The Role of Customer Centricity in Medical Device Innovation - An Irish Perspective

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Abstract

The objective of this study is to investigate the perspective of Irish medical device companies on customer centric innovation. There is considerable growing emphasis on innovation in the medical technology (med tech) sector as a means of securing industry growth in Ireland. This shift in business orientation is not overtly coupled with calls for increased customer focus. Innovation as a business strategy is all but futile unless it can be commercially expressed and the only means to assure this is to develop new products that meet validated customer needs – the essence of customer centricity.

The research technique employed is in-depth interviewing; this was conducted among industry leaders from ten medical device companies operating in Ireland. These included five foreign direct investment companies and five indigenous companies.

The research findings demonstrate a commitment to customer centric innovation practices and a general understanding of the importance of accurately defining customer needs through user-involvement in med tech innovation. This research indicates that different activities are employed by different companies in implementing customer centric innovation, but that there is room for improvement in how companies and the industry in general execute these activities. Customer centricity is accepted as a means to generating competitive advantage but it is recognised as a complex process that requires consideration for a broad range of stakeholders ranging from clinicians, payers, patients to mention a few. The most significant deficit identified in terms of customer centricity in innovation practice is the gap that exists between the clinical community and the medical technology industry in Ireland.

This research concludes that customer centric innovation is perceived as an important influence in the success of medical technology innovation among Irish based companies; that it is being practised in day-to-day business activities but that improvement in this area will be necessary to sustain the industry's overall success.

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The term "medical devices" includes everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors. The Global Harmonisation Task Force proposes the following harmonised definition:

"**Medical device** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro*
- examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means". (GHTF, 2005)

The term Medical Technology Industry includes companies involved in the design, manufacture and supply of medical technology used in the diagnosis, prevention, treatment of disease and disability.

1 Introduction

1.1 Research Background

The medical technology (med tech) industry started in Ireland in the 1970's with the arrival of American–based firms Becton Dickinson and Abbott Laboratories through the support of the Industrial Development Authority (IDA) Ireland (Stommen, 2005). The industry has grown to be a cornerstone of the Irish economy with eight of the world's top ten medical device companies located in Ireland and with Europe's premier cluster of device companies based in the Galway region (Enterprise Ireland, 2010). There are currently over 200 med tech companies in Ireland, exporting €7.2 billion worth of product which represents an unprecedented 14% growth rate since 2009. With circa 25,000 employees, the Irish med tech industry has the highest number of people working in it than any country in Europe, per head of population (IMDA, 2011).

The industry's roots are predominantly in production, with Ireland earning a reputation as a global centre of excellence for world class manufacturing of high-tech medical devices. However, having a singular focus would ultimately limit the competitiveness of the industry in Ireland and consequently pose a threat to development and growth, a situation the industry is well aware of and working to address. To combat this, more emphasis is being placed on supplementing the industry's distinction in manufacturing with high value-added activities such as research and development (R&D) and new product development (NPD). For this strategy to be effective, the Irish med tech industry needs to expand its core competencies built up during the production-only era. In developing these competencies, Irish operations, especially those of Foreign Direct Investment (FDI) companies, have focused primarily on cost minimisation rather than process innovation. Another feature of the industry's focus on manufacturing is an obvious lack of marketing which means Irish med tech operations are remote from customers and there is insufficient interaction with clinicians (Fennelly & Cormican, 2006). For the purpose of this research, the term clinician is used to describe professionally qualified medical practitioners including doctors, specialists, nurses, radiologists etc.

Innovation is currently very topical across all industry sectors in Ireland as companies tirelessly pursue elusive competitive edges in highly-competitive global markets. Evidence of this is demonstrated by the number of reports published in this area, see Table 1.1. Instituted by the Irish government's "Smart Economy" mandate (Department of the Taoiseach, 2008), the Innovation Taskforce published a report, Innovation Ireland (Innovation Taskforce, 2010), in which it underpins innovation as a priority to future Irish economic success. As part of this, the medical technology industry has been highlighted as a primary focus area with recommendations provided to buoy innovation including convergence focused activities and the creation of an innovation eco-system. Such developments are fully complementary with the med tech industry's plans for itself (IMDA, 2011).

The term innovation is a simple label for a series of very complex and often differing activities. People tend to see innovation strictly in terms of revolutionary, breakthrough products but most innovations are the result of steady continuous improvement (PWC, 2011). Tidd et al. (2005) argue that there are four types of innovation, namely;

a) **Product Innovation** - new products or improvements on products. The new Mini or the updated Volkswagen Beetle, new models of mobile phones and so on.

b) **Process Innovation** - where some part of the process is improved to bring benefit. Just-in-Time production is a good example.

c) **Positioning Innovation** - Lucozade used to be a medicinal drink but was subsequently repositioned as a sports drink.

d) **Paradigm Innovation** - where major shifts in thinking cause change. Apple is a classic paradigm innovator, examples being the iPod and the iPhone.

The first three categories of innovation require a strong customer focus in order to get the product and it's positioning correct, this process is referred to as co-creation, or customer centric innovation. The last category, paradigm innovation, is often more about technology and the possible outcomes achievable through technology that were unknown to customers until related products or services were introduced. That said,

Apple's founder and former Chief Executive Officer (CEO), Steve Jobs, is very much aware of where the customer fits into Apple's innovation practices.

"...you've got to start with the customer experience and work backwards for the technology" (Jobs, 1997)

Report Title	Publisher	Year
Analysis of Ireland's Innovation Performance	Forfás	2011
Investing in Medical Technology – IMSTA Report on €1 Billion	IMSTA	2011
Building Ireland's Smart Economy	Dept. of an Taoiseach	2010
Ireland's Innovation Strategy – Time to Make it Happen	Marketing Institute of Ireland	2010
Innovation Task Force Report	Dept of an Taoiseach	2010
Science, Technology and Innovation – Delivering the Smart Economy	Dept. Enterprise, Trade and Employment	2009
Powering the Smart Economy – Strategy 2009-2013	Science Foundation Ireland	2009
Ireland's International Engagement in Science, Technology and Innovation	Forfás	2008
Innovation for a Green Economy	Environmental Protection Agency	2009
Services Innovation in Ireland – Options for Innovation Policy	Forfás	2006
Strategy for Science, Technology and Innovation, 2006-2013	Dept. Enterprise, Trade and Employment	2006
The Ahead of the Curve Report	Enterprise Strategy Group	2004
Building Ireland's Knowledge Economy	Forfás	2004

Table 1-1. List of Innovation Related Reports Published in Ireland 2004-2011

The med tech industry's partial-shift from a solely manufacturing-based orientation to a research, development and innovation orientation is driving the need for increased customer centricity. In addition, as Ireland is a mass exporter of medical devices,

customer centricity is the only reliable road map to navigate the changes taking place in global healthcare systems that affect product sales and adoption. These changes include the rising costs of healthcare, aging populations, reduced decision-making power of physicians, complex regulations and the threat of commoditisation (Management Centre Europe, (2011); Korn/Ferry Institute, (2011)).

1.2 Objective of Research

A research gap exists in relation to understanding how customer centric the Irish med tech industry's approach is to innovation. Innovation needs to be grounded in fulfilling customer needs in order to deliver its full commercial potential. Companies need to continually improve their understanding of who their customers are and what they need in order to drive innovation (Selden & MacMillan, 2006).

The research question being addressed in this dissertation is:

> ***How well is customer centricity understood and subsequently practised in medical device innovation by the med tech sector in Ireland?***

It is intended to investigate the extent of customer centricity in the innovation processes undertaken by med tech industry in Ireland using in-depth interviewing methodology.

This research has two primary objectives. The first is to answer the research question and the second is to propose a list of "best practice" activities relating to customer centric innovation as demonstrated in the research findings.

1.3 Overview of Research

This section provides a brief overview of the subsequent research chapters.

Chapter 2 presents a review of the relevant academic literature on customer centricity as a market led business strategy. Given the ambiguous nature of the concept, a definition of customer centricity is presented. The evolution of customer

centricity is mapped and its relevance to business is discussed. Customer centricity is evaluated in terms of co-creation and open innovation. Models are presented that provide a route towards overcoming organisational challenge in implementing the concept. The overall intention is to provide an understanding of customer centricity and demonstrate why it should be nurtured as a means of ensuring future success.

Chapter 3 provides a review of the literature pertaining to customer centricity as it relates the medical device industry. It sets out to investigate the industry's approach to customer centricity compared to general literature on the subject. The areas investigated included co-creation, open innovation and organisational challenges.

Chapter 4 details the research methodology. The chosen research method is provided and reasons for this choice are discussed. The various available data gathering methods are considered and the methods chosen expanded upon. The chapter considers the sample population required for the research and the issues of data validity and reliability.

Chapter 5 discusses the research findings. The results of the study are reviewed according to the sequence of subject as set out in the different questions.

Chapter 6 presents general conclusions derived from the research and recommendations arising from same.

2 Literature Review – Part 1

2.1 Customer Centricity

> "What the business thinks it produces is not of first importance – especially not to the future of the business and to its success. What the customer thinks he is buying, what he considers 'value', is decisive – it determines what a business is, what it produces and whether it will prosper". (Drucker, 1954, p. 32)

Even though the concept and the benefits of customer centricity have been discussed for more than 50 years (Drucker, (1954); Levitt, (1960); Gulati, (2010a)), companies are still finding it difficult to become customer centric in how they carry out their business activities (Shah, Rust, Parasuraman, & Staelin, 2006). This is possibly due to the ambiguity of the concept not helped in the least by its loose definition whereby most business executives define customer centricity as the capacity to understand and respond to customers' expressed needs (Mitreanu, 2005).

A more encompassing definition is based on Gummesson's (2007) observations that customers do not buy goods or services; they buy something that they perceive to be of value to them. As Barker points out (2006, pp. 197-198) "…the distinction between success and failure in competitive markets may be reduced to two basic issues, first, an understanding of customers needs, and, second, the ability to deliver added value…". Prof. Theodore Levitt, author of the classic Harvard Business Review article "Marketing Myopia", (1960) captured the essence of customer centricity when he said, "People don't want to buy a quarter-inch drill. They want a quarter-inch hole" (Christensen, Cook, & Hall, 2005). Therefore, for the purpose of this research, customer centricity is defined as follows:

> ***The pursuit of delivering customer value through meeting customer needs.***

Customer centricity represents a progressive evolution towards fulfilling customer needs from the mass production, mass distribution and mass communication that was representative of the post World War II era. During this time, marketing emphasis

was on promoting, pricing and distributing products for the mass markets with the emphasis on the products rather than on the customers. As more and more companies entered the market, the increase in product variety ultimately resulted in commoditisation and reduced profit margins. Customer centricity provides a solution to this problem as it focuses on satisfying the needs and wants of individual customers rather than those of mass markets (Sheth, Sisodia, & Sharma, 2000). It focuses on an "outside-in" approach whereby companies aim to creatively deliver something of value to customers rather than focusing on products and sales (Gulati, 2010a). It treats customers as assets (Jain & Siddhartha, 2002). Table 2.1 outlines the evolution of customer centricity within the marketing discipline.

Customer centricity and market orientation are often mixed up in literature and in practice. According to Gummesson (2008), market orientation is broader, including not only customers but also competitors and how markets function. Market orientation establishes three basic tenets for customer behavior including: (1) responsiveness to customers needs; (2) close monitoring of competitors actions; and (3) facilitation of inter-functional co-ordination within an organisation (Narver & Slater, 1990); whereby customer centricity is just one component of market orientation.

Furthermore, customer centricity has many parallels to, but is distinct from relationship marketing. Although relationship-marketing aims to establish, maintain and enhance relationships with customers, it is more strategic in nature than customer centricity (Das, 2009). For relationship marketing to be effective, a customer centric focus needs to emerge, however, the converse is not necessarily so as customer centric marketing can be practised without relationship marketing, for example, in direct marketing situations where the level of customer involvement and interest in an interactive relationship is low (Sheth et al. 2000).

During the period between mass production in the 1950s and the concerted attempts at customer centricity since the 1990s, quality management and lean manufacturing made their debut in an effort to create value for the customer. Value, however, is not only created in the production but also, in the consumption process (Gummesson, 2008) in relation to how the customer extracts value from a product or service

Driving Force	Timeframe	Focus	Some Key Thought Leaders
Production Orientation	1900-1920	Mass Production Techniques • Technological improvement • Productivity focused • Process focused	John Commons Louis Weld Arch Shaw Ralph Butler
Product Orientation	1920-1930	Mass Consumption Society • Product quality • Additional attributes • Designing exceptional products	Fred Emerson Clark Ralph F. Breyer John Mench Percy Straus
Selling Orientation	1930-1960	Intensive Competition • Advertising • Sales promotion • Personal selling • Publicity	Newel H. Comish Robert Bartels William Howard
Marketing Orientation	1960-1970	Market Segmentation • Marketing department • R&D • Customer focus	Peter Drucker Theodore Levitt Wroe Alderson John McKitterick
Customer Orientation	1970 to date	Demographic Convergence • Customer solutions • Convenience • Cost • Communication	Leonard Berry A. Parasuraman George Day Shelby Hunt
Market Orientation	1990 to date	Niche Segmentation • Customer focus • Competitor orientation • Inter-functional coordination	Benson Shapiro C.K. Prahalad Charles Noble Ajith Kumar Bernard Jaworski
Relationship Orientation	1995 to date	Customer Defection • Customer satisfaction • Trust • Commitment • Loyalty	Leonard Berry Evert Gummesson Christian Grönroos Michael Harker
Customer Centric Orientation	2000 to date	Dissatisfied Marketing Productivity • Co-creation • Value • Relational exchanges	Stephen Vargo Ranjay Gulati Roland Rust Adrian Payne Jay Galbraith

Table 2-1. Evolution of Marketing Thought. Source: Adapted from Kaur and Sharma (2009)

In Gummesson's opinion (2008), Womack and Daniel (2005, p. 61) capture the core of customer centricity in their customer-oriented principles:

1. Solve the customer's problems completely by ensuring that all the goods and services work, and work together
2. Do not waste the customer's time
3. Provide exactly *what* the customer wants
4. Provide what is wanted exactly *where* it is wanted
5. Provide what is wanted, where it is wanted exactly *when* it is wanted
6. Continually aggregate solutions to reduce the customer's time and hassle.

Gummesson (2002) suggests that a company needs to look at its total offering and create a balance between production centric and customer centric aspects; and should recognise relationships, networks and interaction as core variables. Payne and Frow (2005) identified five generic processes that are essential for a firm to be customer centric, see Table 2.2.

	Five Key Customer Centricity Processes
1	A strategy-development process including a customer strategy as well as a business strategy
2	A dual value creation process considering both customer and business requirements
3	A silo-spanning integration process that encompasses all the various customer touch points
4	An information management process that includes the data collection and data analysis functions
5	A performance assessment metric that ties the firm's actions to firm performance.

Table 2-2. Customer Centric Processes. Source: Payne & Frow (2005)

Customer centricity is not a philosophy that exists only in the ivory towers of the marketing department. Getting close to customers is a journey the whole company needs to make (Gulati & Oldroyd, 2003) and requires a company to consistently embrace three concepts. Firstly, companies need to learn everything there is to learn

about their customers at the most granular level possible creating a comprehensive picture of each customer's needs, past, present and future. Then, they must get employees to share such information, otherwise it is useless and finally, such customer insights are used to guide not only product and service decisions, but also business strategy.

It is worth noting that in the quest for a more customer centric organisation, there are no fixed methods to follow, rather, different levels of customer centricity are appropriate for different companies depending on their customer relationship strategies (Galbraith, 2005). There are industry and company specific factors that must be weighed when deciding whether becoming customer-centric is less of a choice and more of a necessity. Increased levels of scale and scope (number of products and number of different kinds of products) in an organisation influence the required degree of customer centricity because increasing levels of both require higher levels of integration in order to bundle solutions that customers will find most valuable (Galbraith, 2005). Companies confronted with complex customer needs must stay even closer to their customers whereby there is a strong association between higher complexity of customer needs and customer centricity (Heiko, Gustafsson, & Witell, 2011).

The benefit of customer centricity comes in the form of superior financial performance and the achievement of a competitive edge that is difficult for the competition to emulate (Shah et al., (2006); Gulati, (2010a)). It is logical to conclude that customer centricity leads to customer satisfaction. This in turn creates a virtuous circle of employee satisfaction as demonstrated in the inverse relstionship between customer satisfaction and employee turnover rates outlined in the Service-Profit Chain (Heskett, Jones, Loveman, Sasser, & Schlesinger, 2008).

Increased profitability through customer centricity comes from customer retention or customer lifetime value (CLV). Customer centricity from the perspective of CLV can be defined as:

> "the process for achieving a continuing dialogue with customers, across all available touch points, through differentially tailored treatment, based on the

expected response from each customer to available marketing initiatives, such that the contribution from each customer to overall profitability is maximized" (Kumar, Ramani, & Bohling, 2004, p. 61).

2.2 Customer Centricity and Co-Creation

While customer centricity is applicable across the breadth of an organisation, the focus of this research is primarily in relation to the influence of customer centricity in the innovation process. Customers are able and willing to provide ideas for new products and services that may fulfill needs that have not yet been met by the market or might improve on existing offerings (Holger, Hoyer, Krafft, & Soll, 2010). Modern technology such as the internet, e-mail and social websites make communication easy whereby co-creation can be defined as "a collaborative new product development activity in which consumers actively contribute and select various elements of a new product offering" (O'Hern & Rindfleisch, 2009, p. 87).

In terms of overall innovation, customer centricity is included as one of its primary constructs (CISCO , 2008):

Key Innovation Dimensions

- Pragmatic. A focus on converting "ideas into cash" (revenue growth and profits).
- ***Customer-centric. Discovering and serving customer needs, both explicit and hidden, to create a differentiated customer experience.***
- Open. Cast a wide net to capture the best ideas from internal and external sources, and the capability to capitalise on them.
- Holistic. Innovation is not just about technology or a new product, but also the brand, operating environment, employees, the impact on a business ecosystem, and the impact on society.
- Controlled experimentation. Creating a culture that encourages organisations to experiment, rapidly prototype new ideas, and learn and capture new knowledge.

It would seem that customer centricity has come of age with industry's leaders calling for more customer centric innovation (PWC, 2011). CEOs are approaching innovation with an emphasis on putting customers first, innovating on behalf of customers and participating with them in the process. Even though this CEO mandate is to establish a customer centric innovation culture across an organisation, the learning curve will be steep. The majority of companies pride themselves on giving the customer what they ask for, the use of focus groups and surveys are employed to uncover such needs, yet the post-launch outcomes are so often an anti-climax, resulting in product failures (O'Hern & Rindfleisch, 2009). Successful NPD depends on a deep understanding of customers' needs and product development efforts that meet these needs (Hauser, Tellis, & Griffin, 2006). All too often companies are investing money into R&D processes instead of working to understand what the customer wants and then using that understanding to drive innovation (Selden & MacMillan, 2006). In Mello's (2001, p. 52) opinion:

> "…poor product definition was cited as the single biggest reason products fail to meet market needs…companies define product attributes in terms of what the company has to offer rather than what the customer may actually want"

According to Ulwick (2003) there are three distinct types of information that must be captured from customers to kick-start innovation. These include learning about the "jobs" that customers are trying to get done when using a product or service; the "outcomes" they are trying to achieve when performing these jobs and the "constraints" that stand in the way. In understanding these inputs, Ulwick cautions against literal translations of the "voice-of-the-customer" on the basis that customers do not know what types of information are needed to create better products and therefore voice their requirements in terms of existing solutions, specifications, needs and benefits – none of which are supportive of breakthrough products.

Ulwick and Bettencourt (2008) propose the following characteristics as prerequisite in writing a customer requirement statement that is often used to start the NPD process and which are necessary to make customer input useful:

1. The statement must reflect the customer's definition of value where the unit of analysis must be the job the customer is trying to get done.
2. The statement must have universal acceptance and must not make reference to any technology, solution or product or service feature.
3. The statement must be relevant now and in the future.
4. The statement must prompt a course of action and should be brief.
5. The statement's meaning must not be open to interpretation and must not include ambiguous terms.

When capturing customer requirements, managers should be looking to capture the criteria customers use to measure the value of a solution. This is a difficult challenge because customers do not naturally voice the metrics they use to judge value – yet another reason for avoiding literal interpretation of the voice-of-the-customer feedback, rather, engage in conversations based on the customer's desired outcomes (Ulwick, 2003).

The inability to assess and fulfill customer needs is often the primary reason for new product failure (Ogawa & Piller, (2006); Ulwick & Bettencourt, (2008)). By involving customers in the NPD process, the likelihood of new product success is increased because new product ideas can be generated that are more likely to be valued by customers (Hoyer, Chandy, Dorotic, Krafft, & Singh, 2010). Firms that manage this process effectively will ultimately achieve sustainable competitive advantage (Prahalad & Ramaswany, 2004).

While not an exclusive domain, marketing has a pivotal and increasingly important role to play in driving and facilitating successful co-creation (Payne, Storbacka, & Frow, 2007). There are many situations where the disparity between academia and industry in relation to the practice of marketing is significant. The professionalism of marketing has been called into question (Enright, 2006) and its presence has been noticeably absent from the boardroom for the most part (McDonald, 2006). In order for this to change, the marketing department needs to cultivate customers rather than market products, thereby becoming the "customer department" (Rust, Moorman, & Bhalla, 2010). Figure 2.1, also from Rust et al. (2010) and proposes metrics for developing a customer centric culture.

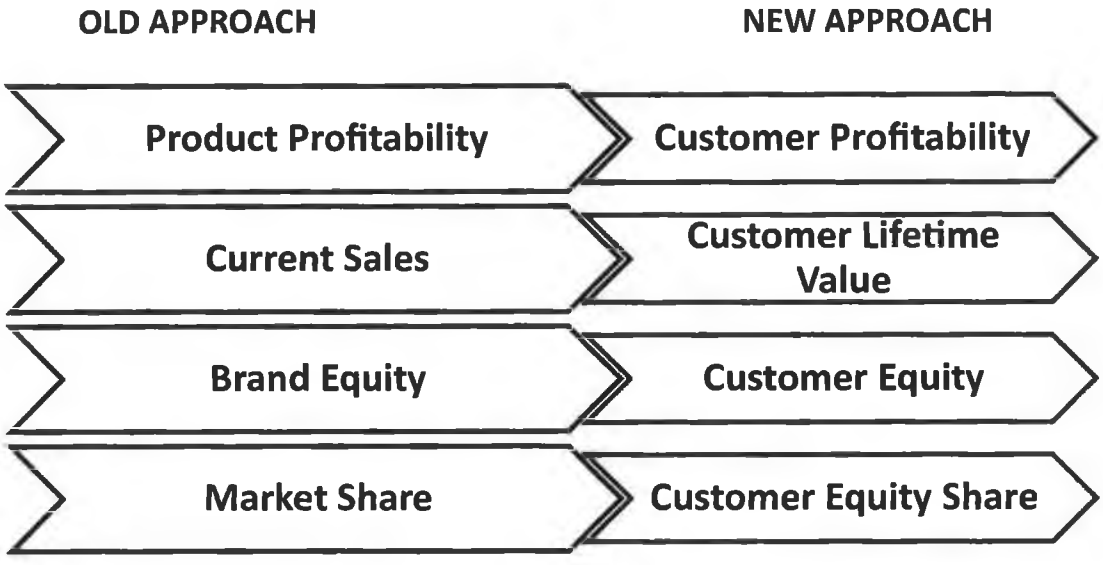

Figure 2-1 New Metrics for Cultivating Customers. Source: Rust et al. (2010)

Christensen, Cook and Hall (2005) are critical of the marketing department's input into market segmentation and product innovation. Borrowing on Theodore Levitt's insight into the requirement for a quarter inch drill bit to create a quarter inch hole, they accuse marketing of continually focusing on the drill bit and the price. The focus needs to shift to the "jobs" that customers want to get done rather than the tools used to achieve that end-result (Kavanagh, Walther, & Nicolai, (2010), Christensen et al., (2005)). To make sure that product decisions reflect the customer's real-world needs, the customer must be brought into the design process (Rust et al. 2010). The active involvement of users is also recommended by the International Standards Organisation (ISO 13407) to understand user requirements and equally important, task requirements (Kujala, 2003).

2.2.1 Capturing Customer Input

Verbal homage to customer centricity is all but meaningless unless it can be distilled down into practical observations to guide the alchemy of innovation. In order to be best positioned to capture meaningful customer input, the right cultural and organisational environment must exist within a company. One of the main obstacles in converting to being a more customer centric organisation is the belief that a company is already customer centric when it is not (Galbraith, 2005). To aid in understanding how customer focused a company actually is, Peppers, Rogers and

Dorf (1999) developed the "One-to-One Gap Tool" for internal use within an organisation to conduct a robust analysis about the company's relationship with its customers. The tool consists of eighteen multi-choice questions designed to highlight gaps, see Appendix A. Only when the internal environment is primed is it time to engage the customer.

Sole reliance on traditional means of capturing customer insights often falls short, these methods include customer surveys and focus groups (Mello, 2002). Ulwick (2002) provides cautionary advice in terms of companies' expectations from customer input into innovation whereby the traditional approach of asking customers for solutions actually undermines the innovation process. This is because customers only know what they have experience of and therefore they cannot imagine what they do not know about emergent technologies and new materials for example. The oft-quoted Henry Ford's statement, "If I'd asked my customers what they wanted, they'd have said a faster horse," sums this up best.

Ulwick proposes a focus on required outcomes and not the solution itself. A slightly different slant on Ulwick's thinking is presented by Tuli, Kohli and Bharadwaj (2007) whose in-depth research concludes that the focus does in fact need to be on the solution, but on the solution in terms of the customer:

> "The winners will be those who deliver solutions from the users' point of view. This is a big part of marketing's job". –Jack Welsh (Kumar, 2004)

As part of Tuli et al.'s (2007) research which involved approaching customer solutions as a relational process, they worked with both customers and suppliers. A key finding was the striking contrast between the customer's concept of a solution versus the supplier's concept of a solution. The customer identified (1) requirements definition, (2) customisation and integration of goods and/or services, (3) their deployment and (4) their post-deployment support as critical components of a solution whereas out of these four criteria, the supplier only ranked customisation and integration as having any significant merit. This identifies a significant gap in understanding what is of value to a customer.

Alternative means of identifying what represents value to a customer must be identified. Selden & MacMillan (2006) refer to customer centric innovation as involving "customer R&D" in addition to traditional product R&D into the design process, insisting that customer R&D is a frontline activity which ensures R&D includes those closest to the customer. They propose a defensive and an offensive strategy for developing customer centric innovation. This includes developing a deep relationship with core customers to understand their every need, extending the number of customers beyond the core, enlarging the business by including new customers and defensively continually scanning for potential competitive disruptions.

Selden & MacMillan's (2006) recommendation for defensive and offensive strategies may be too vague for today's busy managers. Mello (2001) provides a practical, broadly applicable systematic process that can be employed in almost any setting:

A. Gather customer information with a specific recommendation for one-to-one interviews that extend beyond an organisation's best customers and to include lost accounts and users of competitor's products.
B. Process customer data to create image maps that reveal both articulated and unarticulated needs, which in turn identifies gaps between the customer's world and the company's perspective of the customer's world.
C. Analyse customer requirements using a Kano survey, which captures how customers feel about particular requirements.
D. Generate solutions, making the results of Steps A-C real.

Prahalad and Ramaswany (2004) developed the DART model of value co-creation to identify its building blocks, a synopsis of which is as follows:

Dialogue. Shared learning and communication between supplier and customer.

Access. Giving the customer access to manufacturing, design and quality processes.

Risk Assessment. Empowering customers through informed choice about risks associated with products and services.

> **Transparency.** The epitome of any-relationship building exercise, transparency is necessary as information about technologies and business systems becomes more accessible.

Ethnography; an observational methodology that has many benefits in unearthing insights related to the setting that a product or service is used in (Kelly & Gibbons, 2008) and subsequently is very useful in collecting customer input. Ethnography is interpretative in nature whereby such research provides insights and human experiences that words alone do not capture. It facilitates the impact of social and cultural influences in a consumer's engagement with a product or service. At its base, ethnography is about studying users "in the wild"—in their natural habitat—to see what they are actually doing and saying in context (Delcore, 2009). Arnould and Price (2006) describe three approaches to ethnography namely:

a) **Macro-level** approach where the researcher tries to "get inside the consumer's head".
b) **Meso-level** approach which involves building relationships that allow observation of how products and services fit into the conduct of everyday consumer lives in consumer centric marketplace.
c) **Micro-level** approach, which focuses on how a consumer "feels" about a brand.

Companies can identify new opportunities and increase value by understanding where they stand in consumers lives, by understanding who and what really matters to consumers. The fast moving consumer goods (FMCG) giant Procter & Gamble (P&G) regularly use ethnographic research in their innovation processes to improve existing products or find opportunities to create new ones. They have gone so far as to create a program called "Living It!" whereby P&G staff live with consumers to understand their lives and come up with products based directly on their needs (A.J.Lafley, 2008).

Ethnographic research is broadly applicable across many industries but is not without its drawbacks that include its expense and unearthing findings without producing

actionable research results. Although a highly customer-centric technique, ethnographic research should not be used in isolation (Cohen & Crabtree, 2008).

While not fully ethnographic, Meyer & Schwager (2007) endorse "customer experience" which they refer to as the internal and subjective response customers have to any direct or indirect contact with a company. Most times companies think they are providing a better product or service than customers say they experience. Customer experiences happen at "touch-points" and a series of touch points represent a "customer corridor" which provides an observant organisation with company-wide opportunities to improve product and service offerings.

2.2.2 Open Innovation and Customer Centricity

Many companies are bringing their innovation activities closer to their customers by giving customers a say in the design of product and service offering, or opening innovation up to more partners (Ahonen, Antikainen, & Mäkipää, 2007). The term 'open innovation' has been used to characterise a system where innovation is not solely performed internally within a firm, but in a cooperative mode with other external parties (Fredberg, Elmquist, & Ollila, 2008). Inspired by the research of Henry Chesbrough (2003), it has been perceived as a useful tool for solving the problems of lack of innovation and idea generation. Open innovation can be described as combining internal and external ideas as well as internal and external paths to market to advance the development of new technologies.

Today, the common understanding of the innovation process builds on the observation that companies rarely innovate alone and that the innovation process can be seen as interactive relationships among producers, users and many other different institutions (Laursen & Salter, 2006). Open innovation requires a shift in a company's attitude from a strong resistance to "not invented here" to embracing a "proudly found elsewhere" way of thinking (Huston & Sakkab, 2006).

Open innovation is made possible by the internet, which serves as a platform for customer engagement and has greatly enhanced the ability of a company to interact with customers in product innovation (Dahan & Srinivasan, 2002). In the current global economy, informed, networked and empowered customers who are eager to

co-create are only a click away (Odekerken-Schroder, 2011). Social media and mobile devices will prompt significant change in open innovation strategies as consumers turn to these media to voice their opinions (PWC, 2011); particularly in emerging markets where the term "land line" has no context. The evolution of open innovation has taken hold because companies are realising the benefit of having access to a global network of qualified available citizens who are willing to provide input on problem solving or providing suggestions on new products (Deloitte, 2009), see Table 2-3. It facilitates active involvement of a company's customers into its innovation processes through a virtual environment where interactions can take place in real-time and with a much higher frequency than traditional market research techniques like surveys and focus groups (Sawhney, Verona, & Prandelli, 2005).

Open innovation is not confined to consumer goods although P&G had led the way since 2002 with the emergence of its web based open innovation portal "Connect and Develop". P&G claim that the company's open innovation strategy now produces more than 35% of the company's innovations and billions of dollars in revenues (Huston & Sakkab, 2006). Pharmaceutical giant Eli Lily was the driving force behind a global leader in open innovation, InnoCentive, that acts as an agent for 120,000 technical professionals in the biomedical and pharmaceutical fields from over 175 countries. IBM is one of the pioneers of open innovation through its online Innovation Jams, which the company has been running since 2001.

Successful open innovation requires significant information technology capability and investment in order to be able to mine all the data submitted (Gordon & Tarafdar, 2010). Such infrastructure effectively limits internet powered open innovation to large and midsize companies.

Consumers' role	Mostly uninvolved	Reactive	Champions
Degree of company control	Interactions controlled by company	Consumers given freedom to express aspirations	Company can empower end users and others throughout the innovation process
R&D Philosophy	Closed innovation	Consumer-guided	Dynamic open innovation
Organisational Design	Organised by manufacturing process	Organised by product purpose	Organised by consumer segment
Role of Computers /Internet	Computer-aided design, quantitative testing of concepts and advertising	Testing, but also used for product information, advertising	Mining blogs and social networking sites for insights, leveraging virtual private communities, enabling co-design /customisation of final product
Critical issues	Lack of ideas, conviction, for most innovation	Tendency towards incremental innovation, easily copied	Right system and structure for R&D, marketers, and consumers enables use of consumer insights across the process

Table 2-3. Evolution of Customer Centric Open Innovation. Source: (Deloitte, 2009)

2.3 Organisational Challenges for Customer Centricity

Somewhere between the Utopia of developing an impenetrable competitive edge and the common sense of giving customers what they want, customer centricity has become a very challenging and complex practice to institutionalise (Shah et al. (2006); Gummesson, (2008); Gulati & Oldroyd, (2003)). According to Gulati (2010b, p. 4) "the vast bulk of enterprises talk the customer talk while consistently failing to walk the customer walk". The culture of an organisation has a big influence on how

customer centric it really is and its associated values and assumptions, see Figure 2.2 below:

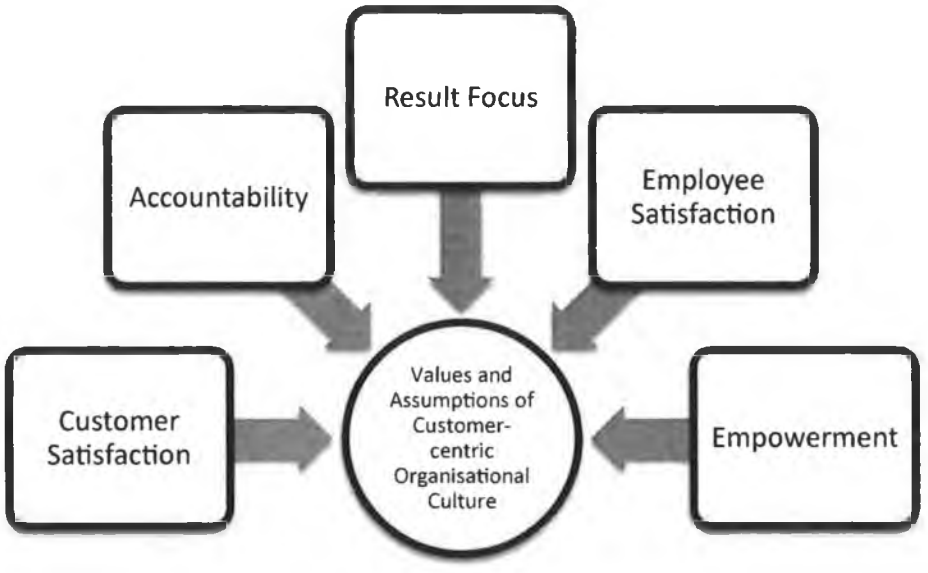

Figure 2-2. Values and Assumptions of Customer Centric Organisations. Source: Appelbaum et al. 2010

There is much written about the barriers to customer centricity (Band & Guaspari, (2003); Gulati, (2007); Sheth et al., (2000); Shah et al., (2006)) with the common denominators regularly being lack of leadership and accountability, and a silo mentality within organisations. While some companies are making great strides developing a truly customer-centric culture, others are lost in the quagmire, with many managers running product-centric companies that are quite simply touched up with a cosmetic gloss of customer focus (Galbraith, 2005). Customer centricity seems to be easy to assert yet difficult to implement with managers often believing they give higher priority to customers than lower ranking employees perceive (Hart, 1999).

The benefits of customer centricity have been discussed earlier in terms of increased profits, customer satifaction and consequently employee retention; all of which serve as strong impetus for organisations to endure the growing pains of becoming more customer centric. Shah et al. (2006) propose that it can be implemented once it is consistently managed throughout an organisation. Jayachandran, Sharma, Kaufman, & Raman (2005) reiterate this observation by stating that "an organisational management system consistent with the culture is necessary to drive organisational processes", such as customer centricity.

	Product Centric Organisation	Customer Centric Organisation
Basic Philosophy	Sell products: we'll sell to whoever will buy	Serve customers: all decisions start with the customer
Business Orientation	Transaction-oriented	Relationship-oriented
Product Positioning	Highlight product features and advantages	Highlight product's benefits in terms of meeting individual customers needs
Organisational Structure	Product profit centres, product managers, product sales teams	Customer segment centres, customer relationship managers, customer segment sales teams
Organisational Focus	Internally focused	Externally focused
Performance Metrics	Number of new products, profitability per product, market share by product	Share of wallet of customers: customer satisfaction, customer lifetime value
Management Criteria	Portfolio of products	Portfolio of customers
Selling Approach	How many customers can we sell this product to?	How many products can we sell this customer?
Customer Knowledge	Customer data are a central mechanism	Customer knowledge is a valuable asset

Table 2-4. Comparison of Product-Centric and Customer-Centric Organisations. Source: Shah et al. (2006)

Most product-centric organisations (see Table 2.4) are departmentalised and such an organisational structure lends itself to knowledge and expertise being housed within organisational silos whereby such resources become trapped behind internal boundaries (Gulati, 2007). Companies need to transcend these silos in the interest of customer needs; otherwise, the analogy of six blind men exploring an elephant (see Figure 2.3) becomes appropriate in relation to interpreting and understanding such needs. An ideal customer centric organisation implies having all functional activities integrated and aligned to deliver superior customer value (Shah et al. 2006). A

company that practices customer centricity is more likely to integrate marketing and non-marketing functions when compared with companies that do not practice it (Sheth et al. 2000). Such integration processes are not inherent in most companies and require senior management commitment, persistence and intense communication to overcome the inevitable resistance (Shah et al. 2006).

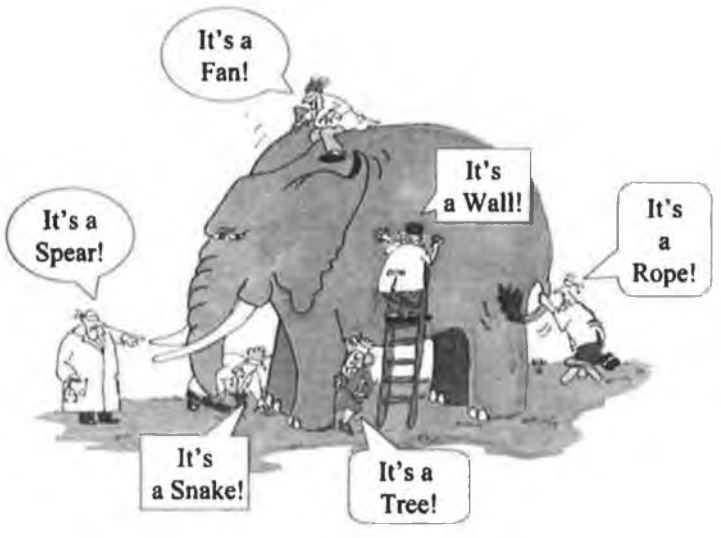

Figure 2-3. Six Blind Men and the Elephant.

According to Day (1999) , the commitment of senior management to a customer centric orientation can be signaled by the following three actions:

1. An emphasis on the superior quality of service and customer relations involving direct contact with customers to help them solve their problems.
2. Spending time visiting customers and listening to their point of view.
3. An emphasis on all customer and market related issues - including trends, needs, requirements, opportunities for advantage – during strategy reviews.

Human resources (HR) has an important role to pay in the path to customer centricity by redefining itself and managing with the philosophy that customer satisfaction results in employee satisfaction (Shah et al. (2006); Heskett et al. (2008)). HR also has a greater role to play in promoting the link between employee performance, customer satisfaction and the outcome on the business (Lockwood, 2007) because

competitive advantage can be attained through the development of a relationship-building culture inside the organisation as well as customer relationships. Successful customer relationships rely on successful internal relationships (Herington, Johnson, & Scott, 2006).

In many companies, "what gets measured gets done", and to this point, customer centric evolvement must be coupled with customer centric metrics (Shah et al. 2006) and these metrics should consist of customer equity, customer satisfaction, loyalty, customer lifetime value and so on. To truly embed customer centric metrics within an organisation, companies should include at least two or three of the most important customer metrics among the key performance indicators that are reported regularly to the senior management team and the board (Johnson & Schultz, 2004). This must also be translated into individual employees' goals, which need to be aligned with corporate goals. Employees expect recognition from their direct managers for their positive contribution to customers (Appelbaum, Zinati, MacDonald, & Amiri, 2010) thus creating an opportunity to include some form of incentives into customer-centric related performance achievements.

Gulati (2010b), in his focus on the need to deconstruct organisational silos in order to deliver solutions to the problems customers care about most developed his Five Levers model to create a more resilient, customer centric organisation:

> **Coordination:** Connect, eradicate, or restructure silos to enable swift responses.
> **Cooperation:** Foster a culture that aligns all employees around the shared goals of customer solutions.
> **Clout:** Redistribute power to "bridge builders" and customer champions.
> **Capability:** Develop employees' skills at tackling changing customer needs.
> **Connection:** Blend partners' offerings with yours to provide unique customer solutions.

The Star Model was developed by Galbraith, Downey and Kates (2002) as a foundation on which a company can base its design choices and consists of a series of design policies that are controllable by management and can influence employee

behaviour. In the model, design policies fall into five categories as depicted in Figure 2.4.

Figure 2-4. The Star Model

Ingraining customer centricity in the culture of an organisation means it becomes a highly competitive core competence of the organisation that reflects the collective learning about the company's customers into all that a company sets out to achieve (Prahalad & Hamel, 1990). Moving an organisation from a nonchalant silo-mentality existence to a committed customer centric one requires significant change. In order to ensure success, senior management with full support from the CEO must implement change. The task on hand is realigning the organisation around customers and not around products (Shah et al. 2006). The odds for success lie in how convincingly senior management demonstrate the necessity for customer centricity in a time of information free-flow where the locus of power has shifted to the consumer and major discontinuity exists in the competitive landscape. Once the compelling arguments have been constructed in relation to the necessity for customer centricity, Kotter's (1995) eight-step approach (See Appendix B) to leading change can be

successfully applied whereby the odds of success are greatly improved as there is a sense of urgency and a compelling strategic rationale.

2.4 Conclusion

The purpose of this chapter is to introduce the concept of customer centricity as a component of business strategy. This is achieved through presenting a definition of customer centricity and progressing to identify its importance, its determinants, its influencing organisational factors, and the management challenges it poses. A specific review of the literature in relation to how customers are involved in innovation is undertaken and this is expanded to open innovation, a relatively new concept that presents opportunity to maximise a company's existing innovation potential. The content of this chapter forms the backdrop as the research scope is narrowed to customer centricity in medical device innovation.

3 Literature Review – Part 2

3.1 Customer Centricity in Medical Device Innovation

With respect to medical devices, there is often more than one customer whom a med tech company needs to consider when designing new products, which in turn has a direct impact on a company's customer centric practices. Shah and Robinson (2008) define a medical device "user" as a person who uses a medical device to administer a treatment on themselves or another person, and an "end-user" as the person who benefits from the usage of the medical device, pointing out that often the end-user and the user can be the same person.

Determinants of the uptake of medical devices among users and end-users include the utility of the innovation, and disruptions it may cause to existing habits, personal or social values, social status of opinion leaders and the cultural propensity of individuals to tolerate or resist change (World Health Organisation, 2010).

There are other key stakeholders who also have to be taken into consideration during the design process and these include the payers, who can be largely split into governments and private health insurers; the regulators, educators and of course the end-users' families. This diverse range of stakeholders makes it necessary for med tech companies to adopt a holistic, customer-centric approach to innovation and thereby ensuring effective stakeholder management (Kavanagh, Walther, & Nicolai, 2010).

Each of the stakeholders involved in the use of medical devices has different primary concerns that at times are not complementary. The regulators primary concern is patient safety but the resulting clinical trials can cause delays in getting innovative products to market and can be prohibitively expensive for small to medium sized med tech companies (Frank, Rucker, Ferguson, & Sweeney, 2011). There can be a conflict of interest between payers also, with government payers seeing more value in an innovation with a long-term cost impact such as an obesity reduction treatment than would a private insurer who typically sees an annual attrition rate of 20% of customers (Herzlinger, 2006).

Aside from looking after the needs of their primary stakeholders, med tech companies are on a direct collision course with more macro-influencers that are rapidly coming down the line. The Organisation for Economic Co-operation and Development (OECD, 2010) reports that in its mainly developed member countries, total spending on health care is rising faster than economic growth, pushing the average ratio of health spending to GDP from 7.8% in 2000 to 9.0% in 2008. Factors that are pushing health spending up include technological change, population expectations and population ageing and will continue to drive cost higher in the future. The med tech industry needs to be aware of such changes and how they will impact the types of products they will bring to market; how associated value propositions will have to be proven in order to gain market acceptance and reimbursement.

The internet has changed the traditional patient-doctor relationship of years ago when doctors were the primary, and in many cases, the only source of medical information available. Now however, patients are educating themselves comprehensively and this factor, coupled with the direct-to-patient advertising that the med tech industry is starting to partake in, is leading patients to have a significant influence on the devices used in their treatments. Golfing pro Jack Nicklaus, who himself had a hip replacement involving a Stryker implant was used in a direct-to-patient advert to endorse Stryker's products and resulted in patients requesting "the Jack Nicklaus hip" (Burns, 2007).

Turf wars involving doctors reserving the right to choose which devices to use on their patients, their tendency to use high-cost and high-quality devices frequently referred to as physician preference items (PPIs) can put a strain on hospital supply-chain efficiency and financial well being. This in turn may mask product acceptance in the short term, but may have a negative influence on mid-long term mainstream adoption (Robinson J. , 2008).

In the pursuit of demonstrating health economics, med tech companies must keep their "value antennae" constantly on. Even technologies that unambiguously reduce costs, for example by substituting capital for labour, or shortening a patient's length of stay may still face challenges. This is because insurers tend to analyse costs in silos and don't always see the link between a reduction in hospital labour costs and the

new technology responsible for it, seeing only the costs associated with the new technology (Herzlinger, 2006).

Customer centricity in the med tech industry is no different to customer centricity in any other industry. It is about providing solutions for the jobs, in this case treatment processes, rather than just selling new products that embed the newest technology; because the core competency of a hospital is to provide high quality healthcare for patients (Fähling, Köbler, Leimeister, & Krcmar, 2010).

The complexities of the healthcare industry and its competitive consequences have been heralded by the godfather of competition, Michael Porter, as very different to other industries whereby as the market expands, value-adjusted prices fall (Porter & Olmsted Teisberg, 2004). On the contrary, in healthcare delivery, costs are high and rising despite efforts to reduce them, and the rising costs cannot be explained by improvements in quality. While the scope of Porter's work on competitive issues in healthcare delivery is for the most part outside the field of this research, it is suggestive of positive patient outcomes that would result from measuring and competing on medical results rather than standardised care (Porter & Tesiberg Olmsted, 2006).

This transition in terms of how healthcare might and should be delivered identifies a significant opportunity for med tech companies. It provides a strong impetus to become customer centric whereby companies are designing the right devices that clearly demonstrate improved patient outcomes and therefore economic value. Better health being less expensive than illness. Product improvement should not just consider the products, but should also consider the processes that products are embedded in (Fahling et al. 2010) thereby changing a product-centric development process to a development process focussing on the usage of the product and on the results of usage.

3.2 Medical Device Innovation and Co-creation

Medical device companies spend about 9-11 percent of sales on R&D, second only to the pharmaceutical sector and four times more than the average manufacturing company (Chatterjii, Fabrizio, Will, & Schulman, 2008). Detailed involvement of users is recognised as being very important in the case of medical device development because of the interaction of users with devices, thereby allowing them to better judge the performance of the device (Shah & Robinson, 2008). In fact, devices that are designed in isolation of the users are vulnerable to failure (Grocott, Weir, & Ram, 2007) with failure to incorporate customer needs being one of the key reasons for the inability to develop effective and innovative medical devices (Cooper R. , 1999).

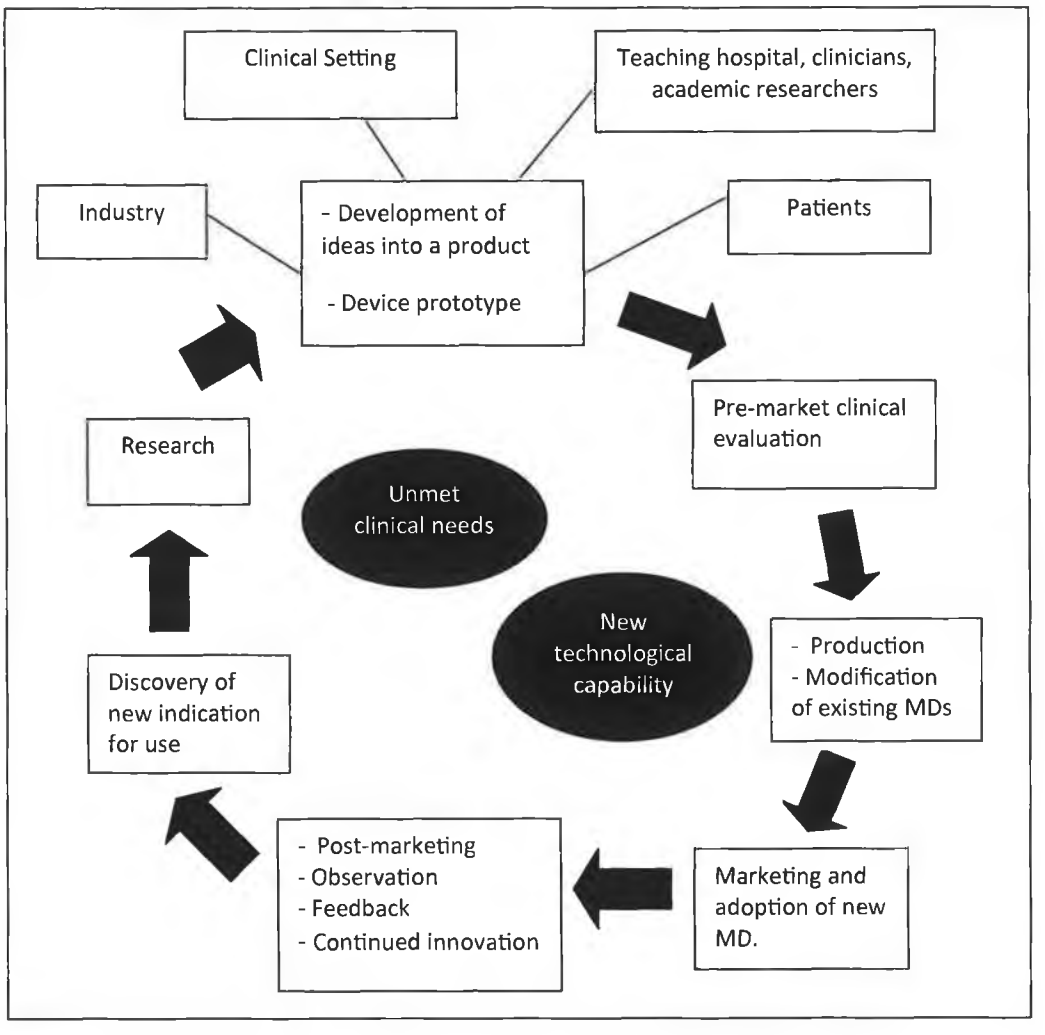

Figure 3-1. Medical Device Innovation Process. Source: WHO, 2010

User-involvement in innovation was a key finding in a study undertaken by Brown, Dixon, Eatock, Meenan, & Young, (2008) on the factors that influence success in new product development carried out among 68 medical device companies in the UK and Ireland. The study identified the following four criteria as being heavily influential on successful outcomes:

1. The degree of technological innovation.
2. ***The involvement of end-users in the development process***
3. The dissemination of new product development priorities to staff
4. The use of financial analysis throughout the development process

With the leading med tech companies making the majority of their revenues from products that are less than two years old, this puts significant pressure on product innovation (Chatterjii et al. 2008) and identifying and acquiring knowledge that resides outside the company is a proven way of sustaining a competitive edge. In the med tech industry, the most frequently used external resource is practicing clinicians. Access to this knowledge is through close communication and relationships built on trust. When managed effectively, user-involvement in medical device development has multiple benefits to the med tech industry (Shah, Robinson, & AlShawi, 2009) including:

- Generation of new ideas
- Access to users and end-users actual requirements and expectations
- Reduction in development costs
- Improvements in design, usability and safety
- Identification of potential problems early on in the device development cycle.

From a regulatory perspective, the international standards bodies including the Food and Drug Administration (FDA) suggest that user-involvement via the incorporation of human factors (HF) testing in medical device design and development offers many benefits (Money, Barnett, Kuljis, Craven, Martin, & Terry, 2011). Human factors is described by the FDA (2010) as

> "... the study of how people use technology. It involves the interaction of human abilities, expectations, and limitations, with work environments and system design."

The primary base for HF testing is patient safety, followed by improved compliance and health outcomes resulting from higher levels of user and end user satisfaction (Money et al. 2011).

For the external observer, HF would appear to be an unavoidable customer centric mandate that the med tech industry has to fulfil, except that a commonly held view of HF is to serve as a means of facilitating a "cake-frosting" exercise (Gulliksen, Boivie, & Göransson, 2006, p. 576). Sales, product advocacy, customer loyalty and brand equity are all closely linked to how well a customer can use a device in achieving their treatment goals. HF is critical in achieving this and its incorporation throughout the entire new product development cycle rather than as a cosmetic after-thought can eliminate hours of customer service demands after launch (Drake, 2002).

3.2.1 Open Innovation in Medical Devices

Innovation in health care is a complex process involving new medical technologies and clinical services emerging from a highly dispersed competence base. Given the challenges in developing new medical devices including the time and expense of clinical trials, regulatory approvals etc; the adoption of open innovation can fast-track new innovations and increase their own competitiveness (Davey, Brennan, Meenan, & McAdam, 2010). Also, cooperation with external partners for NPD is increasingly important due to the complexity of medical devices and the fragmentation of the market where in many cases, highly innovative products include a number of technologies (Pullen, Weerd-Nederhof, Groen, & Fisscher, 2008)

In reality, most med tech companies agree that open innovation is key to the future success of the business, but relatively few have so far adopted a structured or company-wide approach to it. There are those who say that existing med tech industry engagement with clinicians to advance NPD is open innovation (Boudreau & Lakhani, 2009), however, few companies have a formal open innovation strategy or plan in place, the result of which has caused open innovation efforts to progress slowly or even stall (Barrett, (2010); Shah & Robinson, (2008)). Johnson & Johnson's Ethicon Medical Devices is an example of a company with a unique approach to open innovation in its use of lead user workshops, an established practice since 2004 (Piller & Ihl, 2009). According to (Eisenberg, 2011);

> "The lead-user research method provides a unique way to uncover rich information on emerging and future customer needs. By studying the innovations of users at the leading edge of an industry and mining the insights of those users who have solved analogous problems in other industries, a company may find the next breakthrough innovation. The method can help a company break away from "me-too" product extensions and accelerate the creation of new markets, products, platforms, or even strategic directions."

Melese, Lin, Chang, & Choen (2009) recommend collaboration between med tech companies and academic medical centres through open innovation networks which provide unique learning opportunities about diseases and response to treatments and to users. Open innovation networks between industry and academia represent the opportunity to integrate the knowledge to provide the most accurate picture of the patient, and of the disease on which to base the development of new breakthrough therapies of higher value (Melese et al. 2009). This supports the opinion of Porter and Teisberg (2004) in terms of improved patient outcomes and a holistic approach to healthcare.

Medical device multinational, Medtronic is an example of a med tech company availing of the benefits of open innovation, albeit not from the lofty heights of traditional industry-academia alliances. Rather the company is using a mix of on-line tools to help drive its innovation activity. The company uses the open innovation network, Innocentive, with several thousand people involved in its endeavours. In addition, and because the company has over 5,000 scientists and engineers working for it all over the world, it also uses Microsoft's SharePoint internal social-networking platform to allow these people to pose questions of one another (Singer, 2011).

3.3 Does the Med Tech Industry Walk the Customer Centric Talk?

The concept of customer-centred product development is well acknowledged in medical devices to the extent that new devices are often co-created between physicians and industry (Chatterjii & Fabrizio, (2008); Chatterjii et al., (2008);

Mykleby, (2006); Galbrun & Kijima, (2010)) however, there are inherent issues and opinions within the med tech industry that detract from best intentions.

A study carried out by Money et al. (2010) demonstrates considerable short-falls in the med tech industry's approach to customer centricity. The study points to how the industry generally gravitates to key opinion leaders and individuals who will be most influential in purchasing decisions rather than the users of the devices who in the many instances do not constitute either of these stakeholders. Although some evidence did emerge on user-involvement during the design process, however this was largely during the clinical trial stages.

An approach called the stage-gate process is the predominant new product development model used in the med tech industry. The stage-gate process includes the following five phases (Pietzsch, Shluzas, Pate-Cornell, Yock, & Linehan, 2009):

1. Initiation - opportunity and risk analysis
2. Formulation - concept and feasibility
3. Design and development - verification and validation
4. Final validation - product launch preparation
5. Product launch and post-launch assessment

Stage-gate processes typically do not do well in contexts that are forward-looking (market-driving) as compared to extrapolating from past experience (market-driven). Companies are at risk of becoming so caught up in their process that they lose sight of the outcomes (Loewe & Dominiquini, 2006) whereby stage-gate system can create a false, highly linear, process (Mugglestone, Maher, Manson, & Baxter, 2008) that loses its customer focus in lieu of stage gate exits. In implementing development processes in companies, it is necessary to strike a balance between sufficient process rigour and enough room for flexibility and creativity to ensure meeting customer needs is the priority (Pretzsch, Shluzas, Pate-Cornell, Yock, & Linehan, 2009).

Innovation in the medical device industry has traditionally suffered from a technical push approach whereby new technologies are developed and then the search commences for problems to solve (Management Centre Europe, (2011); Korn/Ferry Institute, (2011)). This tactic is product centric rather than customer centric; however, in the absence of the "job-based" approach to truly understand customer needs

(Ulwick, (2002), Kavanagh et al., (2010)) such an approach has its supporters. According to Van der Panne, Van Beers, & Kleinknecht, (2003, p. 326), user-involvement at an early stage may tend to gravitate towards imitative products, with users being less able to envision or express novelty and thus "bias innovation efforts towards incremental innovation". Medical device companies need to factor this potential limitation into their user research, according to Kavanagh et al. (2010), a customer's frame of reference is based on existing products and services.

Innovation can be described in terms of incremental innovation or radical innovation. Lettl, Herstatt and Gemuenden (2006) propose that specific users can substantially contribute to radical or disruptive innovation. They identify certain characteristics of such users that companies should seek out to aid and drive the pursuit of radical innovation. These characteristics indicate that the innovative user should be:

1. Motivated to develop new solutions
2. Open to new technologies
3. Categorised as an "extreme user", for example, neuro-surgeons and cardiologists who have the need for extremely high precision
4. Embedded in a supportive environment
5. Able to recognise the relevance and benefit of new technologies because of the users' specialised knowledge.

Involving users in medical device design and development is generally seen as being highly resource intensive in terms of time, money and labour (Brockhoff, (2003); Money et al., (2011)) with user needs research considered disproportionately expensive in light of the perceived pay-off. In addition, there is generally significant pressure on companies to reduce the time to market and the cost of new product development programs (Robinson, et al., 2005). Two additional perceived impediments of user-involvement include (1) user needs research is sometimes perceived to generate enormous amounts of data that does not appear to provide a clear route to directing the design and development process (Money et al. 2011) and (2) ethical considerations limit access to appropriate users (Robinson, et al., 2005).

3.4 Improving Customer Centricity in Med Tech Innovation

A customer centric guiding principle can create the dominant culture in any med tech organisation whereby priority is given to acting in the best interest of the end user of the medical devices. This must be cultivated at senior management level in order to be sustained (Appelbaum et al. 2010).

Robinson et al. (2005) reference the overall absence of formal structures for incorporating user and end-user information in the medical device development process. Money et al. (2011) attribute a contributory factor to this as the lack of engagement with formal methods of user-involvement, and lack of education, familiarity or confidence in their use; whereby the perception exists that formal methods would generate unmanageable volumes of data which would still not provide clear direction for design considerations.

Part One of this literature review discusses customer centric models including Galbraith's STAR model or Gulati's "Five Lever" approach. Whilst this literature review is not exhaustive, it is comprehensive and therefore it is note-worthy that these tools had no prominence in the med tech's approach to customer centricity.

As a starting point for a useful model of customer centricity in the med tech industry, a focus on "outcomes" (Ulwick, 2002) - or "jobs" (Christensen et al. 2005) is recommended. Ulwick (2002) provides Cordis, the interventional cardiology company, as an example of how a focus on the results the doctors and nurses wanted to achieve in their jobs rather than the feature and benefit profile of Cordis' products led to remarkable growth. Interviews with these professionals identified important, unsatisfied needs in new market segments, namely, the value of a device that could be placed in an artery treated with angioplasty balloons to prevent the blockage recurring. Cordis went on to collaborate with two doctors to develop the coronary stent which became the fastest-growing product in medical device history.

The hearing implant company, Cochlear made a deliberate choice to pursue the job-based approach on the basis that users are more qualified to express and validate jobs and results they expect than they are to propose the attributes of a solution that does not yet exist (Kavanagh et al. 2010). In order to discover important, unsatisfied needs, the company undertook qualitative and quantitative research that cumulated in its

ability to identify these needs. The outcome was a series of statements relating to the job to be done based on levels of importance and satisfaction. A job that has a high importance rating but a low satisfaction rating in terms of the users experience represents an opportunity for value-adding innovation.

The practice of ethnography has merit in medical device development. Such observation serves to unearth potentially unexpected opportunities for product improvements as was the case with former Medtronic CEO, Bill George (Kaihla, et al., 2006). He watched a surgeon perform an angioplasty using a Medtronic balloon catheter as the catheter disintegrated in use. George made sure an improved catheter was launched within three months and the experience spurred him to require all engineers and designers to attend at least one surgical procedure per year to see a Medtronic product in action.

Ethnography also features as one of Cooper and Edgett's (2008, p. 51) six methods in incorporating the customer input as follows:

i. Customer visits with in-depth interviews
ii. "Camping out" or ethnography
iii. Lead user analysis
iv. Focus group problem detection sessions
v. Brainstorming group events with customers
vi. Crowd sourcing online or IT-based approaches.

The use of a customer expert team or a key opinion leader (KOL) panel as they are often referred to provides useful clinical insights (Mykleby, 2006). In many cases, experts or KOLs do not actually use the devices themselves and therefore they should not be the only source of input at the risk of missing valuable feedback from actual users or end users (Money et al. 2011).

3.5 Conclusion

This chapter is designed to put the theme of the research into context through an assessment of the literature relating to customer centricity in medical device innovation. It identifies themes and topics that are subsequently investigated in the research interviews including the stakeholders, user-involvement in co-creation, open

innovation, and techniques used in needs identification. This part of the literature review presents some of the difficulties encountered by a highly technical industry in becoming customer centric and proposes models for improving customer centric innovation. Examples of customer centric learning curves and practices from existing medical device companies are provided to give relevance to the overall content.

4 Research Methodology

4.1 Introduction – Rationale and Significance of the Research

A research gap exists relating to the role of customer centricity in innovation processes in the med tech industry in Ireland, which is in contrast to the overt emphasis on product-centric innovation (Innovation Taskforce, (2010); Department of the Taoiseach, (2008); IMDA, (2011)). Informed by the literature review, there is a systemic role for user-involvement in medical device development, yet this is rarely referred to in the discussions and reports on increasing the value and "stickability" of the medical device industry in Ireland.

Given the manufacturing heritage of the med tech industry in Ireland, and the strong overtones of engineering as the sector strengthens its R&D capabilities, the sector needs to ensure it has the means and methods of maximizing user-involvement in the development of new devices, thereby improving the prospects of commercial success.

Based on this observation, the rationale for this research is to begin to close the research gap by exploring the understanding and the practice of customer centricity in medical device innovation by the industry players in Ireland. The significance of the research will be to identify current best practices in this area. This should be of relevance, interest and value to med tech companies participating in medical device innovation.

This chapter sets out to:

a. Describe what method is being used to conduct the research and explain why this method is most appropriate
b. Detail how data is collected
c. Outline how the data is analysed
d. Identify the research limitations.

The aims of the research in relation to innovation in the Irish med tech industry are to:

i. Determine how well customer centricity is understood and practised
ii. Identify areas where customer centricity is seen of most value

iii. Determine perceived advantages and drawbacks of involving customers in the innovation process

iv. Identify best practices in relation to how customer centricity in innovation is practised among indigenous and FDI companies.

4.2 Research Strategy – In-depth Interviews

The strategy chosen for this research is the interpretive qualitative method of semi-structured in-depth interviewing where the questions have been prepared beforehand.

Qualitative research is used to gain insight into people's attitudes, behaviours, value systems, concerns, motivations, aspirations, culture or lifestyles. It is used to inform business decisions, policy formation, communication and research. It refers to all non-numeric data or data that have not been quantified (Saunders, Lewis, & Thornhill, 2009). The goal of qualitative research is to offer an explanation of some kind and not just a description of the findings (Draper, 2004). For the purpose of this study, qualitative research is preferred over quantitative research. Ghosh and Chopra (2003) define these two types of data as follows:

> **Qualitative data** is data in the form of descriptive accounts of observation or data that is classified by type.
>
> **Quantitative data** is data that can be expressed numerically or classified by some numerical value.

The in-depth interview technique uses extensive probing during the course of a personal interview to get the respondent to explore their perspectives on a particular topic (Domegan & Fleming, 2003). Due to the nature of the research topic (customer centricity), a concept that is still evolving in business practices and is subjective in terms of perceived value, in-depth interviews are expected to reveal more detailed information on the subject matter than other qualitative methods. The interviews are semi-structured thereby allowing the researcher to use the questions in the survey as a general framework on which to base additional questions requesting clarifications, examples and more details into potentially interesting ideas.

Easterby-Smith, Thorpe and Lowe (1991) suggest semi-structured interviews are appropriate in the following situations:

- When it is necessary to understand the basis for the interviewee's opinions or beliefs about a particular matter or situation
- To develop an understanding of the interviewee's world whereby the researcher wants to influence it (for example, action research)
- The step-by-step logic of a situation is not clear
- The subject matter is highly confidential or commercially sensitive
- The interviewee is most susceptible to in-depth feedback only in a one-to-one situation.

The target population for the research includes the med tech's industry leaders comprising of chief executive officers, managing directors, general managers, vice presidents or senior corporate executives with overall responsibility for a subsidiary or an entire corporate function. To contextualise the target population, the research is restricted to this cohort as these people represent the change agents who are needed to commit to and support customer centricity if it is to develop a firm standing within an organisation (Jayachandran, Sharma, Kaufman, & Raman, 2005). It is unlikely that customer centricity will become part of the culture of an organisation if only supported by departmental managers, but not by the chief executive. The general criteria for inclusion in this research also require the existence of an R&D department engaged in product innovation. Both FDI and indigenous companies are included in the research.

Aspects of the in-depth interview as outlined by Easterby-Smith et al. (1991), including the need to understand the basis for the respondents' opinions on the topic of customer centricity and the potential for discussing confidential subject matter also makes this technique most appropriate as a research technique. These considerations combined with the hectic schedules executed by the target population eliminate other qualitative techniques including focus groups or written surveys.

4.2.1 Sampling

With over 200 med tech companies in operation in Ireland, it is impractical to collect data from the entire target population; therefore, non-probability convenience

sampling is chosen to support the primary research. Convenience sampling is chosen for the following reasons:

i. The researcher works within the med tech sector and has access to members of the target population either directly or indirectly through industry contacts.
ii. Due to the time, cost and travel input required to conduct in-depth interviews; convenience sampling accommodates the geographic preferences of the researcher for access purposes.
iii. With one exception (See Chapter 5), the target sample meet the inclusion criteria for the research (their position within the organisation and the practice of product development activities), and to this extent are representative of an ideal sample that would be randomly selected, however, the extent of this representativeness is not known.

Non-probability sampling used in this research is appropriate as it is takes into account the need for prior permission and/or an introduction in order to secure the interview and is considerate of the demands and constraints on senior executive's time. These considerations all but eliminate the success potential of probability random sampling by any other method such as a postal survey or a telephone survey.

Unlike probability random sampling, there is no formula to determine the size of a non-probability convenience sample and indeed probability sampling techniques used for quantitative research are rarely appropriate for conducting qualitative research. "An appropriate sample size for qualitative research is one that adequately answers the research question", (Marshall, 1996, p. 523). A sample size of ten (n=10) was chosen, this number was chosen based on researcher's discretion and on the research timeline.

As innovation is undertaken by both indigenous and FDI medical device companies conducting business out of Ireland, both segments are represented in this research. Five indigenous companies and five FDI companies are included in the research.

4.3 Data Collection

In-depth personal interviews are chosen as the means to collect the research data. Details of the companies included are provided in Table 6, Chapter 5. The identities of the interviewees and information on the interview timelines are provided in Appendix G. (Note: Appendix G will be omitted from the hard-bound copies of this dissertation to preserve the anonymity of the participants)

Personal interviews have the advantage that they enable a rapport to be established with the people being interviewed. They enable the interviewer to direct the attention of the respondents to the material and to motivate them to answer the questions carefully (McBurney, 2001). Given the target population for the research, that is, senior executives of their relevant organisations, it is expected that this method will yield more useful information than any other form of survey.

The in-depth interviews are based on a ten-question survey. The format is semi-structured which involves asking the predetermined questions, but also accommodates probing in order to obtain more detailed information about a particular answer or to explore new, but relevant issues that arise from a particular answer (Collis & Hussey, 2009). The questions are open-ended versus closed-ended. Open-ended questions are particularly good for identifying the unexpected and therefore are valuable in the exploratory context. The flexibility of open-ended questions makes them more useful for small-scale and preliminary studies in preference to close-ended questions suitable for large studies (McBurney, 2001). Close-ended questioning, a quantitative technique, is not appropriate at this stage of research as it would not provide the opportunity to sufficiently scope the research topic.

For designing the questionnaire, guidance from Crowther and Lancaster (2005, p. 153) is used in constructing the questions as follows:

The questionnaire should

- Be as short as possible
- Have a logical structure (a clear focus and evolution from topic to topic)
- Have questions which are simple wherever possible, avoiding jargon and over-complex language or question structure

- Avoid ambiguous questions
- Avoid leading questions.

The format of the interview process includes directly contacting target candidates or using industry contacts to secure an introduction. Thereafter, an explanatory e-mail is sent to provide further information on the objective of the research, and on securing agreement for participation, an appointment is scheduled to conduct the interview. Due to the open-ended nature of the questions, a copy of the questionnaire is e-mailed to the candidates in advance of the meeting in order to review and prepare, refer to Appendix C. An opt-out is offered at all stages of communication. The interviewees are provided with a copy of the code of ethics that is used to guide the research in advance of the interview, including information on anonymity, how their information would be used and assurance that company confidential information is not being sought, see Appendix D. Permission is required from all interviewees to record the interviews for subsequent analysis. An incentive for participation is provided by means of sharing the research data directly with the participants.

4.3.1 Questionnaire Design Rationale

Questionnaire design is a significant influence on research outcomes. A poorly worded survey is a primary reason for errors in survey research (Bryman & Bell, 2007). Using the principles for questionnaire design as outlined by Crowther and Lancaster (2005), the research survey has a logical structure and is split into sections relating to the customer, innovation and organisation practices. This enables compartmentalisation of thought and aids research analysis.

A breakdown of the rationale behind the research sections and each of the questions is as follows:

Section One: Customers

Question 1. From your point of view, what does the term "customer centricity" mean?

The term "customer centricity" is not common speak in business terminology. The purpose of asking this question is to ascertain what the interviewees' interpretation of

the phrase is and to see how this matches the definitions as outlined in the literature review in terms of an organisation's pursuit in understanding and delivering customer value (Gummesson, 2007)

Question 2. Who are your customers?

According to Shah and Robinson (2008), medical devices are used by both "users" and "end-users" where the end-user benefits from the therapeutic aspect of the medical device and the user deploys the device. In home-care devices, often the user and the end-user are the same person. Both stakeholders have different needs that should be met in the design process. In terms of customer centricity, this question serves to unearth if this distinction is readily made.

Question 3. According to Kavanagh et al. (2010), *the first task in medical device innovation is to develop a detailed understanding of the unmet needs of customers and then focus internal development efforts on a prioritised list of the most important needs identified. How do you determine what your customers need from you?*

Satisfying customer needs is a cornerstone of customer centricity. This question probes the techniques used by a company to determine what their customers' needs are. The question is framed in a relevant quotation in order to give it proper context. This question is wholly biased in terms of the customers' needs rather than anything to do with product technology and this is deliberate to investigate how focused the answer is in terms of the customer or to see if it strays to product technology.

Question 4. How do you ensure you deliver customer value?

This question is designed to identify how a company ascertains the value of innovations in terms of what is important to their customers. An innovation has no long-term value to an organisation, irrespective of how technologically advanced it is, unless it has value to its customers. Thus, being able to determine if value is extracted from the use of a product is a vital diagnostic in terms of commercial viability of the product.

Section Two: Innovation

Question 5. What do you see as the pros and cons of user-involvement in the R&D process?

The literature review demonstrates that customer involvement in innovation is not always seen as beneficial (Band & Guaspari, (2003); Shah et al., (2006); Gulati, (2007)). This question is structured so as to elicit the interviewees opinions on advantages of customer centric innovation, but also, allows them to air what they see as issues or drawbacks in terms of user-involvement in innovation processes.

Question 6. How does your company ensure user-involvement in the R&D process?

This question is included to find out about what if any processes are employed to involve users in the R&D process and to determine if this forms part of a documented process or if it is ad-hoc.

Question 7. Open innovation, or the "not invented here" ideology offers medical device companies the possibility to engage external scientists, engineers, clinicians and indeed patients in new product development (Davey et al. 2010). Where does open innovation fit into your product development strategies?

Open innovation is being used more and more as a source of innovation for new product development. Open innovation, when triggered by clinicians and patients is customer centric. It is a relatively new concept and this question explores its impact in the interviewees' relevant organisations.

Section Three: Organisation

Question Eight. How is the culture of customer centricity in the innovation process developed in your company?

The culture of any organisation is most influenced by the leadership and by the example set by the CEO or MD. Given that the research is targeted at this group, this question is most useful in relation to the how responsible the interviewees see

themselves in terms of customer centricity and culture. The question has a broader possible scope than just the CEO/culture dyadic, and provides the opportunity to identify specific customer centric initiatives that have become institutionalised in the innovation process.

Section Four: General

Question Nine. On a scale of 1 to 10, how customer centric do you think innovation processes are in the Irish med tech industry and why?

Question nine is a scaling question designed to ascertain the interviewees overall opinion on customer centricity practices in the med tech industry in Ireland. This question also allows the interviewer to probe what the interviewee identifies as customer centric proficiencies and deficiencies how the interviewee compares Irish activity to that practised by the med tech industry in other countries.

Question Ten. Kavanagh et al. (2010) talk about fulfilling a customer need being more important than providing a solution. What is your opinion on this statement?

This question challenges the interviewee's opinion on the core philosophy of customer centricity in terms of medical device innovation. The fundamentals of the statement in the question puts customer's needs above any form of product technology (although technology may be a means to meeting a customer's needs) and unearths how rooted the interviewee's commitment is to customer's needs over product technology.

4.3.2 Validity and Reliability

According to Bloom, Fisher and Orme (2009), the quality of a questionnaire must satisfy five key criteria: purpose; directness; utility; reliability and validity. The author of the questionnaire must be absolutely clear about its purpose and about what kind of information they are trying to obtain. The study is reliable only if similar results would emerge in studies by others using the same questions and sampling criteria. The study is valid only if it captures the data that it set out to capture. To this

purpose, pilot respondents representative of the target population are used to validate the questionnaire (refer to Appendix E) and determine its reliability.

The first candidate chosen to pilot the questionnaire is the CEO of an indigenous med tech company with an active R&D and marketing department. The company sells its proprietary products through distributor networks globally and all of the company's innovation and new product development takes place in Ireland.

The second candidate chosen to pilot the questionnaire is the European Manufacturing Director of a global multinational healthcare company. The company's Irish subsidiary is involved in product sustaining activity but does not have a formal R&D function operational in Ireland, a criteria set out for the target candidate. However, the second candidate's experience in innovation practices in the Irish medical device sector with leading blue chip companies qualifies this individual to be a suitable candidate to review the research questionnaire.

The feedback from the pilot tests of the questionnaire resulted in re-designing it into two sections. One section consists of five open-ended questions and the second section involves Likert scaling of five statements relating to customer centricity in medical device innovation designed to measure the interviewees' attitude. Advice was received from the review process that the ordered original list of ten open-ended questions might elicit answers that the interviewees may deem to be the right answers, or answers that may find general acceptance rather than provide for differing viewpoints.

The five open-ended questions that were preserved in the new questionnaire layout were those that cannot be structured into a Likert scale. The remaining five questions were malleable in terms of Likert scaling.

The Likert scale's invention is attributed to Rensis Likert in 1931. It is an ordered, one-dimensional scale from which respondents choose one option that best aligns with their view. There are typically between four and seven options. Five is very common. The response categories in Likert scales have a rank order, but the intervals between values cannot be presumed equal, therefore Likert scales fall within the ordinal level of measurement whereby the mean and standard deviation cannot be measured (Jamieson, 2004).

For the purpose of this research, the Likert scale is used as a tool to make the interviewee commit to a position relating to a statement about customer centricity and for the interviewer to use this attitudinal positioning as a means to probe underlying perspective and opinions, thereby reducing the risk of an otherwise "canned" answer.

Another change that resulted from the review process included changing the use of the specific term "R&D" from the original questions five and six. It was advised that such terminology would restrict the interviewee's thinking to the mechanics of R&D to the exclusion of other influencing aspects of the new product development including marketing, management influence, financial considerations etc. The reference to "R&D" is replaced with "new product development process".

The original question four is re-worded to accommodate value from the customer's perspective. It was advised that the original wording, "how do you ensure you deliver customer value" might be open to interpretation in relation to the word value; value in terms of the company's perspective rather than in terms of the customer's perspective.

The review process concluded that the questionnaire is valid and reliable. The amended questionnaire is detailed in Appendix F.

4.3.3 Ethical Considerations

For the intention of conducting ethical market research, the European Society for Opinion and Marketing Research (ESOMAR) guidelines of researcher responsibilities are used. Hence, the following provisions are made under ESOMAR's code of conduct (Domegan & Fleming, 2003):

- Respondent's cooperation in this research project is entirely voluntary at all stages. They will not be misled when being asked for their cooperation.
- Respondent's anonymity will be strictly preserved.
- The researcher will take all reasonable precautions to ensure that respondents are in no way harmed or adversely affected as a result of their participation in this study.

- Respondents must be told if recording equipment is being used. If the respondent so wishes, the record or relevant section of it must be deleted or destroyed.
- Respondents are entitled to withdraw from the interview at any stage, or refuse to answer any question.
- The researcher will not use information to identify respondents without the permission of the respondent.

A copy of the ethical guidelines is provided to all the interview participants in advance of the interview, see Appendix D.

4.4 Frame work for data analysis

4.4.1 Primary Research Analysis

Qualitative data analysis is a complicated process. Because qualitative data deriving from in-depth interviews is largely unstructured written and audio material, it is not straightforward to analyse. In addition, unlike quantitative data analysis, there are no clear-cut rules for qualitative data analysis (Bryman & Bell, 2007). Most approaches follow the broad basic precepts of grounded theory, in that a 'bottom-up' approach is taken in identifying themes within the data and the dimensions of these themes, and developing coding frames and analysing data. A key process in grounded theory is coding, whereby data is broken down into component parts that seem to be of potential theoretical significance (Bryman & Bell, 2007). The researcher's interpretation of the data forms the basis of emergent codes in grounded theory. This is the nature of data analysis applied in this research.

4.4.2 Practice Evaluation

Practice evaluation as part of the research methodology is appropriate in this research given the openness to interpretation of the meaning of customer centricity in medical device innovation. According to Shaw and Faulkner (2006):

> "Practitioner involvement in evaluation, research, development, and other forms of disciplined inquiry that are small scale, local, grounded, and carried out by professionals who directly deliver those selfsame services is embraced

> across a wide range of professions as an essential ingredient of good professional practice."

Kumar (2005, p. 287) describes a method of practice evaluation by asking experts in the area of a particular service to make recommendations about the process who in turn supplement information gathered with their own knowledge. This approach works because research is becoming increasingly problem oriented and more socially open (Nowotny, Scott, & Gibbons, 2001), where terminology to describe knowledge-related practices include evidence-based practice, best practice, collaboration, and knowledge diffusion (Shaw & Faulkner, 2006).

Practitioner evaluation for the purpose of this research serves to supplement the researcher's findings. The expert identified to carry out the practice evaluation is Michael Kavanagh, BSc, MBA, Senior Vice President of Global Marketing for the Australian medical device company, Cochlear Ltd. He is responsible for the development of global marketing initiatives for Cochlear's product portfolio. This spans the identification of new development opportunities through to product introduction and lifecycle management. Kavanagh is the lead author of a paper on customer centric medical device innovation published in Medical Marketing in 2010 and referenced in this research. The paper is entitled:

> "Hearing the hearing impaired customer: Applying a job-based approach to customer insight discovery in product innovation in the implantable hearing solutions market".

Kavanagh's practitioner evaluation involves providing an opinion on the level of customer centricity among Irish medical device companies based on a review of excerpts from the interview transcripts as shown in Appendix D.

4.5 Research Limitations

A limitation of the chosen research method, survey by in-depth interviewing, is that due to the one-to-one nature of the research, the sample sizes generally tend to be small which makes statistical extrapolation of the findings a problem (Domegan &

Fleming, 2003). In addition, in-depth interviews are susceptible to researcher bias. This vulnerability emanates if this is the only research method that is relied on for data collection thereby eliminating the validation provided by triangulation.

A research limitation exists in the form of potential for researcher bias in the questioning process. An interviewer may unknowingly introduce bias into a respondent's answers through things like, for example, tone of voice, physical appearance, rephrasing of questions (Domegan & Fleming, 2003). To minimise researcher bias, the questionnaires are piloted to determine reliability and validity and to provide the opportunity to eliminate ambiguity that may exist in the questions. Another well-documented and frequent limitation with qualitative research is the lack of experience of the researcher in carrying out data analysis (Dingwall et al. (1998), Miles & Huberman (1994, p. 10), Grafanaki (1996), Johnson & Waterfield (2006)).

Yet another research limitation is the sampling method used, that of convenience sampling. Despite the fact that in the field of business and management, convenience samples are very common, convenience sampling has been criticised on the basis that it results in generalisations that may not be representative of the entire research population (Bryman & Bell, 2007). Convenience sampling is subject to systematic bias because of sampling bias that would imply a difference between the results from the sample population and the entire population. This limitation can be dealt with through additional research.

5 Survey Findings & Analysis

This chapter details the results of the survey described in the Research Methods. The objective of the survey is to gain an insight into the Irish perspective on customer centricity during medical device innovation and to investigate what practices are used in its implementation with a view to identifying best practice. The survey is targeted at industry leaders. A total of ten senior executives from five FDI organisations and five indigenous organisations were interviewed. See Table 5.1 for an overview of companies included in this research.

The research is targeted towards senior executives from within the Irish med tech industry, and specifically, from companies actively involved in R&D and NPD. One exception is included in the research findings, this exception is the Site Director of a FDI company whose site is not engaged in active R&D or NPD. The reason for allowing the exception is that the site does partake in product modifications in line with customer needs and the individual in question holds a senior position in the industry trade body, thereby giving this participant a good general knowledge of industry practices across many disciplines.

Company	Structure	Primary Product Focus	Employees in Ireland	Interview with
1	FDI	Cardiology	>2,000	VP of Operations
2	Indigenous	Contract Design and Development	0-50	Managing Director
3	Indigenous	Cardio-Respiratory Diagnostic Devices	50-100	General Manager
4	FDI	Urology	350-400	VP of R&D (Global)
5	FDI	Contract Design and Development	150-200	Managing Director
6	Indigenous	Contract Design and Development	650-700	Chief Executive Officer
7	Indigenous	Ischemic Stroke	0-50	Chief Executive Officer
8	FDI	Minimally invasive devices	>3,000	VP of Endoscopy
9	FDI	Pharma, Med Device, Diagnostics, Nutrition	Circa 4,000	Site Director
10	Indigenous	Gastroenterology	0-50	Chief Executive Officer

Table 5-1. Portrait of Respondent Companies

The research findings are presented on a question-by-question basis as each question is merited with its own specific objective and the topic of each question serves as the primary code in the data analysis.

5.1 Customer Centricity

Question: From your point of view, what does the term "customer centricity" mean?

Companies are still finding it difficult to become customer centric in how they carry out their business activities (Shah, Rust, Parasuraman, & Staelin, 2006). This is possibly due to the ambiguity of the concept. Based on the definition of customer centricity as it relates to this research, that is, the pursuit of delivering customer value through meeting customer needs; the objective of this question is to investigate the general understanding of the term as it applies to the innovation practices of the companies included in this research.

The indistinctness of the term "customer centricity" is broadly reflected in the research. Although the terminology itself is not common, with five respondents stating they are not familiar with it, an alternative terminology is proposed in the form of customer service that extends beyond order taking and order processing.

This question was answered by all in the context of product innovation. Of the companies interviewed, three are involved in contract design and development, broadly defined as sub-supply within the med tech industry, one is in start-up stage and fully engaged in product development and the remaining six are involved in delivering finished products.

Customer centricity has a different resonance among the different types of companies interviewed, and is reflective of the nature of their business. One sub-supply company explains the relevance of customer centricity on the basis that the company cannot create demand for the products they design and develop, rather their customers (other med tech companies) have to decide they want to buy from the sub-supply company, hence the importance of being customer centric. The company in start-up phase advocates the organisation of business units based on customer needs and acknowledges that such activity is easier for a start-up it is likely to be focused on just a few customers initially. In general, companies with an existing portfolio of finished

products tend to extend customer centricity to a broad set of stakeholders and refer to customer centricity in terms of a philosophy, or as a pre-requisite to future success.

5.1.1 Discussion

The research confirms a good understanding of customer centricity; albeit the terminology is not every day speak. The words most often used to describe customer centricity are "customer needs" and "value". Figure 5.1 provides examples of the variety of words used by respondents to describe customer centricity.

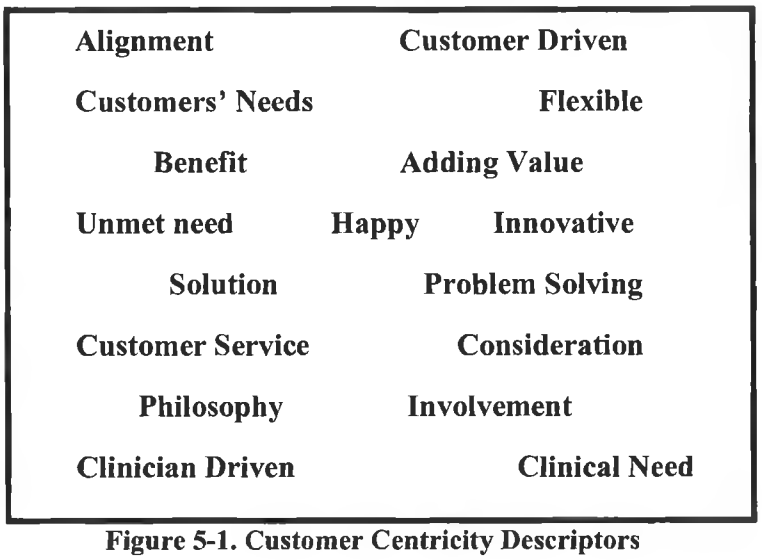

Figure 5-1. Customer Centricity Descriptors

It is prudent to note that an understanding of the general concept of customer centricity is not evidence of customer centricity.

5.2 Customers

Question: Who are your customers?

For med tech companies, the answer to "who are your customers" is not straight-forward which was reflected in the research findings. There are many stakeholders to consider, but broadly speaking these include the clinician, the patient and the payer. The objective of this question is to identify whom the med tech companies see as their customer when designing and developing products.

The research findings enable assignment of customer classification into five different categories, namely the clinician, other med tech companies, the patient, the payer and the user-innovator. Figure 5.2 identifies the frequency of reference to each category.

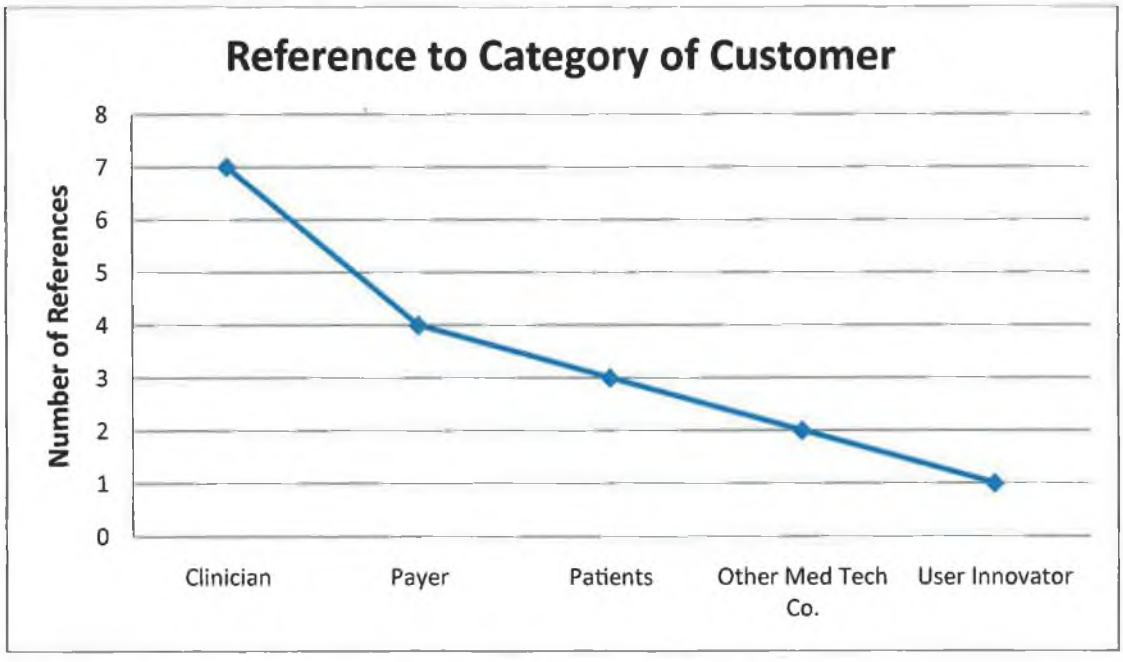

Figure 5-2. Number of references to specific customer groups

5.2.1 The Payer

Of note-worthy significance to this research is the reference by the majority of respondents to the growing influence of the payer in medical device innovation, and consideration of this throughout the NPD process. The payer in this context refers to the hospital administrators, the private health insurance companies or the national health systems that fund public health provision, for example, the NHS in the UK and Medicare in the USA.

The research findings concur with the OECD (2010) findings that rising healthcare costs is a serious global issue. According to the OECD, healthcare spending is pushing the average ratio of health spending to GDP from 7.8% in 2000 to 9.0% in 2008. With the onslaught of the global recession since the timeline of the OECD findings there are even less resources available for healthcare provision. According to one research respondent, "every healthcare system is broke", whereby companies

need to offer "the same medicine at better prices or better medicine at the same price". It is the shared opinion of a number of respondents that the proposition around a new medical device has to be clinically based *and* have sound economic argument. Clinical arguments used to be key, but economical based arguments are growing in influence.

While reimbursement, referred to by one respondent as a "monster", is a characterless participant in the process of commercialising medical devices, it has enormous influence on the payer. For this reason, the payer has to be considered in the customer mix, med tech companies have to think about reimbursement from the start of any NPD process.

5.2.2 Discussion

It is an interesting research finding that although all medical devices are ultimately used on patients, only three companies' referenced this stakeholder as featuring in their list of customers. A possible explanation of this is that although medical devices are used in one way or another for treating patients, the patients' involvement may be minimal as is in case of diagnostic devices where their use may be overseen by a clinician; or the patient may be passive in terms of choice of implantable devices such as coronary stents.

None-the-less, medical devices ultimately end up being used with patients and can greatly impact a patient's quality of life. A response rate of three out of ten in terms of reference to patients as customers is indicative that more effort needs to be made in addressing and understanding patient needs. In general, the med tech industry's focus is on the decision maker, which in the majority of cases is the clinician. It is the clinician who most likely decides whose brand of product to use. It may be argued that some devices are tools that enable the clinician to perform a procedure and have no further role to play, but such an approach diminishes the patients' required and anticipated outcomes and how the tools used may impact this.

5.3 Determining Customer Needs

Question: According to Kavanagh et al. (2010)***, the first task in medical device innovation is to develop a detailed understanding of the unmet needs of customers and then focus internal development efforts on a prioritised list of the most important needs identified. How do you determine what your customers need from you?***

The objective of this question is to gain an insight into how companies determine and understand their customers' needs, and to identify what techniques are used to do so.

The general opinion on needs identification is that getting this part of the NPD process correct is imperative to the future success of a device, but with the knowledge that it is not a simple matter of asking a customer what their needs are. One respondent described it as "an evolving picture that gets progressively more comprehensive…pennies drop all the time". There is a consensus that customers don't always know what they need, but that if needs are articulated properly, most reasonably good engineers can design the solution.

According to the research, understanding customer needs is harder than meeting them whereby uncovering unmet needs requires a significant amount of strategic marketing without which, according to one respondent, "you're goosed". The business imperative for fully understanding unmet needs is accelerated by the rate of commoditisation of medical devices, what was leading edge three to four years ago is often a commodity today and if a company wishes to stay on the leading edge, it needs to be focused on customer needs.

A wide variety of techniques, processes and tools were reported in this research as means of identifying customer needs. These are identified on a non-prioritised basis in Table 5.2.

5.3.1 Ethnography

Observation or ethnography was reported to be an invaluable tool for learning about customer needs. This was true for both finished product companies and for sub-supply companies, where being present when and where a medical device is to be used provides a wealth of knowledge. In terms of surgical procedures, as one respondent states "when you hear a swear word, then there's an unmet need". This remark was expanded on by another interviewee in terms of "moments of discomfort"

during a procedure which usually reflects the riskiest part of a procedure where there is room for improvement and thus an unmet need.

The majority of companies interviewed routinely send design engineers into clinical settings to observe and learn about the application environment of a new device, this is part of standard practice.

	Means employed to identify customers' needs
1	Observations (Ethnography)
2	Key Opinion Leader (KOL) input
3	One-to-one meetings with clinicians
4	Focus groups
5	Surveys
6	Physician preference evaluations
7	Scanning the journals for un-served opportunities
8	Use of physician advisory councils
10	Getting engineers to interact with clinicians
11	User requirements document (in case of sub-supply)
12	Establishment of Marketing Core Teams
13	Opportunistic learning during customer visits
14	Interviewing end-users about their experience with product
15	Concept design and validation using "Customer Experience" scenarios.

Table 5-2. Means of identifying customers' needs

In terms of sub-supply companies, an example was provided whereby engineers were sent into a customer's factory to observe how the products the sub-supply company designed and manufactured were used. This exercise identified an opportunity to increase the customer's overall yield on a production line through a product modification. This would not have been possible without observing the process, and although the improvement actually meant a drop in units provided to the customer, it resulted in significant customer satisfaction and a wealth of good-will for future business.

Ethnography is not always possible, particularly with products used by end-users or patients. One company works towards bridging this gap in the form of post-clinical trial follow-up. A group of participants on a clinical trial are interviewed about their product experience. This is carried out after the clinical trial report has been completed so as not to bias the report and enables invaluable feedback that can be used to make further product refinements. The only drawback cited to this and to other means of capturing first-hand information is the significant time and effort it takes to complete these tasks.

5.3.2 Use of Key Opinion Leaders (KOLs)

Based on the research findings, the use of KOLs is fundamental to how medical device companies identify customers' needs. KOLs are on the cutting edge of innovation in their chosen specialities and heavily influence regular clinicians in terms of the use of new procedures and new devices. They are early adopters in terms of the product life-cycle. For this reason, they are much sought after by industry to help drive the quest for innovative products.

KOLs tend to be expert at the most complicated procedures, often their workload consists of referred patients who are too complicated for a regular clinician to treat. The general opinion is that KOLs make difficult procedures look simple. Their experience and insights make them valuable resources for determining unmet needs. This has its drawbacks in terms of basing product usage assumptions solely on feedback from KOLs and all respondents demonstrated an awareness of this. As advised by Money et al., (2011), the respondents acknowledge that KOL feedback has to be interspersed with feedback from regular users who make up the vast majority to ensure new devices accommodate their skill sets too.

KOLs are also much in demand for their propensity to publish peer reviewed papers and speak at conferences. As one respondent noted, KOLs are excellent with data, they can present data that can add credibility to a new product or procedure.

5.3.3 Interviews, Focus Groups and Surveys

Traditional market research tools such as one-to-one interviews, focus groups and surveys are routinely used to determine customer needs by all the research companies. For sub-supply companies, the emphasis tends to be on the initial

meetings with other med tech companies or with user-innovators. These meetings are used to determine the nature of the problem and serve as an opportunity to try to understand where the customer is coming from, how they came upon the problem, to identify deficiencies in current methods, all with a view to fully understanding the "gap" or unmet need.

This point was supplemented in three interviews with the necessity to acquire as much information as possible about the target disease state, to read the journals about current work in this area whereby such additional information can refine a concept further and occasionally, lead to alternative product options. This was referred to by a sub-supply company as "market scanning".

Focus groups, although used, have limited utility unless conducted correctly. If the group includes one or two very opinionated people, they can lead the focus group along one particular direction.

One-to-one meetings with clinicians in a clinical setting need to be managed well to uncover needs and therefore add value to the NPD process. According to the research, clinicians who are "closet engineers" will have very specific product ideas whereas clinicians who have a therapeutic focus will tend to be more needs oriented. A company's primary focus with regard to clinician involvement in NPD should be clinically oriented more so than design input oriented. One respondent provides a cautionary example of the danger of accepting design input from a clinician whereby work that was carried out on a medical device based on a clinician's requirement for it to be bigger, only to learn to the company's regret, that in fact the customer required the device to be stiffer and not bigger. "Clinician's do not speak the same language as engineers" and for this reason, undertaking validation of the clinical need as part of the NPD process was adopted by this company to prevent recurrence of this incident.

Discussion involving engineers and clinicians are productive in identifying needs relating to challenges the clinicians have in treating certain patients, including what groups of patients can't be treated today, why they cannot and what sort of intervention the clinician would ideally like to carry out. According to the research, clinicians tend to prefer to talk to engineers than sales people and sales people gain kudos for bringing engineers into hospitals to meet the clinicians.

5.3.4 Advisory Councils

Clinician advisory councils comprising of KOLs provide a steering mechanism for some interviewed companies to stay on track either in terms of overall portfolio management (current and pipeline products) or in terms of single product development. One of the large FDI companies interviewed operates two councils, one with a US market focus and the second with an international remit. These councils meet 4-5 times per year to review the company's overall portfolio development strategy.

Advisory councils are used by indigenous organisations also. The start-up indigenous company interviewed recognises the value of this approach and has established a core scientific advisory group. Credibility is an important factor in a company's ability to set-up an advisory council.

Physician Preference Evaluations is a technique used by one company to test the utility of new devices before they are launched. These are normally carried out among KOLs on product that does not require a formal suite of clinical trials and provides the opportunity to garner valuable practical information in relation to needs fulfilment, thereby allowing the company to make final refinements if needed.

5.3.5 Customer Experience Corridors

Changes during a NPD process can have onerous impact on the process administration in terms of regulatory responsibilities and record keeping. In order to minimise the impact of change during NPD, one company has introduced a customer experience corridor as part of its needs gathering process before official design and development commences. Compatible with the customer experience corridor that Meyer and Schwager (2007) write about in relation to the customer's interaction at all possible touch points with an organisation, the interviewed company places particular focus on capturing customer insights at the earliest possible stage in NPD. This involves the creation of a lot of prototypes, getting input from the company's Marketing Core Team (comprised of sales, marketing, and engineering personnel) and getting input from KOLs. Such activity takes time, but it is better and cheaper to make changes if possible before products enter the formal NPD process. For the

company in question, this provides a good time to cull projects if needed, therefore again, saving a lot of time and expense early on.

In terms of customer experience, another research finding relates to products destined for use by patients; whereby med tech companies tend to overlook product aesthetics and do not tailor such products to meet the customers' or patients' desires as well as clinical needs. While needs are more important, products that look nice should help drive compliance. Aesthetics may seem trivial when a product is being market tested by clinicians where they feel it is not appropriate to comment that the colour isn't nice or that the plastics feel cheap.

5.3.6 User Requirements

For sub-supply companies, their customers are other med tech companies or user-innovators who usually present their needs in the form of a User Requirements Document (URD). While a URD is necessary in order to structure a project, it is often more solution focused than needs focused. Findings from two sub-supply companies state that one of the hardest parts of NPD is to move the customer away from the solution oriented approach in order to open up the channels of true innovation. This can be difficult especially if dealing with engineers within the customer's organisation whose tendency is to come up with solutions.

Another technique used by sub-supply companies is business reviews with the management teams of customer companies. For one organisation, this extends up to executive management level for the top five accounts on an annual basis and with business unit leaders on a quarterly basis.

In the case of sub-supply, unmet needs also extend into pricing. Customer organisations that are targeting the emerging markets of Brazil, Russia, India and China are experiencing downward price pressures where primary requirements are functionally safe products. In order to respond to this need, one sub-supply company interviewed used a series of trade-offs on customised product versus standardised product to help a customer achieve the necessary price point. According to the CEO, there will be increased incidences of this whereby innovation is more business model driven than product driven based on the customers' fundamental needs. Being able to

respond to this need positions the company as a solution provider that can add value to their customers' business.

5.3.7 Discussion

Overall, a comprehensive range of techniques are employed by the research companies to define customer needs but their implementation is not standardised and in some cases, such as opportunistic learning during customer visits, it is ad-hoc.

A general observation from the research findings is a reverence towards KOLs. This is reflected by their much sought after input, the use of physician advisory councils and physician preference evaluations. Even the practice of scanning peer reviewed journals, albeit a secondary method of needs research, is focused on papers written by KOLs. Although these companies are aware of the danger of over-reliance on KOLs to the detriment of regular users' needs, the research demonstrates a bias in favour of KOL input.

The second part of the Literature Review (Chapter 3) focuses on customer centricity in medical device innovation. The two methods specifically referenced to identify customer needs in medical device innovation are ethnography and the "outcome" (Ulwick, 2003) or "jobs" (Christensen et al., 2005) based approach where the focus is on the outcome the customer wishes to achieve. The research findings are supportive of ethnography as a means of identifying needs, but there is little evidence to support the outcome based approach. The start-up company in this research uses a needs based approach by going through the target procedure on a step by step basis to identify un-met needs along the way. An indigenous company makes humourous reference to a clinician cursing during a procedure as indicative of an un-met need. Although this observation was made during ethnographic research, it can be argued that if the clinician hadn't reacted this way, the learning would never have occurred, where by the step by step approach provides a higher likelihood of success.

5.4 Pros and Cons of User-Involvement

Question: What do you see as the pros and the cons of user-involvement in the new product development process?

Based on the research findings, there are differences in the pros and cons as perceived by the sub-supply companies versus the finished product companies.

In terms of the finished product companies, the over-riding opinion is that the pros of user-involvement far out-weigh the cons. Among the specific advantages outlined are:

i. The clinician becomes an evangelist for the product.
ii. User-involvement results in clinical studies and peer-reviewed papers.
iii. Exposure to the clinical need.
iv. Fundamentally cannot develop medical devices without the input of customers; engineers and marketing people cannot provide the clinical insights that can only come from the clinician.
v. Alignment with clinical needs and expectations.
vi. Subtle needs often emerge in discussions with clinicians.
vii. More time spent with clinicians equals a better product.
viii. One clinician can offer the consolidated view of several hundred end-users.

From the perspective of sub-supply companies, the benefits are as follows:

i. Alignment with customers' needs and expectations.
ii. User –involvement means customers have a realistic and more objective view on pricing, service and quality deliverables.
iii. Excellent opportunity for networking and relationship building. Such rapport can be very beneficial if the project runs into difficulties as there is more trust between the parties.
iv. Real-time involvement means the customer knows what is happening which can save a lot of time and money.
v. User-involvement can be an aid to innovation and design by providing input from the end-users point of view.

User-involvement in new product development is not without its drawbacks. Again, based on research findings, there were differences between finished product and sub-supply companies. In the case of finished product companies, the challenges of user-involvement include but are not limited to:

i. Clinicians don't think or articulate like engineers do, this increases the risk of misinterpretation.
ii. Clinicians and/or patients don't know what they need, they use current product offerings as a basis for considering new alternatives, and therefore user-involvement may result in only incremental improvements.
iii. If a company over-depends on KOLs as a source of identifying unmet clinical need, this could result in products that will only ever have niche applications.
iv. It takes a significant amount of time and resources to acquire the needs inputs from end-users (patients) resulting in excesses of data generated.
v. Clinicians tend to focus on their own particular set of problems which can result in niche solutions being provided.
vi. Managing expectations. The worst thing that a company can do is to engage a doctor, get them excited and then not follow through.
vii. Clinicians are not overly concerned about costs; this can impact final product health economics.
viii. Trying to keep everyone happy.

From the sub-supply perspective, the drawbacks of user-involvement include:

i. The customer has already a preconceived idea of the solution which means they are less likely to be open to alternatives. This can be particularly true when working with engineers.
ii. The customer can unwittingly add costs – a phenomenon also associated particularly with engineers.
iii. If the customer fails to meet their own commitment deadlines, they become the delay factor in executing a program.
iv. The customer tries to take over ownership of the process. The company needs to be resilient and assertive enough to diplomatically ensure the customer does not become too involved.

Logic dictates the pros and cons listed above. However, for one of the participant companies interviewed, whose customer base includes user-innovators, they have an emotive aspect of use-involvement to deal with which ultimately complicates the NPD process. According to the CEO, the user-innovator normally has a very strong emotional attachment to their product idea, they think about it all the time. In itself this is not intrusive, but user-innovators in the CEOs opinion tend to change their minds regularly throughout the process. Steps to control this include getting sign-off at various stage exits of the NPD process as the company implements Stage Gate processes and by applying project management disciplines. The success rates are not guaranteed and in some cases, the user-innovator overlooks or forgets they have already signed-off on a development. Prototypes when used with user-innovators can be viewed as yet another opportunity to make changes rather than to facilitate moving the NPD process to the next stage.

5.4.1 Discussion

The answers relating to the advantages and disadvantages of user-involvement in the NPD process are supported in the literature. However, an unexpected research finding is obvious in the distinct differences between the outlook of finished product companies and sub-supply companies to the pros and cons of user involvement in NPD. The finished product companies refer to clinicians and/or patients in their answers whereas the sub-supply companies refer to other med tech companies, who are their paying customers, in relation to pros and cons with no reference to clinicians or patients. An obvious explanation is that the sub-supply sector has no direct interface with the clinician or the patient, yet it was one of the sub-supply companies who made reference to an opportunistic learning encounter that arose in the hospital setting which formed the basis for a needs-driven product improvement. The research indicates there may additional scope for the sub-supply sector to learn about un-met needs by extending user-involvement to the end users, albeit in conjunction with their paying customer, the contracting med tech company.

5.5 User-Involvement throughout NPD Process

Question: How does your company ensure user-involvement throughout the new product development process?

Gyula (2001) found that user involvement was higher in the initial and marketing stages of NPD. To prevent a situation developing whereby a company obtains user inputs only at the outset of the NPD process, and therefore runs the risk of a product becoming de-railed because of design changes, it is necessary to keep the customer involved right throughout the whole process. This part of the research investigates how med tech companies maintain engagement of users throughout the NPD stages.

Nine of the companies interviewed use prototypes as a means of continuing to engage the customer as the NPD process progresses. For some companies, several iterations of prototypes are used to ensure successful outcomes. In one case, the objective is to design, build and test prototypes within a week right throughout the process so as to provide something to "show and talk about" which in turn, generates credibility. This company works from the philosophy that there is a lot to be learned from what does not work.

In the opinion of one senior executive, if a company makes the mistake of disengaging with a clinician once the product is designed, the company will face the issue of getting the device used once it is launched; companies need clinicians to be supportive of them. One of the FDI organisations continuously engages clinicians in product development activities during the course of on-site clinician visits. Approximately four hundred clinicians visit the company's Irish facility every year and a significant amount of these spend time talking with and in the lab with design engineers, supporting on-going product development activities.

Human Factors or how the patient or user will interact with a medical device is growing in importance (Money et al., 2011) and provides a valid conduit to the customer throughout the NPD process. HF was identified specifically as having an important role for user engagement by two of the research companies. Consideration of the user in the design process can entirely alter the look and feel of a new product. One indigenous company employs usability studies internally to identify obvious

findings before doing external usability studies. The internal team is recruited from among staff that is not part of the NPD process to minimise the potential for bias.

For sub-supply companies, regular review meetings, constant communication, getting customer sign-off at stage exits and the interaction of cross-functional teams with the customer are the tools identified in keeping the customer involved throughout.

One of the companies interviewed actually involves users in the composition of marketing materials to support the launch. Several companies work with users to generate clinical data in the form of published peer-reviewed data or engaging users, normally KOLs, to speak at conferences and exhibitions on clinical findings.

5.5.1 Discussion

The most commonly used means of sustaining user-involvement throughout the NPD process is customer evaluation of prototypes. The findings from this part of the research are more ambiguous than for other questions (See Appenxix F, Question 5). There is definitely no other strong trend evident to continuously engage customers throughout the process. On-site visits by doctors, on-going communication, keeping the KOLs up-to-date etc. are all informal tactics to supplement customer input. This is not surprising because the opportunities for engagement during NPD are fewer. This finding highlights the requisite to fully exhaust the needs gathering stage at the outset of NPD and to validate identified needs before NPD commences.

5.6 Open Innovation

Statement: Open innovation, or the "not invented here" ideology offers medical device companies the possibility to engage external scientists, engineers, clinicians and indeed patients in new product development , Davey et al. (2010). Open innovation is an integral source of new product inspiration for my company.

Respondents were asked to rank their commitment to the statement using an ordinal scale based on their level of agreement. The results are shown graphically in Figure 5-3.

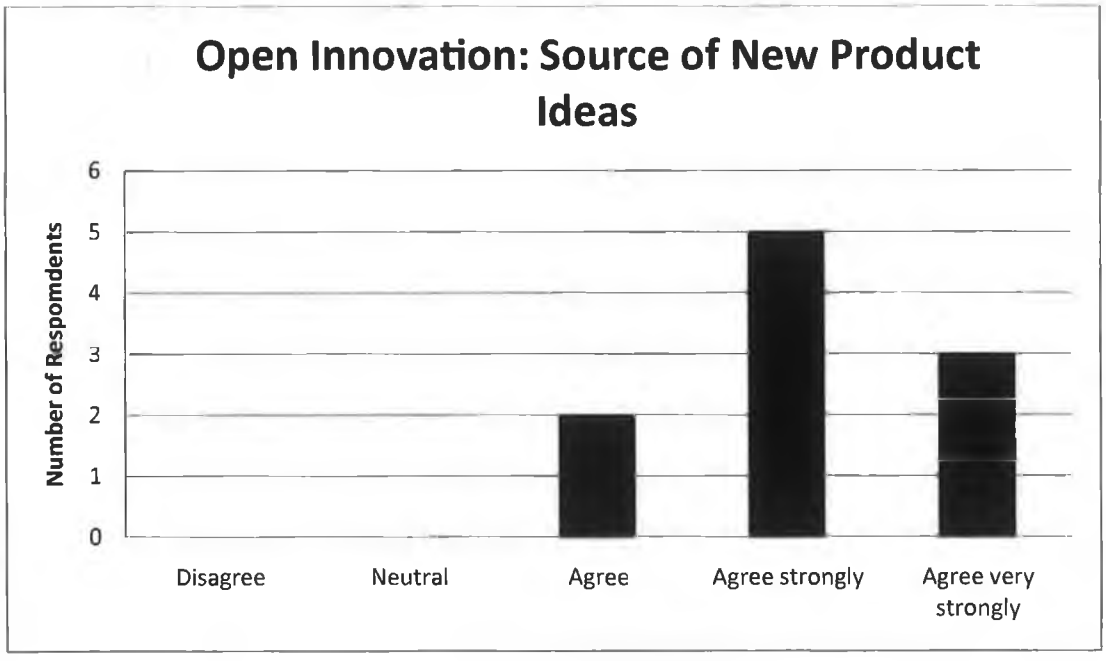

Figure 5-3. Open Innovation

There is much written on the growing trend of open innovation as a new paradigm in the development of innovative products (Chesbrough, (2003); Fredberg et al., (2008); Ahonen et al., (2007)). It represents a break from the traditional approach of solely using internal resources and ideas in next generation product innovation. The opposite of open innovation is closed innovation which embraces a strategy of vertical integration and exclusive control. Both approaches to innovation have associated advantages and disadvantages. Open innovation is more customer inclusive than closed innovation and requires external parties to become actively involved in NPD rather than being a passive contributor to it. This aspect of the research is designed to probe the outlook and involvement of the companies towards open innovation and to determine to what, if any level it is being adopted.

Certain themes are evident on the topic of open innovation. The concept is accepted among the research companies with 80% agreeing strongly or very strongly that it serves as a source of new product inspiration. The drive towards open innovation comes from the growing demand for complex products spanning multiple technologies. The general consensus is that open innovation is a relatively new practice which can help support a company's innovation agenda in areas outside their existing core competencies. The companies interviewed acknowledge that they

cannot develop the full range of new technologies often required to solve unmet market needs; and that trying to do so would prove expensive, take too much time and have a higher risk of failure than seeking solutions elsewhere. As one interviewee states, "we are not experts at everything".

The success of open innovation is dependent on the culture within a company with a prerequisite for success being the acceptance and support of senior management. According to one CEO, if open innovation isn't part of the culture it will not be embraced and it can be very hard to change the culture of an organisation.

The respondents general interpretation of open innovation related to collaborations with other organisations more so than collaboration with customers. This also holds true for sub-supply companies, where in one case the CEO spoke of the company's value being its ability to offer complete solutions, positioning itself as a solution provider, an integrator of technology and platforms rather than a technology provider. The exception to this is the company who includes user-innovators among its customer base.

In relation to some of the indigenous companies, particularly the start-up company interviewed, financial and resource constraints make them very proficient at leveraging external capability. Another opinion based observation from an indigenous respondent is that small to medium sized organisations are better at doing product development than research which drives the research quest externally.

Three interviewees make specific reference to the barrier that intellectual property poses to open innovation endeavours whereby the legal implications can often be a deterrent. This finding is of particular concern to the larger FDI companies interviewed.

There is a distinct difference in approach to open innovation between the smaller and the large companies interviewed, particularly the large multinationals. Although large companies are fully supportive of the need to look beyond the company's boundaries in the search for innovative product ideas that will meet customers' needs, the quest for required technologies begins internally among other subsidiaries. Two of the companies included in this research are active in scouting new compatible technologies from among small innovative companies with the view to acquisition or

licensing technology. According to one senior executive, purchasing technologies is part of the expansion strategy of any multinational whereby a "number of small bets are made" and the risk in developing innovative products or technologies is greatly reduced.

5.6.1 Discussion

The research findings reveal an element of caution in the companies approach to open innovation. The most notable concern relates to ownership of intellectual property as this is what endows a product with competitive advantage. The approach to open innovation taken by the smaller indigenous companies is different to the larger FDI companies with the smaller companies having to work around the associated risks whereby the FDI companies tend to acquire new technologies thereby such risks are eliminated.

None of the companies interviewed referred to using the internet as a catchment area for open innovation. A more specific and targeted approach is used in capitalising on open innovation and this is largely applied in a business-to-business setting. The nature of open innovation as practised by the research companies is largely exclusive of clinicians and patients, this indicates that while it is not directly customer centric, it is indirectly customer centric on the basis that it is used to develop products to meet customer needs. The research findings show that open innovation is an emerging trend in the med tech sector in Ireland, one which companies are embracing, however cautiously.

5.7 Value

Statement: We work hard to ensure that we deliver value in terms of the customers' needs.

Respondents were asked to rank their commitment to the statement using an ordinal scale based on their level of agreement. The results are depicted in Figure 5.4.

The objective of this question in the research survey was to ascertain what consideration is given to value as perceived by the customer in relation to medical

device innovation, to understand how companies determine such value and to determine how they set about meeting value requirements.

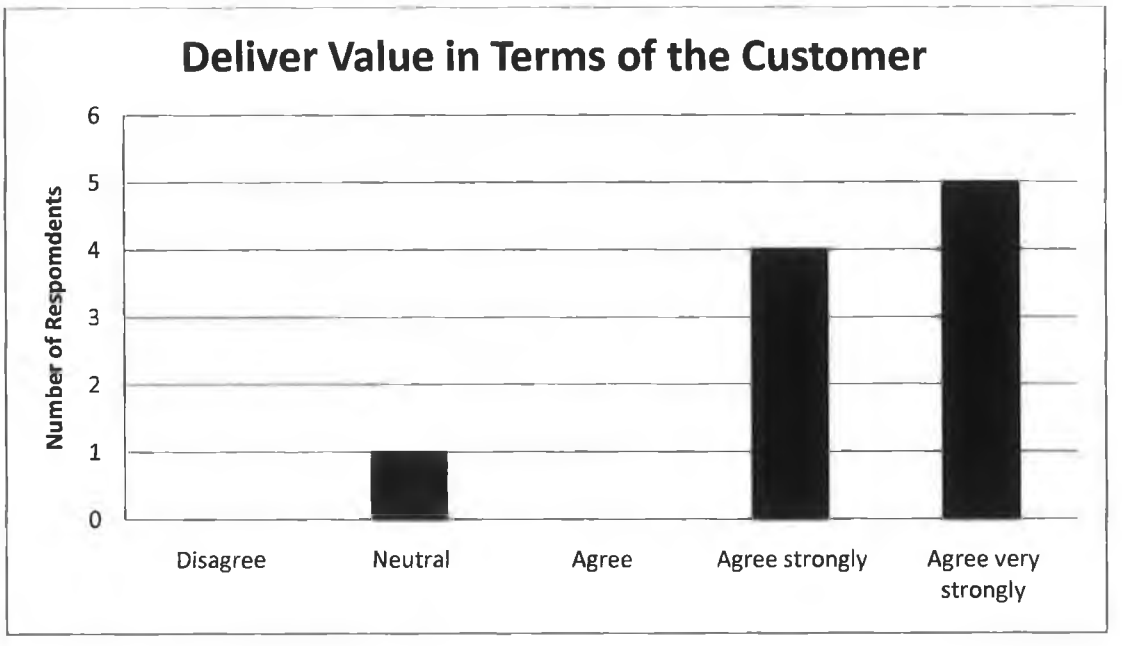

Figure 5-4. Value as perceived by the customer

Value, in terms of the customers' perception is generally very important to the research companies and this is reflected in the rating on this statement with 90% agreeing strongly or very strongly that they work hard to deliver value in terms of customer's needs.

The research findings reveal that value is an elusive concept. Reference is made to value in terms of the need to develop products that can be used by clinicians of varying skill-sets, of developing global products and in one specific example, of avoiding surgery. Non-specific reference to value is made in terms of product improvements and the use of key performance indicators.

The response from one sub-supply company best describes the quest for customer value in terms of the alignment of the company's view of value with the customers' view of value. Work is invested into understanding what is of value to the customer. Features that are not perceived as inherently valuable to the customer are eliminated, otherwise they become the source of unnecessary cost and expense. Approaching value in this way enables the company to charge fairly for what is of value and to offer cost-savings by eliminating excess whereby the customer is satisfied, both sides

of the value equation are met and the product meets the customers' expectations. Although less specific, a FDI respondent states "we simply are not going to start down the NPD route unless it meets an existing market need".

Delivering products of true value involves trade-offs and this is supported in two responses. One finished product company mines through a list of potential product features to define the final feature set that offers most value. This involves a series of trade-offs through a negotiated elimination and inclusion process on the basis that the company cannot practically offer the full gamut.

5.7.1 Discussion

Value can be a very elusive and subjective concept unless it is rooted in immutable customer needs. Some of the research companies approached this question in terms of all of their general activities undertaken in their endeavours become more customer centric. The definition of customer centricity used in this research is incorporated in the question, that is, the pursuit of delivering customer value through meeting customer needs. With two exceptions, the research companies did not make reference to the link between "needs" and "value". Reference to using a process of elimination of product features may capture needs based value if the features under negotiation are based on customer needs. This was not validated in the research.

5.8 Processes to Develop a Customer Centric Culture

Statement: Customer centricity is a priority for my company, we have processes in place to develop a culture supportive of this.

Respondents were asked to rank their commitment to the statement using an ordinal scale based on their level of agreement. The results are as illustrated in Figure 5.5.

Culture within an organisation is reflected in the manner that people perform tasks, set objectives and administer the necessary resources to achieve objectives (Barthorpe, Duncan, & Miller, 2000). The simple and most commonly cited definition is "the way we do things around here" (Lundy & Cowling, 1996). There is interdependency between culture and processes. This question is designed to validate if customer centricity is intrinsic within the research companies by identifying the processes supportive of it.

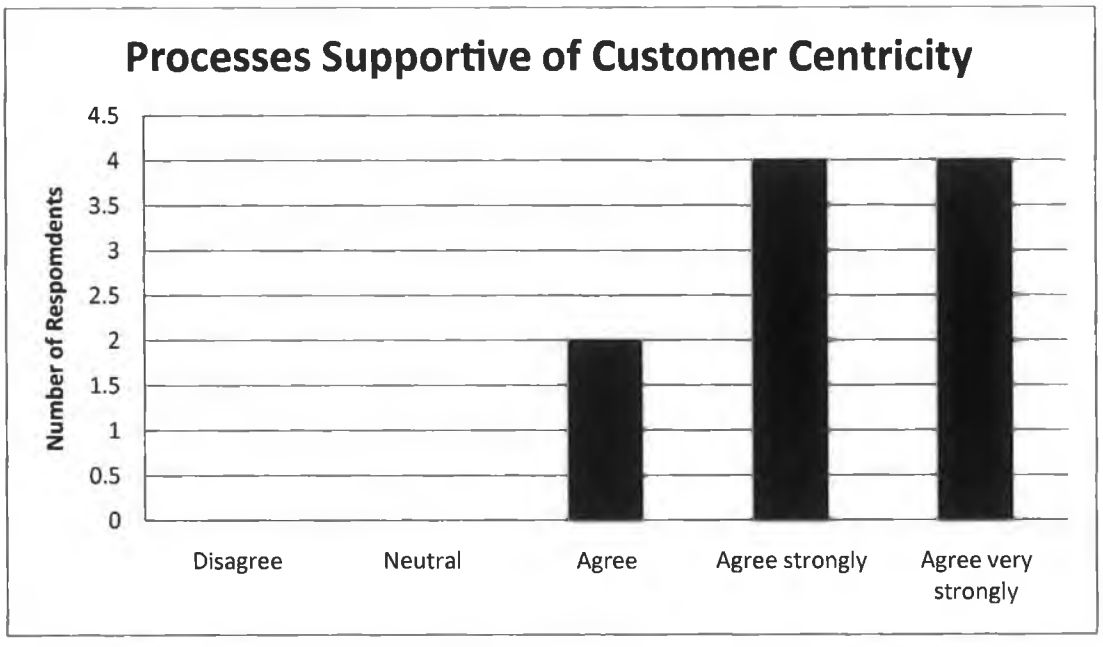

Figure 5-5. Customer Centric Processes

In terms of commitment to the statement, 80% of respondents agree strongly or very strongly that their organisations have processes in place designed to increase customer centricity. In addition to the research companies, one of the reviewers of the questionnaire comments;

> "Customer centricity is not something that resides in an oasis in the R&D department, for it to be of relevance, it has to exist across the entire organisation"

In terms of processes that exist among the research companies, these range from "no formal processes" because the company is too small right up to inclusion of customer related goals and objectives in employees' performance objectives a method endorsed by Lockwood (2007).

Table 5.3 summarises the processes identified that support a culture of customer centricity. Communication is the most prevalent way of ensuring a culture of customer centricity. This ranges from weekly to quarterly updates that include key performance metrics, updates on business performance and links to how employees contribute to overall company goals. One company uses specific examples where

employee effort and input led to winning contracts, and where work output that could be improved put business under threat.

Customer Centric Supportive Processes	# References
Bring in patients that have been treated with the company's device to talk about their positive experience and improved quality of life	3
Bring in clinicians to talk with staff about the relevance of the products	4
Regular communication and staff updates	6
Knowledge sharing – educating staff on the clinical relevance of products	1
Include customer related goals in employees performance objectives	2
Design engineers are obliged to attend clinical procedures	3
Recruitment process focused on identifying people who can also respond to customers' needs	2
Quality Management system is used to ensure product integrity and quality	2
Use of clinical advisory groups	4
Mentoring new recruits	1

Table 5-3. Customer Centric Enabling Processes

Regular communication is used to keep the customer real in the minds of employees who are reminded at updates that customer's have the ability to change their minds about whether or not to use the company's products. Bringing customers in-house and having them meet and interact with design engineers and employees is also a popular means of developing a customer centric culture based on the research findings. This method forms part of the DART model of value co-creation as proposed by Prahalad and Ramaswany (2004) referenced in Chapter 2.

In general, formal processes form part of how companies work towards developing a customer centric culture. Such processes include:

- Implementation of the companies quality management systems
- Human Resources activities
    - Hiring policies
    - Employee induction and training
    - Employee work objectives
    - Mentoring

In reference to a customer centric culture, according to one respondent, "we aspire to be better", whereby efforts are underway to create a more customer centric culture on the basis that "it's our future". The influence of customer centricity within organisations is recognised to be growing, one senior executive of a FDI organisation remarks that a few years ago, customer centricity only existed at executive level and within marketing, but that today, an awareness of the customer exists at every level within the organisation, from senior management to the shop floor.

The research reveals that a customer centric culture is of relevance to one of the organisations in terms of acquisitions. The CEO of this organisation, being cognisant that the culture of an organisation is very hard to change includes cultural alignment in terms of customer focus as a consideration in an acquisition bid.

5.8.1 Discussion

This part of the research elicited a high volume of response. There is a lot of on-going activity in keeping employees informed about customers and in making employees aware of their responsibilities to customers. Such activities could however take place in the absence of customer centric innovation, having an impact on the broader range of business functions ranging from quality to manufacturing. It is not realistic to expect that a company's product innovation processes can be customer centric if there is not a broader understanding of customer responsibility across the entire organisation, this is supportive of the reviewers comment relating on the need for a customer centric culture to extend beyond the R&D department.

5.9 Customer Centricity in the Irish Med Tech Industry

Statement: Please rank how customer centric you think innovation processes are in the Irish med tech industry. 1 = not customer centric, 10 = very customer centric.

Thus far, the survey results account for internal observations and insights into customer centricity in medical device innovation. The objective of question nine is to investigate the opinions of the industry's leaders on how customer centric the Irish med tech industry's innovation practices are. The respondents are asked to rank their opinion based on a scale of 1-10.

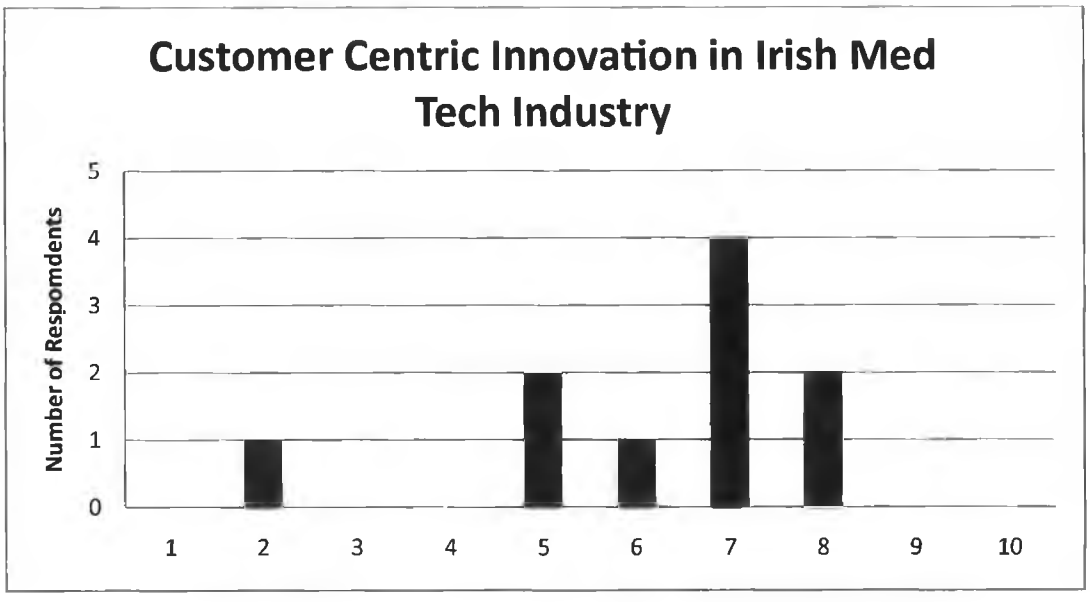

Figure 5-6 Ranking for customer centric processes in Irish med tech industry

The general opinion in terms of overall performance is that there is room for improvement in how customer centric the industry's innovation processes really are. 70% of respondents assign a score of six or more to overall industry performance, and 30% score the industry performance at five or less. The over-riding consensus is that a clinical gap exists in the industry in Ireland and that this has a direct negative impact on the industry's ability to be more customer centric.

5.9.1 Clinical Gap

The research identifies that involvement with clinicians is a primary method used by companies to identify user needs and in particular, some level of involvement with KOLs. The research indicates that in relation to the companies interviewed, there are

no KOLs from their target disciplines working in Ireland. As one respondent stated the clinicians' brief in Ireland is clinical procedures.

The side effect of such a low level of interaction is that Ireland is not a good destination from which to run clinical trials, it simply is not practical. Clinical trials serve as an excellent platform to facilitate close industry-clinician interaction. One respondent speaks of positive developments underway to establish a central clinical approval board for running clinical trials. Currently, if a company wishes to set up a trial in Ireland, it would have to obtain ethical approval and permission individually from every hospital it is targeting. Given the relatively small population in Ireland, and taking into consideration that clinical trials normally have exacting inclusion criteria, it is necessary to enrol patients from more than one hospital. The clinical approval board would grant permission covering several hospitals, making the clinical trial process much easier and patient enrolment much faster.

Reference was made by a number of respondents that the industry-academic ties are stronger in Ireland than the industry-clinical ties. One respondent believes the linkage should triangulate the government:

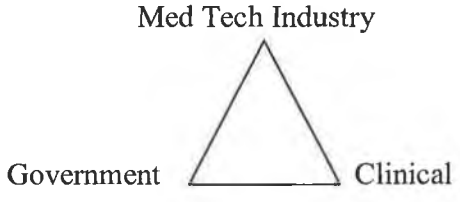

Figure 5-7. Proposed Collaboration for Improving Clinical Input

The government involvement would include funding through bodies such as Science Foundation Ireland to increase clinical research and also, to provide guidance on issues such as reimbursement and legal issues.

5.9.2 Ireland versus USA

Three respondents make specific reference to innovation and clinical involvement in the Irish med tech industry compared to the globally renowned med tech hub in Minnesota, USA. According to one senior executive, there are 60,000 people working in the med tech industry in Minneapolis, and approximately 30,000 working in the industry in Ireland. This executive poses the question, is there half of the innovation

coming out of Ireland that there is coming out of Minneapolis, and given that the answer is no, this is cause for concern.

It is recognised in the research that there are significant gaps between the med tech industry in Ireland and the med tech industry in the USA, but that the body of knowledge and the network is entirely different in the USA. The industry is a lot older in America and hospitals in the vicinity of the American hubs (Minnesota, Massachusetts, northern California) are aligned with industry's needs in terms of clinical research. There is significant involvement between industry and clinicians. The med tech industry debuted in Ireland in the 1970s, and at that, in a manufacturing only capacity where the primary roles required to be filled were for good engineers. A research finding determines that the med tech industry cannot take people out of these roles and assume they can be slotted into product development roles; such an evolution takes considerable time.

Stanford University in northern California is a centre of excellence in industry-clinical medical device design. It is home to the BioDesign programme for med tech innovation, a programme that has been adopted by several leading universities across the USA. The programme is the template for an Irish equivalent that is being run out of the National University of Ireland, Galway (NUIG), called BioInnovate. Its aim is to identify unmet clinical needs through a team of Fellows comprised of engineering, medical and business disciplines. This program started in 2011 and according to one respondent heralds the start of a new phase of possibility for industry-academia-clinical interaction.

5.9.3 Manufacturing Legacy

Manufacturing has long been the bedrock of the Irish med tech industry. Lest its value is underestimated as a sustaining facet in the industry's on-going success, one respondent warns that it is necessary to preserve manufacturing competitiveness while moving up the value chain. Based on the research findings, the challenge of increasing innovation cannot be met with the same skill set that endowed the industry with manufacturing excellence, yet there is evidence in the research that this requirement is not fully realised. Feedback includes opinions that in general, the industry is too focused on specifications whereby product design is being approached as just a job – working to a specification. The danger exists that such focus can

exclude consideration for competitive impact, unit price etc. Reference is also made in the research with the industry's on-going love affair with technology. In particular, the impact this has on academia where the propensity exists to follow industry. This leads to chasing after problems that have been around for a long time rather than searching out completely new unmet needs.

Given that the clinician's mandate is not research oriented and the med tech industry is still largely manufacturing oriented, it is easy to explain the clinical gaps noted by the majority of companies interviewed.

5.9.4 Lack of Expertise in Certain Areas

There is optimism among the research companies that Ireland is in a very good position for growth and improvements in customer centric innovation. It is broadly acknowledged that there is an infrastructure in the country supportive of advancing the med tech sector. The industry's inherent acceptance of the need to be efficient and effective will help Ireland advance if some improvements are made in certain areas. In addition to the clinical gaps identified earlier, additional areas for improvement were also identified.

According to the CEO of one indigenous company, there are two things needed for successful NPD, engineering excellence and great strategic marketing. The gap in the Irish med tech industry is in strategic marketing. This CEO assigns this short-coming to structural and circumstantial situations. The career path and opportunities do not currently exist in the med tech industry for strategic marketing people; in the case of FDI organisations, these usually reside in a company's headquarters.

> "As in many other industry sectors, there is an increasing tendency to establish production operations in locations with low pay costs and good labour availability, while locating key corporate roles and roles relating to innovation in higher cost areas with an established base of expertise, which are often more attractive to high skilled professionals." (Expert Group on Future Skills Needs, 2008)

Lack of good strategic marketing can result in companies arriving at product solutions too soon without fully understanding what the customers' needs truly are.

The overall mood on Ireland's customer centric innovation capabilities is upbeat. In the opinion of one senior executive,

> "Ireland has shown itself to be innovative, and if it can balance this with building in a stronger customer focus, the industry in Ireland is going to be streets ahead. This is the prerequisite for future success"

A note worthy research finding on customer centricity in the Irish med tech industry, is that there are other macro influencers on the industry's success that are less noble than engineering and marketing excellence but potentially equally as influential. According to one industry leader, there is no room for complacency, whereby the industry possibly thinks it is more customer centric than in reality it is. He warns that the corporate tax rate of 12.5% is the key reason for the buoyant position the industry boasts today. This opinion is not exclusively that of this executive, in fact Ireland's favourable fiscal environment is cited as the reason for the country's med tech success according to the Swiss med tech industry body's annual report (Swiss Medtech, 2010).

5.9.5 Discussion

The respondents are frank in their opinions and realistic in their expectations on how customer centric product innovation is in the med tech industry in Ireland. Short-comings are identified, therefore improvements can be tailored to address them. The clinical gap between industry and clinicians ranks as the topic of most concern. This is likely to have the largest impact on customer centric innovation as it is defined in this research, that is, the pursuit of delivering customer value through meeting customer needs. The infrastructure in the Irish health system is not conducive to clinical research and while this is the case, the pursuit of clinical input is driven abroad thereby diminishing the Irish industry's self-sufficiency in this regard. Unlike other industry requirements that can positively impact customer centric innovation such as improvements in marketing capability and changes in engineering focus, the clinical gap is outside the direct control of the industry.

5.10 Solution versus Need

Statement: According to Kavanagh et al. (2010), fulfilling a customer need is more important than providing a solution.

The litmus test for customer centric innovation is a company's identification of its customers' needs before its endeavours to provide a solution. The covert objective of this question is to validate all that has been said by each respondent up to this point in the research interview. If there is any doubt in this fundamental philosophy, then it brings into question the overall level of customer focus and understanding required for successful NPD. Respondents were asked to rank their commitment to the statement using an ordinal scale based on their level of agreement. The results outlined in Figure 5.8:

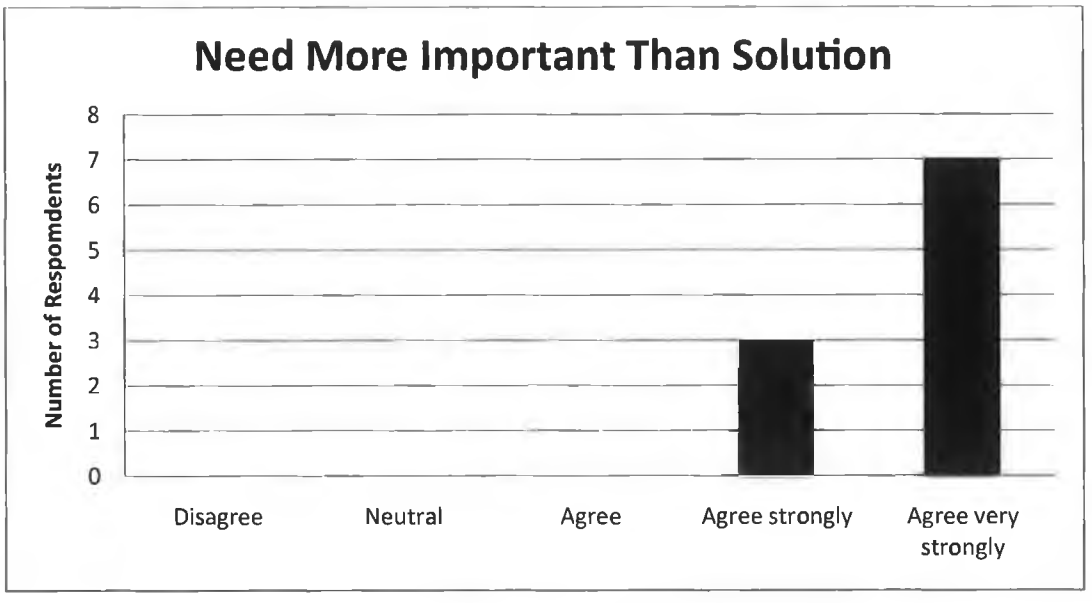

Figure 5-8. Solution versus Need

With all of the respondents agreeing strongly or very strongly that fulfilling a need is more important than providing a solution, the research confirms a vital understanding of the role of needs in customer centric innovation.

The responses to this statement include opinions and observations about the fundamental difficulty in identifying needs. Skilled questioning is needed in order to steer the customer away from solutions and to fully analyse the problem. One respondent talks of marketing's enthusiasm in providing solutions to R&D in

response to customers' problems without first fully understanding the need. When such occurrences happen, the marketing people are sent back out to complete the job properly. It is easy to slip into solution mode; it takes more effort to truly define the need. Focusing on the solution can dampen innovation as it creates a frame of thought; a frame of reference that can be hard to move beyond and can result in incremental improvements as opposed to innovative new products. Such incremental improvements are easy to copy for competitors.

The problem of tabling solutions before scoping needs is common, as one CEO puts it "it is instinctive to propose solutions". Another respondent admitted that putting solutions into the user requirements document is not the best approach. A solution was identified in the findings as being more temporary, whereas a need is more long term and there can be more than one solution to fulfil a need.

A position on the statement from Kavanagh et al. (2010) was probably best summed up by a managing director who said:

> "Your customer's need is also your customer's expectation – if you don't live up to that, no matter what type of solution you provide, if it doesn't meet the expectations, then it is no use"

5.10.1 Discussion

The research confirms a strong acknowledgement of the importance of thorough needs identification. Given the influence that industry leaders have in their respective organisations, the trend that emerges in this aspect of the research is very positive. If the captains of the med tech industry do not fully endorse customer centricity, it will command little attention or respect within an organisation (Day, 1999) therefore the answer to this question bodes well. However, endorsement at this level is merely cosmetic unless it is translated into policies and procedures. While there is evidence of significant customer centric activity throughout the course of the research, there is room for improvement in formalising the processes and in using best practice. The next section compiles best practice activities as demonstrated in the research.

5.11 Best Practice as Determined in the Study Findings

Camp (1989) defined "best practice" as any method or process that is more effective at delivering a desired outcome than any other method or process within that domain. Some researchers contend that best practices vary from firm to firm, evolving over time and with changes to the marketplace (Murray, O'Driscoll, & Torres, 2002). Thus, there is no "one best way" to achieve high performance but rather different routes to the same end goal.

The research findings demonstrate that a lot of customer centric activity is being undertaken in product innovation by the med tech industry in Ireland. Nonetheless, there are no standards of practice generally accepted and a lot of customisation and improvisation is used by all. According to Murray et al. (2002), there can be no "one-size-fits-all" approach to customer centricity, yet customer needs are generally immovable and therefore provides a constant in formalising processes. This research provides a unique insight into how different companies put customer centricity into practice and in the opinion of the researcher; the following list represents best practice with respect to the companies interviewed.

- The use of an exhaustive up-front process based on the "customer experience" with a product to identify design requirements can prevent a lot of re-design during the formal process and therefore provides for a faster, more efficient NPD process with reduced paperwork resulting from mid-process changes.

- Bring the patients and clinicians into the company to talk to the entire workforce about the benefits and improved quality of life resulting from treatment with the company's products – part of culture building process.

- An element of caution is needed in developing products based on KOL input only, as this group may only represent a small portion of the target clinician population and has different skill-sets to the "average" clinician who will be using the product more routinely.

- Determine what aspects of a procedure or a treatment a clinician is not happy with – what parts make the clinician feel most uncomfortable. This can be achieved using a step-by-step review with the clinician of every part of the procedure. This is a good basis for identifying an unmet need.

- Refrain from including possible solutions in the Market Requirements Document; focus on the problem being solved.

- Bringing members of the hospital administration on-site to demonstrate how products are designed and manufactures can be supportive in relation to perceived economic value of a product. An understanding of the complexity of manufacture can help in pricing considerations.

- Engineers and clinicians don't always speak the same language when it comes to product design. Design feedback from doctors needs to be carefully evaluated and validated. Mistranslated feedback can cause serious design issues. "Go prove what they are saying is right".

- Ensure engineers spend time in the clinical setting where the products they are working on are destined to be used.

- Med tech companies need to have credibility among users. This comes from knowing all there is to know about area of application. Learning and reading clinical research to be able to have meaningful conversation is a very important activity for all involved in product design.

- In the interest of pursuing a viable business opportunity and cost containment, it may be necessary to engage in a negotiated feature elimination process where trade-offs are mutually decided upon until a final product specification that meets the primary need is agreed. It is necessary that the complete feature profile is based on customers needs in order for this approach to be meangiful.

- Focus on designing and developing products for a global audience. If a company gets drawn into meeting the specific needs of a specific clinician,

then this will result in a very niche product with very low commercial potential. Needs input should be sought from a representative mix of KOLs and regular clinicians and an averaging of the results applied.

- Include the needs of the users of competitor's products or possibly disgruntled customers of the company's own products to get a lateral outlook on needs assessment.

5.12 Practitioner Evaluation

The expert used in the practitioner evaluation of the research findings is Michael Kavanagh, SVP Global Marketing at Cochlear and author of a peer reviewed paper on customer centric innovation; "Hearing the hearing impaired customer: Applying a job-based approach to customer insight discovery in product innovation in the implantable hearing solutions market" (Kavanagh et al., 2010). He is a strong proponent of needs driven innovation and has successful experience in implementing a process called Outcome-Driven Innovation® created by the thought leader Anthony Ulwick. Ulwick's outcome-driven approach is referenced in Chapter 2 (Ulwick, 2003). Application of this process forms the basis of Kavanagh's paper.

The expert evaluation is based Kavanagh's independent review of the excerpts from the research interviews, see Appendix H. A question by question general summary of Kavanagh's findings are presented in Appendix I.

In Kavanagh's opinion, the research demonstrates a strong understanding of the requirement to put the customer first in innovation. He advocates that needs identification is directly linked with the outcomes the customer is trying to achieve as a means of driving research. In relation to the range of customers identified by the research companies, Kavanagh advises that the needs of each stakeholder group be identified.

Although there is a strong appreciation of customer needs in the research, Kavanagh detects a solutions based approach whereby product iterations are tested and re-tested with customers. His recommends that companies ensure that they test solutions with

the right customer segment, and cautions on the engagement of KOLs, advising companies to be aware of how representative this group is of the larger target customer segment. In terms of testing solutions, this is demonstrated in the research through the use of prototypes. Kavanagh suggests that as solutions are presented, that the needs should also be presented in order to link the concepts to the needs and get customer feedback based on this approach.

Kavanagh quells the expressed concerns of intellectual property in relation to open innovation and proposes that if a company truly understands the un-met needs of a customer, that this knowledge is a source of competitive advantage, but acknowledges the needs for structures to protect this knowledge.

With regard to processes to develop a customer centric culture, in Kavanagh's opinion the research points to general processes and he advises on a more formalised, structured approach to define customer needs. In relation to the med tech industry's performance in customer centric innovation, Kavanagh zones in on the role of strategic marketing, stating that without it, it is very difficult to implement innovation based on customers' needs.

Kavanagh's overall conclusion is as follows:

"Customer centricity seems to be alive and well in the Irish Medical Device industry. The benefits associated with being customer centric are well understood as is a needs based approach versus solutions based approach to directing innovation practices (note there is some evidence that solutions based approach still does exist). There are a range of methodologies practised with the skew definitely towards needs based versus solutions based innovation. Some companies could potentially benefit from implementing a more formal structured approach upfront to ensure the needs based approach unearths the real needs that an organisation should focus on. The important role that upstream strategic marketing should play is also identified and for some organisations this is an area that should be assessed as to its current effectiveness and opportunities" (Kavanagh, 2011).

6 Conclusions and Recommendations

6.1 Conclusions

This final chapter summarises the findings of the research, presents observations on some findings, and provides recommendations for future research. Due to the limited scope of the survey, the findings are indicative rather than conclusive, and interesting trends have emerged.

6.1.1 Research Findings

The research question that is posed in this body of work is:

> ***How well is customer centricity understood and subsequently practised in medical device innovation by the med tech sector in Ireland?***

The research findings indicate a strong sense of awareness on the importance of customer centricity in medical device innovation in the industry in Ireland. This is coupled with the reality that there is room for improvement in certain areas in order for the industry to maintain its competitive edge. It is acknowledged that customer centricity is not a choice, it is an imperative for continued success.

Customer centricity needs to be extended to include all stakeholders. These primarily include clinicians, patients and payers. Health economics pose a challenge to the industry. Based on the research, one of the most complex aspects of customer centricity is designing and developing devices that not only incorporate the needs of the patients and the clinicians, but also the payers' needs, because this stakeholder is growing in importance on the basis of reimbursement.

While all the research companies demonstrate customer centric innovation practices at some level, there are no industry-wide models or road-maps used in its implementation. This is in contrast to the regimented design process discipline and regulatory paths that the industry follows in other aspects of their business. A practical sense of realism exists in relation to the benefits and complexities of incorporating customer centricity into the NPD process. It is generally understood

that customer centricity needs to be supported at senior management level, with processes put in place to guide its execution.

Accurate identification of customer needs is identified as the most challenging aspect of customer centricity in innovation, and informed by the literature review, this is the most fundamental aspect. The methods used by the research companies to determine customers needs vary widely, and range from traditional marketing tools such as surveys and focus groups, to ethnography and physician advisory councils among others. An awareness exists among the research companies that most people are inclined to be solutions oriented rather than needs oriented when it comes to NPD. There is room for improvement in how the research companies undertake this task. The expert practitioner used to review the research findings, Michael Kavanagh, recommends using an outcome based approach that focuses on the jobs the customers want to get done. This echo's the opinion of Ulwick (2003) and Christensen et al. (2005).

Open innovation, which extends to all forms of external stimuli, including customers, is a relatively new concept for NPD. The research companies have begun to embrace open innovation but there is an element of caution applied in relation to intellectual property rights. The primary expression of open innovation extends to other companies rather than to customers.

From a practical perspective, Irish based companies rely strongly on international key opinion leaders. The driver for this is early adoption of newly launched products, but this tactic is not without its recognised concerns which include the potential exclusion of consideration for the needs and skill sets of the majority of future users. One of the key findings of the research is a consensus that there is a significant gap in the Irish med tech industry between Irish based clinicians and the industry players. This is seen as a barrier to the industry's ability to run clinical trials in Ireland. Irish clinicians are focused on practice rather than research, an impediment that prevents the industry from engaging with the clinical community and ultimately, a lost opportunity in terms of customer centricity.

It is generally accepted that Ireland's med tech sector is well poised for continued growth but that reliance on what worked in the past will not deliver future success. There is awareness among the captains of the industry regarding what areas of their businesses need to be bolstered and that increased customer centricity forms part of this. Based on the overall research findings, there is much to be optimistic about in relation to Ireland's path towards being more customer centric and a willingness to achieve this goal. In answer to the research question, yes, customer centricity is well understood by the med tech sector in Ireland, but there is room for improvement in how it is practised.

6.1.2 Research Observations

The research was carried out among a representative sample of ten med tech companies operating out of Ireland. These included five foreign direct investment (FDI) companies and five indigenous companies. Although the research was not set up to identify differences in their approaches to customer centricity, differences are apparent. The FDI companies have access to, and strong reliance on KOLs. They are able to leverage such relationships better than indigenous companies. This is advantageous with respect to getting publications released and in terms of sequestering input from this group at the outset of NPD. The FDI companies are able to cater for large numbers of clinicians visiting their facilities and maximise this exposure through enabling direct contact with design engineers.

In terms of open innovation, the indigenous companies are more receptive to such initiatives than the FDI organisations. The risk exposure for FDIs in terms of intellectual property is determined as the main reason for this. FDI organisations tend to acquire companies of interest rather than collaborate with them. In general, FDI companies tend to have a more conservative approach to customer centricity than their indigenous counterparts. The research does not give any indication on whether this is based on the manufacturing legacy of the FDIs that were interviewed or on the general nature of doing business within a FDI organisation.

Of the ten companies included in the research, a further split can be made between finished goods manufacturers, sub-supply companies and start-ups. Six companies are

involved in finished goods supply, three in sub-supply and one start-up. The sub-supply companies tend to target their customer centric activities towards their direct customer base, that is, other med tech companies with only one reference extended to end-users. The mandate of a sub-supply company is to develop products to their customers' specifications. Because of the vested interest of both parties in the development activities, it is normal that customers are engaged right throughout the NPD process. The finished goods research companies have to be more creative in how they maintain strong links, and their efforts include human factors, prototype evaluation and in one case, customer involvement in the generation of marketing materials.

The research is not comparative in terms of how each of the research companies understand and practice customer centricity, however, the start-up company interviewed demonstrates a significant appreciation of the positive impact of customer centric innovation. Start-up companies, by their very nature have to be very agile in their business activities because the stakes are very high. They simply cannot afford the time or the money to make many mistakes. This is reflective of the start-up company included in the research whose approach to customer centric innovation comes closer to the "jobs" or "outcome" based approach (Ulwick, (2003), Kavanagh et al.; (2010)) for needs identification than was evident among any of the other companies.

6.2 Recommendations

6.2.1 Best Practice as Demonstrated in the US hubs

The research findings infer that customer centric practices are perceived as more advanced in the USA, with specific reference to Minnesota, than they are in Ireland. Indeed part of the research methodology undertaken in the Future Skills Needs of the Irish Medical Devices Sector (Expert Group on Future Skills Needs, 2008) included study visits to Minnesota, Massachusetts and Northern California. The findings from these study visits, while informative, particularly in relation to the symbiosis between industry, academia, clinical and industry representation bodies, are not specific in terms of best practice in any given area and no parallels or divergence were referenced in relation to how the Irish industry compares.

Further research would be beneficial to compare customer centric practices as undertaken by the med tech industry in the established hubs in the USA to similar practices as undertaken by the industry in Ireland. The research should clearly identify the gaps and recommend what is needed to supplement efforts in Ireland. It is only through thoroughly understanding the gaps and shortfalls that appropriate solutions can be proposed.

6.2.2 Clinical Linkages

Further research is recommended in relation to best practice for clinical – industry interaction. Incorporating the overall theme of this current research whereby the med tech industry assumes the role of the customer; the clinical needs of the industry ought to be identified whereby the results would form the basis for the industry to lobby government to ensure improvements are introduced. There are mutually beneficial outcomes to be reaped if clinical linkages can be strengthened.

6.2.3 Leadership and Training

Both the practical and academic research demonstrates that with respect to customer centricity, no one-size-fits-all formula exists to improve performance in this area. That said, there is ample scope to increase understanding in the form of training and awareness programs. Such training and awareness opportunities could be added on as workshops to the agenda of any of the industry gathering events such as the IMDA's Annual Med Tech CEO Conference, Enterprise Ireland's Med-In-Ireland expo, IBEC's CEO conference. Speakers such as Anthony Ulwick (referenced throughout this research) of the growth strategy and innovation consultants Strategyn, or Michael Kavanagh, SVP Marketing at Cochlear and a strong proponent of customer needs identification would be appropriate for such events.

The commitment to customer centricity exists in the Irish med tech industry. Increased awareness, additional efforts and some fundamental changes in terms of clinical interaction are all that are needed to mobilise the industry to go from being good at customer centricity innovation practices to being great.

6.2.4 Outcome of Customer Centric Innovation

This body of research is primarily focused on the determining the general understanding of customer centricity in medical device innovation that exists in the Irish med tech industry and to identify current practices. The research findings demonstrate a good understanding of customer centricity in NPD but there is room for improvement in formalising practices. This is also supported by the expert practitioner, Michael Kavanagh, whose opinion was sought on the research findings. Additional research is recommended to determine the impact of existing practices on commercial product performance, possibly employing a case study methodology and also, to determine the outcomes of implementing a more formal structure such as the Outcome-Driven Innovation process as practised and recommended by Kavanagh.

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8 Appendices

8.1 Appendix A: The One to One Gap Tool

Taken from "Is Your Company Ready for One-to-One Marketing"

Don Peppers, Martha Rogers, and Bob Dorf

Harvard Business Review, Jan-Feb 1999

"This exercise, to be administered to employees at various levels and in various functions, is designed to capture a robust analysis of how your company sees itself both culturally and organisationally. It should also be given to a representative group of customers, with the language tailored appropriately, in order to expose the gap between internal and external perception.

For each question listed below, select the statement that most closely reflects your opinion of the company as you view it today – not as you think it should be or it might be in the future."

PROCESSES

1. Has the organisation established quality assurance processes?

   A. We do not consider quality management practices
   B. We would like to have formal quality management initiatives
   C. We have some methods in place to ensure quality management initiatives
   D. We have a formal quality management organisation

2. Are the organisation's business processes customer-centric?

   A. We do not pay any attention how our customers and our business processes interact
   B. We have some understanding of the link between customers and our business processes
   C. We understand most of the interactions between customers and our business processes
   D. We have a full understanding of all the possible interactions between customers and our business processes

TECHNOLOGY

3. Does the company take customers' needs into consideration when selecting and implementing technology?

A. Our IT department is rather autonomous and in charge of technology acquisition
B. We ensure that our customers' needs, not just our own internal needs, are considered when selecting technology
C. We use some degree of customer validation when selecting technology
D. We ensure that all technology selections are customer-centric. For example, we research how to improve customer convenience.

4. Does the company provide its employees with technology that enables them to help customers?

A. We are not particularly advanced when it comes to technology
B. We encourage the use of technology that helps our daily interactions with customers
C. We provide technology in many areas to improve our daily interactions with customers.
D. We provide the most effective technology available to all employees who interact with customers

KNOWLEDGE STRATEGY

5. Does the company maintain a strategy for collecting and using information about customers?

A. We handle information about customers poorly.
B. We encourage the collection and use of information to gain knowledge about customers
C. We have programs to collect information and use our knowledge about select customers.
D. We continuously enhance our strategy to collect and use our knowledge about our customers

6. How effectively does the company combine information on customers with its experiences to generate knowledge about its customers?

A. We have poorly developed and inadequate processes for combining our data on customers with our own experiences and views.
B. We encourage using processes and systems that support the collection of both customer information and experiences about some customers
C. We have implemented systems and processes that collect and combine information and experiences about selected customers
D. We have rigorous processes to combine information and experiences about each customer.

PARTNERSHIPS

7. How does the company select its partners?

A. We pay little or no attention to whether the partners we select are customer centric.
B. We try to select partners that are customer-centric.
C. We evaluate strategic partners based on their customer centricity.
D. We evaluate all potential partners based on their customer centricity.

8. Does the company understand the relationship amongst its customers and partners?

A. We have little or no understanding of the relationships among our customers and our partners
B. We try to understand the relationships among our customers and our partners
C. We understand the relationships among our customers and our partners
D. We understand and use the relationships among our customers and our partners.

CUSTOMER RELATIONSHIPS

9. How effectively does the company differentiate its customers?

A. We do not differentiate among customers
B. We try to differentiate among customers

C. We collect and use information gleaned from interactions with customers to differentiate each customer and evaluate the importance of each relationship.
D. We have a continuously updated customer knowledge database that provides all the critical business information about our relationships with individual customers.

10. What steps has the company taken to improve the total experience of its customers?

A. We pay little or no attention to the total experience of customers.
B. We know all the points where customers are in contact with the business, and we manage these areas effectively
C. We conduct frequent surveys with selected customers and make improvements based on their feedback.
D. We have a continual dialogue with each customer and use well developed methods to improve our relationships.

11. How effectively does the company measure and react to customers' expectations?

A. We make no efforts to understand our customers' expectations.
B. We have some idea of our customers' expectations and use them in building relationships.
C. We periodically solicit customers' input about expectations and take actions to improve the relations where possible.
D. We work as a team with our customers to ensure that their expectations are met or exceeded.

12. How effectively does the company understand and anticipate customers' behavior?

A. We pay little or no attention to the behavior of our customers.
B. We understand the trends and buying patterns of our customers and consider them when making crucial decisions
C. We collect data on our customers' preferences and other behaviors and use that information in our business planning.
D. We maintain a profile of each customer and refer to it when dealing with customers.

EMPLOYEE MANAGEMENT

13. To what degree are employees empowered to make decisions in favour of the customer?

A. We encourage employees to strictly follow procedures and policies developed by top managers.
B. We encourage employees to make independent decisions within the guidelines set by management.
C. We strongly encourage employees to make decisions that positively affect our customers' satisfaction.
D. We require every employee to take whatever action is appropriate to ensure the ultimate satisfaction of the customer.

14. Has the company formally linked employee's rewards with customer centric behavior?

A. We make no link between employees' rewards and their treatment of customers.
B. We use ad hoc methods to reward customer centric behavior.
C. We make customer- centric behavior a part of performance appraisal criteria.
D. We make customer-centric behavior a significant part of performance appraisal criteria.

CUSTOMER & COMPETITIVE STRATEGY

15. To what extent does the company understand how customers affect the organization?

A. We attach little significance to the views and opinions of customers.
B. We place some importance on understanding the impact of our customers on the business
C. We place importance on understanding how a select group of customers affects our business
D. We place vital importance on understanding how each customer affects our business

16. How much influence do customers' needs have on the company's products and services?

A. We pay little or no attention to the needs of our customers when we design our products and services
B. We attempt to develop our products and services that meet our customers' needs
C. We use input from selected groups to assist with the development of products and services.
D. We design products and services to meet the needs of individual customers.

17. How effectively does the company build individualised marketing programs?

A. We build all marketing programs to reach a mass market.
B. We build all marketing programs to fit a perceived niche market.
C. We build some marketing programs that are specific to each customer's needs.
D. We build all marketing programs to be specific to each customer's needs.

18. How aware is the company of other organisations' approaches to building customer relationships?

A. We pay no attention to the customer- centric strategies of other companies
B. We know which companies are customer-centric regardless of the industry.
C. We know how our competition approaches customer centricity.
D. We know the best-in-class approaches to customer centricity.

8.2 Appendix B: Kotter's Eight Phases for Implementing Change

Leading Change: Why Transformation Efforts Fail

John Kotter, Harvard Business Review, March-April 1995

Kotter identifies eight phases that a successful change process must go through. These include:

1. **Establish a sense of urgency.** "Without motivation, people won't help and the effort goes nowhere….Executives underestimate how hard it can be to drive people out of their comfort zones" Kotter suggests that the urgency level is high enough when 75% of the leadership is honestly convinced that business as usual is no longer an acceptable plan.
2. **Form a powerful guiding coalition.** Change efforts often start with just one or two people and should grow continually to include more and more. The need in this phase is to gather a large enough initial core of believers. This initial group should be pretty powerful in terms of the roles they hold in the organisation, the reputations they have, the skills they brings and the relationships they have.
3. **Create a vision.** Successful transformation rests on a picture of the future that is relatively easy to communicate and appeals to customers, stockholders and employees. A vision helps spark motivation and keeps projects and changes aligned.
4. **Communicate the vision.** Kotter suggests the leadership should estimate how much communication of the vision is needed, and then multiply that effort by a factor of ten.
5. **Empower other to act on the vision.** This entails several actions. Allowing organisation members to make changes in their areas, allocating budget money to the new initiative, carving out time at meeting agendas to talk about the vision. In short, removing any obstacles that get in the way of implementing the change.
6. **Plan for and create short-term wins**. As real transformation takes time, the loss of momentum and the onset of disappointment are real factors. Most people will give up on change unless they begin to see compelling evidence

that their efforts are bearing fruit, therefore leaders need to plan and achieve short term gains which people will be able to see and celebrate.

7. **Consolidate improvements and sustain the momentum for change**. As Kotter warns, "Do not declare victory too soon". A premature declaration of victory kills momentum and until change becomes embedded in the culture of an organisation, new approaches are fragile and subject to regression.
8. **Institutionalise the new approaches**. Change sticks when it becomes "the way we do things around here". To achieve this, people have to be able to make the connections between the effort required to make the change and the desired outcome. Another key aspect is to ensure that the next generation of the organisations leaders believe in and embody the new ways.

8.3 Appendix C: Interview Request

The following is a sample copy of the content of the e-mails that were sent to confirm the research interviews and to provide the interviewee with a copy of the questions and a copy of the Code of Ethics that governs the research:

Dear XXXX,

Following on from my phone call just now, first of all, thank you very much for arranging this meeting and thank you to XXXX for being so kind as to accept it.

The meeting will comprise of an interview which is directly related to research I am doing for a thesis for my MSc in Marketing, entitled "The Role of Customer Centricity in Medical Device Innovation – an Irish perspective". I have attached a copy of the questions I will be asking during the interview and a copy of the ethics that I am using to guide the research process.

My objective is to get XXXXX's understanding and perspective on customer centricity in innovation practices. I will use his inputs along with that from the other people I am meeting to determine how the Irish med tech industry involves customers in innovation and to identify best practices.

The meeting will last no longer than one hour. I just need to confirm that it will be alright to record the interview for follow-on analysis. All XXXX's inputs will be presented anonymously in my findings.

If there are any questions, or if for any reason XXXX cannot proceed with the meeting, please feel free to contact me by e-mail at this address or on my mobile at 086 832 0898.

Kind regards

Gail Molloy

Marketing Manager

Aerogen Ltd

8.4 Appendix D: Code of Ethics Used in the Research Interviews

Code of Ethics Governing Research into "The Role of Customer Centricity in Medical Device Innovation – An Irish Perspective"

For the intention of conducting ethical research, the European Society for Opinion and Marketing Research (ESOMAR) guidelines of researcher responsibilities for market and social research are used in the conduct of this survey. These guidelines are summarised as follows:

- Market research shall be legal, honest, truthful and objective and be carried out in accordance with appropriate scientific principles.
- Respondent's cooperation in this research project is entirely voluntary at all stages. They will not be misled when being asked for their cooperation and they are appropriately informed of the survey's intentions.
- Unless otherwise agreed, the Respondent's anonymity will be strictly preserved.
- The researcher will not use information to identify respondents without the permission of the respondent.
- Market research shall not abuse the trust of respondents
- The researcher will take all reasonable precautions to ensure that respondents are in no way adversely affected as a result of their participation in this study.
- Respondents must be told if recording equipment is being used. If the respondent so wishes, the record or relevant section of it must be deleted or destroyed.
- Respondents are entitled to withdraw from the interview at any stage, or refuse to answer any question.
- Respondents shall be able to check the identity and bona fides of the researcher without difficulty.
- Researchers shall ensure that market research projects are designed, carried out, reported and documented accurately, transparently and objectively.

- Researchers shall ensure that adequate security measures are employed in order to prevent unauthorised access, manipulation to or disclosure of the research data.

8.5 Appendix E: Original Questionnaire – pre-Review

MSc in Marketing Research Survey

The Role of Customer Centricity in Medical Device Innovation
An Irish Perspective

Research Purpose: This research forms the basis of a Masters thesis investigating customer centricity in the innovation processes of Irish medical device companies in both the multinational and indigenous segments. The findings will be used to make observations on the level of customer centricity in innovation processes and to identify best practices. The information gathered from this questionnaire will be represented anonymously in the research findings, and will be referred to in terms of Company A or Company B etc. All information requested is opinion based. Confidential, proprietary information does not form part of the research agenda. This research is guided by a Code of Ethics, see accompanying document.

Section One: Customers

1. Who are your customers?
2. From your point of view, what does the term "customer centricity" mean?
3. According to Kavanagh et al (2010), the first task in medical device innovation is to develop a detailed understanding of the unmet needs of customers and then focus internal development efforts on a prioritised list of the most important needs identified. How do you determine what your customers need from you?
4. How do you ensure you deliver customer value?

Section Two: Innovation

5. What do you see as the pros and cons of user involvement in the R&D process?
6. How does your company ensure user involvement throughout the R&D process?
7. Open innovation, or the "not invented here" ideology offers medical device companies the possibility to engage external scientists, engineers, clinicians and indeed patients in new product development (Davey, Brennan, Meenan, &

McAdam, 2010). Where does open innovation fit into your product development strategies?

Section Three: Organisation

8. How is the culture of customer centricity in the innovation process developed in your company?

Section Four: General

9. On a scale of 1 to 10, how customer centric do you think innovation processes are in the Irish med tech industry and why?
10. Kavanagh et al (2010) talk about fulfilling a customer need being more important than providing a solution. What is your opinion on this statement?

Thank you very much for your participation in this research.

Davey, S. M., Brennan, M., Meenan, B. J., & McAdam, R. (2010). The Health of Innovation: Why Open Business Models Can Benefit the Healthcare Sector. *Irish Journal of Management*, pp. 21-40.

Kavanagh, M., Walther, B., & Nicolai, J. (2010). Hearing the hearing impaired customer: Applying a job-based approach to customer insight discovery in product innovation in the implantable hearing solutions market. *Journal of Medical Marketing,* pp. 1-9.

8.6 Appendix F: Research Survey Questionnaire - Final

MSc in Marketing Research Survey

The role of Customer Centricity in Medical Device Innovation – An Irish Perspective

Research Purpose: This research forms the basis of a Master's thesis investigating customer centricity in the innovation processes of Irish medical device companies in both the multinational and indigenous segments. The findings will be used to make observations on the level of customer centricity in product development processes and to identify best practices. The information gathered from this questionnaire will be represented anonymously in the research findings, and will be referred to in terms of Company A or Company B etc. All information requested is opinion based. Confidential, proprietary information does not form part of the research agenda. This research is guided by an accompanying Code of Ethics.

Estimated time required: 1 hour

Section One:

1. From your point of view, what does the term "customer centricity" mean?

2. Who are your customers?

3. According to Kavanagh *et al.* (2010), the first task in medical device innovation is to develop a detailed understanding of the unmet needs of customers and then focus internal development efforts on a prioritised list of the most important needs identified. How do you determine what your customers need from you?

4. What do you see as the pros and cons of user-involvement in the new product development process?

5. How does your company ensure user-involvement throughout the new product development process?

Section Two:

Please rank the following statements. Your response to these statements will form the basis of questions during the interview.

6. Open innovation, or the "not invented here" ideology offers medical device companies the possibility to engage external scientists, engineers, clinicians and indeed patients in new product development , Davey *et al.* (2010).
   Open innovation is an integral source of new product inspiration for my company.

Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐ Very Strongly Agree ☐

7. We work hard to ensure that we deliver value in terms of the customers' needs.

Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐ Very Strongly Agree ☐

8. Customer centricity is a priority for my company; we have processes in place to develop a culture supportive of this.

Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐ Very Strongly Agree ☐

9. Please rank how customer centric you think innovation processes are in the Irish med tech industry. 1 = not customer centric, 10 = very customer centric.

1 2 3 4 5 6 7 8 9 10

10. According to Kavanagh et al. (2010), fulfilling a customer need is more important than providing a solution.

Disagree	Neutral	Agree	Strongly Agree	Very Strongly Agree
☐	☐	☐	☐	☐

Thank you very much for your participation in this research

Davey, S. M., Brennan, M., Meenan, B. J., & McAdam, R. (2010). The Health of Innovation: Why Open Business Models Can Benefit the Healthcare Sector. *Irish Journal of Management*, pp. 21-40.

Kavanagh, M., Walther, B., & Nicolai, J. (2010). Hearing the hearing impaired customer: Applying a job-based approach to customer insight discovery in product innovation in the implantable hearing solutions market. *Journal of Medical Marketing,* pp. 1-9.

8.7 Appendix G: Interview Schedule

Interviewee	Company	Position	Date of Interview	Location	Indigenous or FDI company
Michael O'Reilly	Medisize	Managing Director	09/Jun/2011	Medisize, Letterkenny	FDI
Seamus Kavanagh	Hollister	VP Global R&D	22/Jun/2011	By phone	FDI
John O'Dea	Crospon	Managing Director	27/Jun/2011	Crospon, Galway	Indigenous
Helen Ryan	Creganna	CEO	30/Jun/2011	Creganna, Galway	Indigenous
Frank Keane	Vitalograph	General Manager	07/Jul/2011	Vitalograph, Ennis	Indigenous
Eamon Brady	Neuravi	CEO	11/Jul/2011	Clayton Hotel, Galway	Indigenous
Ger O'Carroll	Arrotek	Managing Director	21/Jul/2011	Sligo	Indigenous
Colin Henehan	Abbott	Site Director	21/Jul/2011	Abbott, Sligo	FDI
Paraic Curtis	Boston Scientific	VP Endoscopy	22/Jul/2011	Boston Scientific, Galway	FDI
Tom Fitzmaurice	Medtronic	VP Operations	04/Aug/2011	Medtronic, Galway	FDI

8.8 Appendix H: Research Excerpts

Section One

1. **From your point of view, what does the term "customer centricity" mean?**
    - Designing products that meet day-to-day clinical needs – can't start to design a product without being able to answer what problem it addresses.
    - Key driver: reimbursement, regulatory approval. If keeping the insurance companies happy, therefore keeping the hospital administrators happy.
    - "We all think we are customer driven but in many cases we tend to be technology driven".
    - Every aspect of the business is aligned with the needs of the customer - things you do today are going to affect what happens tomorrow.
    - Corporate business units are structured based on customers – Easier in a start-up situation because most likely the company is just focused on a few customers and does not have to worry about other business activities such as downstream marketing, sales force etc.
    - Not familiar with the term.
    - Establish what customers need and focus in on this – business has expanded based on meeting customer needs.
    - Providing products or services to the benefit of customers.
    - Focused around customer service.
    - Not familiar with terminology.
    - Talking to doctors about what the product needs to be.

- Not a term that is used in this company.

- Philosophy in the company that they are not going to develop something unless there is an unmet need.

- Customer centricity if strongly influenced in terms of user-versus end user- involvement and results in different considerations for both.

- Not a term have heard of before, tend to use "customer service" instead but not in relation to front end order taking, rather it encompasses everything they do for the customer.

- Being flexible and innovative with regards how we serve the customer – a value of the company.

- The company's growth is dependent on customer centricity.

- As a sub-supply company, we cannot create demand – our customers have to decide they want to buy from us, hence the importance of customer centricity.

- Not a familiar term.

- No formal customer centric processes, but understanding of the term would be that the customer is at the centre of every decision we make. Frequently use a check-point that is "What would the customer think of this".

- Find a solution to the customer's problem, adding value.

- Developing products that customers want and need.

- Giving customers something that solves a problem.

2. Who are your customers?

- Surgeons and gastroenterologists (no patient interaction with company's products).

- Narrowly defined: Doctors. Broadly defined: All players in the therapeutic area infrastructure including specialist doctors, supporting medical practitioners, radiology staff, nurses, hospital purchasing departments, Group Purchasing Organisations (GPOs), payers, and regulators.

- Early stage start-up companies.

- User-innovators (doctors with innovative idea on a clinical problem).

- Patient, physician and payers.

- This has changed, 3 years ago, would have said physicians but now the hospital c-suite are included too. Need an economical model in order to get acceptance among hospital C-suite.

- Internal customers and external customers. Internal customers for NPD include the global marketing organisation that represents the voice of the customer, and the global engineering group. The external customers are broken out into the end user, the user or clinician, the distributor and the payer. Influence of the payer and the distributor is growing because of the growing concern of the cost of healthcare.

- Customers are people who have names, people whom we make commitments to.

- Customer is a known entity.

- Other companies in the medical device industry who we supply to, entities initially who become individuals within these organisations.

- Internal customers, commercial customers, users – "Anyone who contributes in any way to the business".

- Sick people, clinicians, nurses, homecare givers.

- Clinicians looking after sick people. "Patient is prescribed the product therefore the patient is not the customer"

- Companies running clinical trials.

3. **According to Kavanagh *et al.* (2010), the first task in medical device innovation is to develop a detailed understanding of the unmet needs of customers and then focus internal development efforts on a prioritised list of the most important needs identified. How do you determine what your customers need from you?**
   - Cannot go to a doctor and ask "what are your unmet needs".

   - Observation of a procedure can unearth customer needs – "When you hear a swear word, then there is an unmet need".

   - If a multinational does a bad job of understanding customer needs and translating them into innovative products, they can bundle the product into a broad portfolio and sell on the basis of pure marketing muscle. Small companies cannot do this therefore the product has to be innovative and best in class.

   - Have to get up-stream marketing correct or you're "goosed".

   - First of all have to involve specialist doctors with respect to determining the core design needs but design influencing factors must include all the other doctors who would routinely use the product.

- Primary focus is on clinical need at early stage of the NPD process.

- "Determining customer needs is extremely difficult; it is an evolving picture that gets progressively more comprehensive."

- If needs are articulated properly, most reasonably good engineers can design the solution product.

- Many steps in the process of unearthing customers' needs, pennies drop all the time.

- User testing of prototypes.

- Go through the steps of a procedure – ask the clinician what makes them uncomfortable. Level of clinician discomfort usually identifies an unmet need.

- Comfort versus discomfort can be influenced by the level of experience the doctor has. KOLs tend to have higher thresholds of comfort with new devices and procedures that more regular users do. Hence, one of the watch-outs in discovering unmet needs is beware of the KOLs.

- You can't just ask a doctor "what are your needs" – and there is a danger of leading the discussion down a particular path because you may get agreement that a particular concept is useful, but on reflection 6 months later, they might have a completely different view on the situation.

- Need to be sure you are identifying core needs with no ambiguity no matter what physician you talk to.

- Make products simple enough for all doctors to use the product confidently.

- Very hard to uncover an unknown, unmet need. It takes a significant amount of upfront strategic marketing effort.

- Understanding the user's needs is harder than meeting them.

- User-innovators come in with a concept – part of the process is to refine the concept into something that both meets the clinical need and that can be readily manufactured.

- Start with the problem – try to fully understand what the user-innovator is trying to achieve. Observe the problem in a clinical setting; physically see what the problem is. Try to understand as much as possible about where the customer is coming from. How did they come across the problem and what are the deficiencies they have seen in current methods. Identify the gap.

- Fully understanding customers needs and acquiring as much as possible additional information is key to the success of the business. Additional information can refine a concept further and enables the provision of options in coming up with the best design solution for the customer.

- Field based conversations with engineers – clinicians like to talk to engineers, more so then sales people.

- Marketing people on core teams.

- Discussions held with clinicians both in-house and in the hospital setting.

- Use of prototypes.

- Surveys of physicians.

- Physician Advisory Councils. Have one for the US and one for international advice. Consist of 15 key opinion leaders and they meet up 4-5 times per year to review the company's overall development portfolio and strategy.

- Need to have the right mix of people involved in needs gathering process including KOLs and ordinary users.

- Customers do not always know what they need.

- Identify challenges clinicians have in treating certain patient groups, determine what they cannot treat these patients and what kind of intervention they would ideally like to do.

- Scanning disease states that are not being dealt with using minimally invasive procedures.

- Working with clinicians on product iterations.

- Up-stream marketing activities.

- Scanning journals for un-served opportunities.

- Asking clinicians about their challenges, what clinical gaps exist? Doctors who are closet engineers will have very specific ideas. Doctors who have a therapeutic focus will be more needs oriented.

- Opportunities are profiled using standard tools and prioritised based on business opportunity with thresholds and cut-off criteria on commercial size requirements in place.

- Often get clinicians into the test lab with the technicians to do bench testing and to give input on the look and feel of a device.

- Easier to identify needs in therapeutic areas already served – these are opportunities rather than unmet needs. In un-served markets there may not be any physicians with relevant experience, however, opportunities could be massive.

- In the case of a product where a clinical trial is not needed, the use of Physician Preference Evaluations (PPEs) whereby product that is about to be commercialised is evaluated by the physician. This can lead to additional changes required before the product is launched.

- Sometimes the customer doesn't realise the need.

- Through observing customer behaviour, interaction with customers, focus groups and other such tools.

- Developing a product to meet a need may result in developing a technology to enable the product.

- If you talk to a clinician, normally get feedback on problems with current products and if this is the primary source of user input, it will result in predominantly incremental change. If you really want to understand how products are used then you have to talk to end users, this can enable innovation into new areas. It is necessary to determine the needs of both the users and the end users.

- Need to involve a wide mix of clinicians in the needs assessment stage. While KOLs are very influential, a company needs to strike a balance and include regular users and also, users of competitor products.

- Technical staff interacts directly with end users to identify unmet needs.

- Do a lot of market scanning to understand customer space for 2 reasons

  - To be knowledgeable when talking to customers
  - To see if we can identify a new opportunity for the customer

- Work to User Requirements Document (broad specification) and provide options

- Always feel there is something intangible in the URD that can only be realised in prototypes, therefore prototype 2-3 different options for the customer.

- In the case of sub-supply, the customer need may not always be product related, it may be price related. Lots of companies have the emerging markets on their radar for business growth and expansion. The primary requirements for emerging markets are functionally safe products. Understanding the customers' business objectives enabled the us to offer a more standardised product which we could in turn offer to other customers in a similar format rather than a regular offering of customised product. This enables us to pull out a lot of costs primarily associated with the overheads included in customised product.. This whole process involved compromises and trade-offs in order to meet and satisfy the customer's needs.

- Meet with business unit leaders to understand the customer's business objectives and what their challenges are.

- Assign a project team to work through the User Requirement Document. A commercial manager and a technical manager are appointed to each project. They have overall responsibility to understand customers objectives – what is the customer looking for. These managers interact with counterparts on customer's side.

- Quarterly business reviews. This goes right up to the C-suite for the top 5 customers.

- Responsive to problems that on occasion are identified opportunistically in the field through observations and/or direct user feedback.

- Observation – send engineers into customer's factories to observe how the products we work on are used. "Live with customer". This exercise on one occasion resulted in a product modification that increased the customer's yields. This in turn reduced the amount of product we supplied but built up enormous goodwill that can be leveraged for future business or in blocking competition.

- For some devices, particularly home care devices that an end-user has to use, the customer may want devices that are more appealing, be a different colour etc. This "want" is not necessarily a medical "need". Medical device companies do not tailor products to meet customer's desires as well as needs. While needs are more important, consumer oriented products should look nice and appealing and this is often overlooked by med device companies. Such features help drive compliance. Aesthetics may seem trivial when a product is being market tested by clinicians where they may not feel it appropriate to comment that the colour isn't nice or that the plastics feel cheap.

- Strategic marketing is not undertaken in Ireland and as such, some market needs are gathered through a semi-structured process by support people who work directly with doctors, nurses and patients.

- Sometimes small change requests can result in significant costs not understood by the requestor. Changes may even require a regulatory filing and will most certainly result in stock-keeping unit (SKU) proliferation. SKU proliferation results in increased costs and all of the above have a negative impact on the patient in terms of higher costs of product.

- Establishment of Marketing Core Teams (MCTs). There is a MCT on every product range. Meet twice a year and review new and existing pipeline. MCT consists of engineers, quality personnel, sales and marketing personnel.

- High degree of customer centricity at the beginning of a NPD can save a company a lot of money.

- Company has developed a very strong concept stage up front that is based on the "customer experience". A considerable amount of prototyping and checking of prototypes, product iteration after product iteration is done at this stage to make sure concept meets needs. MCT are primary influencers in this process and they in turn involve KOLs, normally about 6 KOLs are used for this exercise. It is better and cheaper to make changes before products enter into a formal regulatory controlled NPD process or indeed to kill off products at this stage.

4. **What do you see as the pros and cons of user-involvement in the new product development process?**

   PROS:

   - Supportive clinician – clinician becomes evangelist.

   - Addressing the needs of practising clinicians can be the basis of good market positioning.

   - User-involvement, particularly with KOLs, drives up the rate of clinical studies and published peer-reviewed papers

   - Clinical involvement is an imperative because engineers and marketers lack the clinical experience.

   - Subtle needs often emerge in discussion with clinicians.

- Clinician is the source of best information.

- Full exposure to the clinical need, the clinicians' expectations of what a product can do and their key drivers.

- Cannot develop medical devices without clinician input. Engineers can come up with ideas that are beyond what the user is anticipating but need the clinician to direct and help develop the product.

- Cannot develop medical devices without user input.

- End users: allows Company to find out about end-users individual experiences – have to be very skilled at this part of research so as not to come away with solutions rather than fully understand the problem.

- Users: One clinician can offer the consolidated view of several hundred end-users, therefore this is a very efficient way of learning about customer needs.

- Get aligned with customers' needs.

- Meet customers' expectations.

- Real-time customer involvement in sub-supply means the customer knows what is happening which can save a lot of time and money.

- Real aid to product innovation and design by giving input from the end users point of view.

- User-involvement means customers have a realistic and more objective view on pricing, service and quality deliverables.

- Excellent for networking and bonding with the customer. Such rapport can be very beneficial if the project runs into difficulties as there is more trust between the parties.

- Pros outweigh cons.

- Need enough structure on the NPD process before engaging customers.

- For med tech developers, the more time spent with a clinician equals a better product.

- Giving customers what they want.

CONS:

- Lot of doctors not concerned about cost – expect change for nothing.

- May end up designing a product for a cohort of KOLS – not a broad enough audience. Need more than one doctor involved in design process.

- KOLs don't have the same points of discomfort that ordinary doctors have.

- Doctors don't speak engineering language, therefore risk if misinterpretation with respect to design inputs.

- Emotional involvement of a user-innovator can be problematic. They think about the product 24/7.

- User-innovators tend to change their minds regularly throughout the innovation process. Can be hard to manage. Need to put Project Management disciplines in place. Normally done through use of technical lead. User-innovators changing their minds can be a challenge to efficient

process. Use Stage Gate system and get the User Innovator to sign off at every single stage.

- With user-innovators, prototypes do not always enable a project to move to the next stage – some user-innovators see the prototype as another opportunity to make additional changes. They even forget what they have already signed off on.

- If use user-input only, this can result in incremental developments only.

- Managing expectations – have to look at an averaging of inputs rather than striving to meet individual requirements and a company usually can't meet everyone's expectations.

- Managing expectations – worst thing you can do is to engage a doctor, get them excited and then not follow through.

- End User: It takes a significant lot of time and effort to access needs information from end-users. It can also result in a lot of "hit and miss" insights and it is a lot of hard work.

- Users: Tend to focus on their own specific problems, if this influences product development, a company can end up with very niche products with low commercial potential.

- The use of focus groups to garner customer input can be difficult if there is one or two opinionated people involved who can lead the focus group in a particular direction.

- The customer already has a preconceived idea of the solution which means they are usually less open to alternatives. This happens a lot when dealing with engineers.

- Unrealistic expectations.

- Customer tries to take total ownership of the process. Need to be resilient and assertive enough yet diplomatic enough to steer the customer away from getting too involved.

- Customer can unwittingly add cost – particularly if it involves engineers.

- Sub-supply con – if customer fails to meet their own commitment deadline – they become the bottleneck.

- Risk of leak of competitor sensitive information – even if NDAs are in place.

- Need to involve innovative users into NPD otherwise people can be fairly single-minded in what they want from a product.

- Easy trap to fall into to try to keep everyone happy.

- Very hard for customers to conceive of something different.

- Could end up disenfranchising people that a company later wants to involve in the Human Factors stage.

- If a company was to try to keep everyone happy, could end up with an unprofitable product.

- Feel obliged to respond if a KOL makes a request.

5. **How does your company ensure user-involvement throughout the new product development process?**

- Keep circling back to the doctors during the NPD process to make sure the evolving product is meeting the clinical need – validate, validate, validate.
- Use of core scientific advisory group.
- Engagement with a global physician base.
- Keep up-to-date with KOLs at seminars etc.
- Design, build and test prototypes to drive meaningful discussions. Provides something to show and talk about, generates credibility. Also, there is a lot to be learned from what doesn't work.
- Need to have credibility among users, this comes from knowing all there is to know about area of application. Learning and reading clinical research to be able to have meaningful conversation.
- Checks and validations right throughout the NPD process.
- First meeting is crucial – need to develop understanding of the customer, the problem and the whole environment.
- Sign-offs throughout the process.
- Keep the focus on the commercialisation of the product, cost implications of change, manufacturing implications of change.
- Use of NPD process which also includes Stage Gate – get feedback from customers throughout the NPD process.

- Bring about 400 clinicians into the Irish facility every year on site visits, and while on-site, these doctors regularly interact with the design teams to provide input.

- Get feedback right throughout the NPD process.

- If a company makes the mistake of disengaging a physician once the device is designed, therefore it is going to face the issue of getting the device used – need physician community behind you.

- Getting clinical feedback on prototypes.

- Active involvement of the customer throughout the entire NPD process.

- Prototype ideas and get inputs from customers, make any required adjustments and then go back to customer again.

- Stage Gate process. At the various stage reviews, the gatekeepers will ask to ensure if users and/or end users have assessed the product. This is inherent in the process.

- A new activity is to conduct post clinical trial studies with a sample of participants and interview them based on their experience with the new product. This has proven to be very enlightening and is carried out after the clinical trial report is written so as not to bias the report.

- Cross functional teams in place until product shifts to manufacturing.

- Customer is required to be involved in the review stages.

- The use of prototypes throughout the process.

- For new customers – have them come-on site to meet the team and demonstrate processes – serves to build confidence.

- Drive the establishment of cross-functional teams between company and customer.

- Constant communication with customer – weekly review meetings.

- Not done in Ireland but it involves a significant amount of Human Factors testing . HF is growing in importance.

- User Requirements Document and human factors.

- Product concepts can take a long time, however, a rushed product is the riskiest product.

- Through use of user trials (as opposed to clinical trials). These are conducted internally and externally. The internal trial is conducted by people outside of the NPD process and this practice often provides the obvious feedback.

- When using a design house, provision of information on whom the product will to be used by can entirely alter the look and design of a new product.

- Getting the product concept right up-front, understanding customer expectations can result in a very fast and efficient NPD process.

Section Two:

6. **Open innovation, or the "not invented here" ideology offers medical device companies the possibility to engage external scientists, engineers, clinicians and indeed patients in new product development , Davey *et al.* (2010).**
   Open innovation (OI) is an integral source of new product inspiration for my company.

   - SMEs better at doing development than research.
   - Company was built on innovation.
   - Financial and resource constraints associated with a start-up company makes it very proficient at leveraging external capability.
   - Driver for OI in start-ups is capital efficiency and any activity that aids this is used.
   - Prefer to use external experts - see it as crucial to providing products designed to meet the customers' needs.
   - Intellectual Property may negatively impact OI.
   - "We are not experts at everything".
   - Try to use internal people and resources as much as possible.
   - Intellectual Property an issue in OI.
   - Large companies tend to have scope to have a lot of strengths in different areas that can be enrolled in the NPD process.
   - Technology acquisition is routine practice to gain access to new innovations. Scouts on the lookout for compatible innovations and

technologies. Can't develop every technology in-house and not all internal development capability is geared towards new business areas.

- Purchasing technologies is part of the expansion strategy of any multinational where by "multiple small bets" are placed.

- OI is practised normally through technology acquisitions. Company has a full time group scanning small start-ups. Element of risk-minimisation involved in technology acquisition.

- OI is not a source of new ideas – have always had people submit new ideas, but that is not OI, its ideation. OI is a process that is used when the company needs solution to a problem that it doesn't have.

- OI is relatively new, a practice that is in use for the past 3-4 years because the innovations required now are bigger and more complex than in the past and if try to execute them internally, it will take too long and the risk of failure is much higher.

- OI is an integral source of innovation and technology, but there are no expectations that OI will result be the source of the next big product. OI is for problem solving.

- OI is used in cases where it makes sense to work with external experts if the technology is not available in-house. The company's value is in providing solutions. For this company, technology itself is not the key business driver, rather being a solution provider, an integrator of technology and platforms.

- If the customer need cannot be solved with one of the company's technologies, the engineers automatically look outside.

- OI is a cultural thing, need cultural buy-in and it can be very hard to change a culture.

- OI is particularly challenging for larger organisations .

- OI is about getting the balance right.

- Intellectual Property is a big barrier to OI. Legal side of OI is complicated and intellectual property could be seen as a business risk.

- OI needs to be supported and driven by the management, otherwise likely to get push-back.

7. **We work hard to ensure that we deliver value in terms of the customers' needs.**

- Would like to deliver more value, it is not a big enough part of the proposition right now. Defining and justifying value is a hard thing to do. Value and performance is not the same thing. Have a technology driven selling proposition at the moment.

- Value is hard to define, therefore justifying value is hard to do.

- Investigate how people value various aspects of the product. Might look at 30-40 aspects of a new product design and work through a negotiated elimination process that includes trade-offs. This process is not carried out in the Irish facility, and it is executed with a representative population of clinicians.

- Need to be able to develop global products that have a feature set that is valuable to the physician.

- Some clinicians do a lot of procedures, others do far less, therefore have to make sure products are robust to accommodate all skill sets.

- Clinical value can be easier to demonstrate than economic value. Have started bringing in payers to show them development and manufacturing processes. This can help create a different perspective on the product cost and can help neutralise pricing objections.

- Could not sell a product without demonstrating value.

- Value proposition is avoiding surgery.

- Simply not going to start down the NPD route unless it meets an existing market need.

- Have to deliver products that are aligned in terms of value with the customer's expectations. The company's view of value must be the same as the customer's view of value. If it isn't, whatever feature is causing the problem needs to come out. Understanding value in terms of the customer is very important as it creates value for the company. Providing services or features that are of no value to a customer is a waste of money, likewise, features and services that are added and have value are charged for. Balancing the product with the customer's value expectations means all sides are satisfied.

- Engaging with both the customer and with end-users to come up with product improvements.

- Providing value in terms of financials – example of redesigning a product to meet a price point need that in turn simplified the overall product offering and allowed the customer to go head-to-head with their competitor in a key market.

- Process of observation enabled company to make a product modification that increased the customers' yields and added significant value to the customer and resulted in an extremely satisfied customer.

- Safety – labelling etc.

- Working closer with the commercial team to better understand what is going on in the field with users.

- Finding a means of better meeting the customers' needs without proliferating stock keeping units (SKUs).

- Key Performance Indicator dashboards are used throughout the process to ensure that the project is on track to meet customer needs and deliver value.

8. **Customer centricity is a priority for my company, we have processes in place to develop a culture supportive of this.**

- No formal process in place – not big enough company but engineers attend surgery to get a better understanding of the application environment.

- All engineers involved in product design have close clinical interactions to develop an understanding of what is happening in clinical practice. Engineers attend surgery to gain understanding of application environment.

- Driven down through the company through the management team – management team focused on customer needs.

- Part of review process – challenges set out for the team must mirror customer needs.

- Processes include training on what the company is all about – an ingrained knowledge of the type of customers they work with and what the company is as a business.

- Staff updates.

- Inform employees about what the products they are working on are designed to do – create a working environment whereby employees are not just turning up for work.

- People are curious and if they can identify the benefit of the product they are working on, then it increases their appreciation of the products that much more.

- Employees now ask about products rather than waiting to be told.

- Bring in patients who have been treated with one of the company's products to talk to employees about their improved quality of life.

- Aspiration to be better at this.

- Over the past number of years, the company has been driving harder towards creating a more customer centric culture. Improvements have been made and are continuing to be made. "It's our future".

- If the company is more focused on the customer, then they are by default, more focused on offering products that meet their needs.

- The markets move towards commoditisation very quickly in medical devices. What was leading edge 3-4 years ago is a commodity today. If a company wants to stay on the leading edge, this means becoming more focused on customer needs.

- Mentoring process outside of direct reporting lines for employees who need it or are new to the industry.

- Communication – a critical part of developing a customer centric culture. Cannot lose sight of the fact that the company's products are going into patients and once they're in, they are in for life.

- Employees are managed by quarterly objectives. Part of these objectives involve customer focus whereby employees have customer focus goals within their work objectives.

- Quality is integral to a customer centric culture.

- The quality management system, particularly training and education, Key Performance indicator metrics, tight processes and constant audits.

- Bring in patients and doctors to meet and talk to employees.

- It is much easier for an employee in medical devices to relate to what they are doing then if involved in some other industries.

- Communication – opportunity to remind employees of their responsibilities

- Engineers, especially those involved in product design spend time in surgery observing the procedures.

- Company is an employee owned company, therefore will not undertake any NPD unless it is adding value to customers. This is inherent and part of the company's core values.

- Some years ago, customer centricity may have only existed in marketing and at executive level, however this has changed and today, an awareness

of customer value exists at every level from senior management to the shop floor.

- Undertake an elaborate recruitment process where they search for people who can respond to customers' needs. The induction process involves exposure to the company's values and the customer comes out loud and clear in that.

- In 2011, have just completed training with the global workforce on the company's immutable principles in customer service.

- At this company, it is unavoidable to understand where the customer fits into the organisation.

- As the company is employee owned, it is not answerable to external shareholders and there is an absolute understanding that if the company doesn't put the customer first – even if that means fore-going some short term profit, that a competitor will and the company is empowered to act accordingly.

- Communicate to employees that they will keep the business if quality and service are good. This makes the business very real for the staff, they know who the customer is and that the customer has the ability to change their minds as to whether to buy the company's products or not.

- Everyone is tuned into the fact that the business is about serving customers – that it is not necessarily about what is manufactured, rather that the customer is served.

- Quarterly staff updates where the primary focus is on the customer. At this, examples of good work that helped win a contract and examples of not so good work that caused the company to put business under threat are provided.

- Openness triggers awareness and is a motivator for employees. Employees not just getting paid at the end of the month, they have higher, loftier goals in relation to keeping the customer satisfied. This is achieved by keeping the customer real.

- Nature of business means they are much closer to customers than a lot of businesses.

- Cultural alignment in terms of acquisitions is an important factor in due diligence because the culture of an organisation is so hard to change.

- A customer prompt that is always used "what would be the customers' opinion on this?"

- Weekly review meeting based on dashboard of metrics.

- Work environment where there is a lateral understanding that problems can be revealed and not hidden, and that they are dealt with objectively.

- Take people's fear away – people worried that if they make a mistake they could lose their jobs. Get rid of this fear and its' easier to build a team that is focused on the customers' needs.

- No formal processes in place.

- Bringing in end-users to talk to employees about how they benefited from treatment with one of the company's devices – how it impacted their lives.

9. Please rank how customer centric you think innovation processes are in the Irish med tech industry.

- Not clinician driven in Ireland.
- Need for more clinicians to be involved in research – BioInnovate program should help.
- If customers are truly customer centric, they should appoint a Chief Clinical Officer.
- Need organisations such as Science Foundation Ireland to fund more clinical researchers and scientists.
- Don't see as much clinical involvement in Irish companies as there is in the US med tech companies.
- Need more research to take place in improving clinical outcomes, this can only be done with clinicians.
- Creation of the BioInnovate programme at the National University of Ireland Galway (NUIG) which is modelled on the renowned Stamford University BioDesign programme is a significant step forward in terms of viable medical device innovation.
- Huge love of technology within the industry – particularly visible in the university sector where there is a propensity to follow industry. This leads to chasing after problems that have been around for a long time rather than searching out completely new unmet needs.
- Need 2 things for successful NPD: Engineering excellence and great strategic marketing. Huge gap in strategic marketing in Ireland. Structural and circumstantial situation. Career path opportunities for strategic

marketing people are not present in the med tech industry. US corporate tend to keep this function close to home, usually in HQ therefore candidates aren't prevalent in industry in Ireland.

- Room for improvement.

- Approaching product design just as a job – working only to spec, excluding consideration of unit price and competitive impact. Too rigid on specs rather than optimising processes in order to design better products.

- Need to think globally – even small indigenous companies.

- Don't have clinicians in Ireland who are geared toward medical device development. KOLs are not based in Ireland.

- Ireland is in a very good position. There is an infrastructure in the country supportive of advancing the med tech industry.

- Comparisons with the US med tech industry are not feasible. Industry in the US has been around for over 70 years, whereas the industry debuted in Ireland in the 70s. Hospitals in the region of the med tech hubs in the US are geared towards research, this is not true in Ireland.

- In the past 15-20 years, there has started to be a re-focus in Ireland on R&D and the Irish med tech industry is evolving and on the cusp of continuing to grow at an accelerated rate but needs to develop in certain areas more than others. The support and technology capabilities exist but there is room for improvement in the business areas, primarily strategic marketing and funding, and also, in clinical areas. Clinicians need to be better hooked into the industry.

- Currently not practical to run clinical trials in Ireland. Significant opportunity for customer centricity. Developments that are underway to

try to establish a central clinical approval board for running clinical trials would greatly enhance this capability. Irish hospitals are individually too small to access large enough patient groups to run a trial. This situation would result in permission being sought from individual hospitals to enrol patients in a trial and increase the complexity of the whole process. A central approval board would make this process much easier.

- It is only the minority of companies in the med tech sector in Ireland who have a brief to do true innovation.

- Ill at ease with the level of customer interaction in med tech in Ireland.

- Scope of what we are doing in Ireland is far too limiting.

- Doctors don't have a brief for innovation.

- Almost no KOLs in Ireland.

- Clinicians brief in Ireland is clinical procedures. Can't do clinical trials in Ireland, it is too difficult. There is no platform in Ireland for clinician interaction so all trials are done elsewhere.

- Unsettling to consider that there are almost 30,000 people employed in the med tech industry in Ireland and 60,000 employed in the Minneapolis region, the global hub of medical devices, yet there is nowhere near 50% of the innovation coming out of Ireland compared to Minneapolis.

- Interaction with Irish clinicians would be great, however it is not the only thing missing from the med tech industry in Ireland. The brief is very manufacturing oriented and the situation won't change overnight.

- The Irish med tech industry is very manufacturing and efficiency based. There are a lot of technologies being developed in the med tech sector in Ireland, but not sure if these technologies are based on customer needs.

- There is room for improvement, but if Ireland gets it right, it will be ahead of everyone else because of the inherent acceptance and realisation of the need to be efficient and effective. There is also a great understanding within the sector that innovation is required. Ireland has shown itself to be innovative, and if it can balance this with building in a stronger customer focus, the industry in Ireland is going to be streets ahead. This is the prerequisite for future success.

- Arrive at solutions too soon – very common in med tech industry in Ireland.

- Lack of experience and knowledge on how important fully understanding customers needs really is.

- Don't have the breadth of experience in certain areas, particularly in marketing and commercial areas.

- Very different outlook in Minnesota. The body of knowledge and network is entirely different over there. Irish med tech industry had very different starting point where the focus was on manufacturing and engineering and where the primary occupations required were good engineers who know how to manufacture and improve processes. Cannot take people out of these roles and assume they can slot into developing products.

- Have much better chance of market exposure to customers in indigenous companies than large multinationals.

- Don't believe we are as customer centric as we think we are.

- Is the growth in our industry down to customer centric innovation or a corporate tax rate of 12.5%. Corporate tax rate very important to the future of the industry in Ireland and a key driver of where it is at today.

- Still very caught up in the industry's manufacturing legacy.

- Room for improvement in order to be brilliant.

- Look to innovative indigenous SMEs as a model. SMEs know what is going on with their businesses intimately. In large multinationals there is a lot of layering on of organisational structure whereby individuals don't know what's going on.

- Better links needed between industry, government and clinicians to develop a better understanding of what the market really needs and what areas to be focusing on.

- We should know what value we bring to a market place before we start working on it.

- Big companies spawned a generation of entrepreneurs in medical device support and services. The industry needs to use this experience to develop other skills and offerings into developing new products.

- Better support for SMEs in terms of marketing, legal issues and reimbursement.

- Need stronger industry-clinical links to get closer to the customer and better understand their needs. The links between academia and industry are much stronger than clinical and industry.

10. According to Kavanagh et al. (2010), fulfilling a customer need is more important than providing a solution.

- Identifying the need is the bigger challenge.
- Generally tend to put solutions into the MRD or URD – not the best approach.
- Instinctive to propose solutions and get focused on solutions too quickly.
- Nothing like a good hard lesson to knock the "solution" approach out of you.
- Solution orientation from the outset constrains innovation.
- Have to distil solutions to make sure the need is met.
- It is best if the clinicians are focused on their needs, and not necessarily how those needs are met. Let the med device companies deal with the technology to meet the needs.
- There is an element of push and pull with regards clinical needs versus technology. Once the need is established and the product is developed for that need, additional refinements that are technology driven may be necessary. For example, stents and in-stent restenosis. There is an element of push and pull between clinical need and technology to overcome this.
- A solution is more temporary. A need is more long term.
- Can have many solutions to fulfil a need.
- More important to start with a need and develop a solution.

- For large multinationals, you simply have to be needs driven rather than technology driven.

- Success rate of solution based products rather than needs based products is very low.

- The biggest problem is separating the need from the solution. Marketing people can tend to come back telling R&D about solutions. They are sent back out to unearth the needs and the under-lying problems. It is easy to slip into the solution mode, its takes more effort to truly define the need. Need to define the scope of the need and let the technical team come up with a solution to meet the need. Focusing on the need rather than the solution opens up the scope for innovative products rather than incremental improvements. Such incremental changes are easy for competitors to imitate.

- Need to be skilled in questioning to steer the customer away from solutions and to analyse the problem fully.

- No point in having a solution if it doesn't fulfil a need.

- See so many products that have a small degree of success because they don't quite hit the mark of the need they are trying to fill.

- Your customer's need is also your customer's expectation – if you don't live up to that, no matter what type of solution you provide, if it doesn't meet the expectation, then it is no use.

- Most start-ups are solution driven but occasionally come across a needs driven product.

8.9 Appendix I: Practitioner Evaluation – Expert Opinion

This appendix outlines the expert opinions as offered by Michael Kavanagh. The opinions are based on an independent review of the research data and are provided on a question-by-question basis.

Question One: **What does the term "customer centricity" mean?**

MK: By in large there is a strong understanding of the requirements to put "customer first". The term "Need" is used in a number of different contexts. What is important is if using a true needs based approach then important to identify all the needs associated with the "job" the customer is trying to do which will guide the organisation on where they should direct their innovation efforts.

Question Two: **Who are your customers?**

MK: A broad range of customers are identified which is fine. Each of the customers will have different needs e.g. Clinician versus patient – will all have different needs based on the "job" they are trying to carry out. Important we know the needs for the different customer groups.

Questions Three: **How do you determine what your customers need from you?**

MK: There is quite a mix in the answers to the question that indicate at one end of the spectrum a good appreciation of the requirement to truly get a detailed understanding of the customer's needs and the importance of investing in this upfront through to the other end of the spectrum where there is a "solutions based" approach where product is developed then goes through iterations after testing with customers. Mention also on leverage of KOL's. This is common and useful in the industry – critically important however to ensure you understand how representative they are of your target customer group.

Question Four: **What do you see as the pros and cons of user involvement in the new product development process?**

MK: A good understanding of the pros and cons is expressed. I would certainly advocate testing the solutions one is developing with customers – what is critical is you are testing with the right customer segment for which the solution is being developed. By having a very good understanding of the need up front then it enables one to position the solution effectively in the testing process.

Question Five: **How does your company ensure user involvement throughout the new product development process?**

MK: Again common practice is demonstrated through the answers. One potential opportunity to consider is to actually present the results of the "needs" research to the customers and link the concepts to the needs when getting their feedback.

Statement Six: **Open innovation is an integral source of new product inspiration?**

MK: Good understanding and appreciation for Open Innovation expressed. Open Innovation of course needs to be targeted towards delivering a solution to an unmet need. There are many sources of open innovation within the organisation also that should be leveraged – best solutions don't always come from Research and Development teams. The IP issue is expressed here also which is important. In the context of IP I would also put forward the proposition that if a company truly understands the unmet needs of a customer then this knowledge can be a source of key competitive advantage. In this respect need to ensure OI practices are structured to protect this knowledge.

Statement Seven: **We work hard to ensure that we deliver value in terms of the customers' needs?**

MK: The concept of identifying where the greatest value lies comes out a bit. In the Outcome Driven Innovation process we try to get to this answer by identifying where

the greatest opportunities lie – the assumption is the largest opportunity scores will net the greatest value.

Statement Eight: **Customer centricity is a priority for my company, we have processes in place to develop a culture supportive of this.**

The answers by and large support the fact that the companies truly value the importance of being customer centric and a lot of customer interaction is evident. Many of the answers about specific processes are quite general in nature versus having a very formalised structured approach to defining the true unmet needs of the customer. Some of the companies may benefit by introducing and investing in a more formalised structured approach.

Question Nine: **How customer centric do you think innovation processes are in the Irish med tech industry.**

MK: The answers here suggest there are still large opportunities for the innovation processes to become more customer centric. The important role that strategic marketing needs to play was identified in one of the comments which is insightful and indeed very correct as in its absence it is very difficult implement what Outcome Driven Innovation proposes.

Statement Ten: **fulfilling a customer need is more important than providing a solution.**

MK: Looks like preaching to the converted on the importance of Needs versus Solutions. The critical element is then making sure the approach taken in unearthing true unmet needs is followed.

Overall Comment:

MK: Customer centricity seems to be alive and well in the Irish Medical Device industry. The benefits associated with being customer centric are well understood as are a needs based approach versus solutions based approach to directing innovation

practices (note there is some evidence that solutions based still does exist). There are a range of methodologies practised with the skew definitely towards needs based versus solutions based innovation. Some companies could potentially benefit from implementing a more formal structured approach upfront to ensure the needs based approach unearths the real needs that an organisation should focus on. The important role that upstream strategic marketing should play is also identified and for some organisations this is an area that should be assessed as to its current effectiveness and opportunities.