literature review. The medical device company should use whatever functions are relevant to them in their development of a new product. However, upper management should not form part of the development team as they are a disruption and can cause project bias. Management should only get involved in the project phase reviews.

In the NPD Tools and Methodologies section, it can be concluded that the following NPD tool usage are must haves for medical device companies throughout the DFSS NPD process; MSA, Benchmarking, VOC, FMEA, Process Capability Studies and DOE.

DFSS recommends that these NPD tools are mapped across the companies NPD process and used by the team members, as per the literature review, and the overwhelming usage of these NPD tools across all team members interviewed. The remaining NPD tools are both team and product dependant. These are QFD, Pugh concept selection matrix, DFx, AFD and Poke Yoke. The final NPD tool of DFSS scorecards is not being recommended for use at all. No company advantages to its use could be cited by team members. In the discussion, it was

concluded that resource usage should be directed at other recommended NPD tools and that the project R&D engineer should take the responsibility of tracking the project by oneself.

8 Conclusions

From the Introduction chapter, the aim of this study is to investigate what New Product Development (NPD) process methodologies and what NPD tools are in use by Irish medical device companies, and to then recommend a best practice NPD process with the appropriate tools to deliver medical device companies a roadmap to choosing and bringing the right product to the market at the right time.

This study set out to fulfil this objective by researching what NPD tools and methodologies are theorised as best practice for a company's NPD process. It then compared these theoretical findings to that of the findings of three separate case studies involving three different medical device companies across six R&D teams. These findings were gathered during face-to-face interviews using semi-structured questionnaires with three team members from each team. The three medical device companies produce medical device products in the Class II and Class III categories. The three companies were varied across their company size, R&D department size and the medical device products they produce.

The conclusion will therefore recommend, based on the study's findings and its literature review, the best practice NPD tools and methodologies that should be used for Irish medical device companies, as a roadmap to bringing the right product to the market at the right time.

- DFSS phase methodology can be concluded as a must have for the Irish medical device company.

The DFSS methodology is used overwhelmingly throughout all the teams interviewed and is very apparent when all the interviewed company's NPD phased structures are reviewed against the DFSS IDOV phases. Each company's NPD process and their phases match the IDOV methodology. They all however have an additional Implementation phase at the end which allows feedback from the customer field before the project is formally closed out. Its benefits are demonstrated by each of the team members interviewed in small, medium and

large Irish medical device companies. Class II and Class III products, including fully assembly products and partial products, can all be developed under the methodology of DFSS.

- DFSS benefits cited are directly aligned to that of the literature review

Benefits such as front loading the NPD process to show issues upfront. Views of caution in the literature review such as over elaborate NPD processes were dismissed by all of the teams interviewed. This did however lead to the need for each company to continually improve their NPD process.

- Medical device companies that use the DFSS approach must allow a feedback loop at the end of their process, which will feed lessons learned back in and allow R&D teams to continually tweak their NPD process for the best fit for them.

DFSS should be a flexible system to work around the product in question that is being developed. This was evident where Company A could demonstrate a matured DFSS NPD system where team members were content with its flow, while Company B had recently introduced DFSS into their NPD system and although the benefits were plain to see, there was frustration where they cited it to be inflexible to their product development needs.

- Lean NPD initiatives of value stream teams and reviewing the companies phase review usage should be followed.

The lean NPD initiative of value stream teams (where there are a large number of R&D employees and a low level of high value new products) and the smart usage of phase reviews during the NPD process are must haves characteristics of the NPD process. The value stream initiative of matching teams to products worked well for Company A. Company B Site A however mentioned resourcing restrictions, which would be overcome if they aligned teams to new products, with 1 product per 1.5yrs, this could easily be done. The second lean NPD initiative of

smart phase review usage is demonstrated by minimally involving the whole R&D team in every phase review, and by using management instead. This leads to where management should not be used.

- Cross functional team usage by the R&D team during NPD is a must.

A medical device company should use whatever functions are relevant to them in their development of a new product. Upper management should not form part of the development team.

The approach of cross functional team usage is demonstrated across all companies and advocated in the literature review within the DFSS methodology. Company C did not have upper management on their cross functional team, with Company A teams (who do have management part of their team] indicating that they would prefer upper management to not be part of their cross functional team, as they are a disruption and can cause project bias. Management should only get involved in the project phase reviews.

- NPD Tools and Methodologies are a must have as part of the companies NPD process. Some are more than others.

The following NPD tool usage are must haves for medical device companies throughout the DFSS NPD process; MSA, Benchmarking, VOC, FMEA, Process Capability Studies and DOE.

DFSS recommends that these NPD tools are mapped across the companies NPD process and used by the team members, as per the literature review, and the overwhelming usage of these NPD tools across all team members interviewed. The remaining NPD tools are both team and product dependant. These are QFD, Pugh concept selection matrix, DFx, AFD and Poke Yoke. The final NPD tool of DFSS scorecards is not being recommended for use at all. No company advantages to its use could be cited by team members. In the discussion, it was concluded that resource usage should be directed at other recommended NPD tools and that the project R&D engineer should take the responsibility of tracking the project by oneself.

9 Further Research

Below are some suggested areas of research from interesting observations and findings during the study.

NPD Tools and methodology for Class I medical device products. These products would be of lower value and would therefore be in a more highly competitive market. It would be interesting to review if the same conclusions would be reached.

Another area of research would be best practice NPD for breakthrough medical device products. All Companies interviewed were either derivative or platform product types. It was interesting that Mader cautioned against DFSS for leap of development type projects (2003).

A study of other NPD methodologies such as PACE[®], a product and cycle time for excellence methodology for the development of new products, manufacturing processes and systems in manufacturing.

Another area of research that is interesting is Obsolescence phase of NPD, where planning should be taken in phasing out the end of life product and phasing in the new one without losing any existing customers.

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11 Appendices

11.1 Appendix A – Semi-Structured Questionnaire

Attached to the appendices is the semi-structured questionnaire the interviewer used as a guide through all the interviews with the teams of the 3 companies interviewed.

Section 1: Company Profile

1. How long has your company been carrying out R&D in Ireland?

_____ years

2. Approximately how many employees does your company have at this location?

_____ employees

3. Approximately how many employees do you have in R&D?

_____ employees

4. How has your company performed with respect to:

Market Share performance

☐ Exceeded Goals ☐ Met Goals ☐ Missed Goals

Profit Performance

☐ Exceeded Goals ☐ Met Goals ☐ Missed Goals

5. What is your position title?

6. How long have you been working in the medical device industry?

_____ years _____ months

Section 2: New Product Information

- 1. When did you introduce your most recent new product?**

_____ Month _____ Year

- 2. How many new products do you introduce per year?**

- 3. What percentage of turnover do you spend on NPD?**

- 4. What percentage of turnover comes from new products (less than 3 years old)?**

- 5. How would you categorise your most recently introduced new product in terms of its newness?**

(Please check only one category that most closely represents this new product.)

- ☐ **Derivative**
- ☐ **Platform**
- ☐ **Breakthrough**

Section 3: New Product Development (NPD) Process

1. Popular NPD enhancements: familiarity and usefulness

(Please fill in the boxes provided)

Popular NPD Enhancements				
Design For Six Sigma (DFSS)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Lean Product Development	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Other (not on list above) Please state:	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful

2. How helpful were upper management in supporting its implementation and usage throughout your NPD process?

☐ Not at all Helpful
 ☐ Not Very Helpful
 ☐ Somewhat Helpful
 ☐ Very Helpful

Elaborate with Examples.

8. Do you use the value stream approach around product development teams?

9. Do you follow any lean approaches? [Emails, mtgs etc]

10. Phase-gate reviews – do you use? Are you flexible and can deviate project to project? [Lean] – allow you to make leaner, efficient, natural flow..

11. Do you know the product target cost price?

12. Do you consider product cost in design?

Section 4: Cross Functional Teams

1. Do you use cross-functional teams to develop new products?

☐ Yes ☐ No

2. Did you use a cross-functional team to develop your most recently introduced new product?

☐ Yes ☐ No

3. From which of the following functional areas did members of the cross-functional team come?

(Please check all that apply.)

<input type="checkbox"/> Accounting Finance	<input type="checkbox"/> Production Sales	<input type="checkbox"/> Suppliers
<input type="checkbox"/> Customers	<input type="checkbox"/> Marketing	<input type="checkbox"/> Quality Control
<input type="checkbox"/> Engineering	<input type="checkbox"/> Packaging	<input type="checkbox"/> R&D
<input type="checkbox"/> Upper Management	<input type="checkbox"/> Other Functional Area (please specify):	

4. How helpful was the cross-functional team in developing this new product?

☐ Not at all Helpful ☐ Not Very Helpful ☐ Somewhat Helpful ☐ Very Helpful

Give Examples:

Section 5: NPD Tools & Methodologies

1. NPD tools and methodologies: familiarity and usefulness.

(Please fill in the boxes provided)

NPD Tools and methodologies				
Phase-Gate project reviews	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Measurement system Analysis (MSA)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Benchmarking	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Voice of the Customer (VOC)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Quality Function Deployment (QFD)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful

NPD Tools and methodologies (Continued 1)				
DFSS Scorecards	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Pugh Concept Selection Technique	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Design for X (DFx) [DFM, DFA]	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Failure Modes and Effects Analysis (FMEA)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Anticipatory Failure Determination (AFD)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful

NPD Tools and methodologies (Continued 2)				
Poka Yoke	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Process Capability and Performance Studies	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Multi – Vari Analysis	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Design of Experience (DOE)	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful
Triz	If you are familiar with this indicate:			
	<input type="checkbox"/> Currently using	<input type="checkbox"/> Currently implementing	<input type="checkbox"/> Currently training	<input type="checkbox"/> Not used
	Indicate Level of Usefulness found from for NPD:			
	<input type="checkbox"/> Not at all Helpful	<input type="checkbox"/> Not Very Helpful	<input type="checkbox"/> Somewhat Helpful	<input type="checkbox"/> Very Helpful

- 2. What benefits, if any, have you seen from the use of these tools and methodologies?
Examples.**

END

11.2 Appendix B – Abbreviations

A list of abbreviations used throughout the study

A1	Company A, Team 1
A2	Company A, Team 2
A3	Company A, Team 3
AFD	Anticipatory Failure Determination
AHP	Analytic Hierarchy Process
B1	Company B, Team 1
B2	Company B, Team 2
CTQ	Critical to Quality
C1	Company C, Team 1
DOE	Design of Experiments
DPMO	Defects per Million Opportunities
DFSS	Design For Six Sigma
DFA	Design for Assembly
DFM	Design for Manufacturing
DFx	Design for X
FDA	Food and Drug Administration
FMEA	Failure Modes and Effects Analysis
HOQ	House of Quality
IBEC	Irish Business and Employers Confederation
IBP	Integrated Business Plan
IDOV	Plan Identify Design Optimize Validate
IMBA	Irish Medical Devices Association
IP	Intellectual Property
KDPD	Knowledge Driven Product Development
LPDA	Lean Product Development System
LNPD	Lean New Product Development
MSA	Measurement System Analysis
NPD	New Product Development
PDP	Product Development Process
PIB	Project Investment Board

QFD	Quality function deployment
R&D	Research and Development
R&R	Repeatability and Reproducibility
SIPOC	Supplier Input Process Output Customer
USR	User Requirement Specification
VOC	Voice of the Customer