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Title	An Analysis of Innovation Management in Irish Medical Device SMEs
Author(s)	Cormican, Kathryn
Publication Date	2013-06
Publication Information	Ronan, D. and Cormican, K. (2013) An Analysis of Innovation Management in Irish Medical Device SMEs IEEE International Technology Management Conference & 19th ICE Conference The Hague, Netherlands, 2013-06-24- 2013-06-26
Publisher	IEEE
Item record	<a href="http://hdl.handle.net/10379/3895">http://hdl.handle.net/10379/3895</a>

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# An Analysis of Innovation Management in Irish Medical Device SMEs

David Ronan<sup>1</sup>, Kathryn Cormican<sup>2</sup>

<sup>1</sup>*Vascular Solutions Zerusa Ltd., 208 Business Innovation Centre, National University of Ireland, Ireland, dronan@vasc.com*

<sup>2</sup>*College of Engineering & Informatics, National University of Ireland, Galway, Ireland, kathryn.cormican@nuigalway.ie*

## Abstract

This paper focuses on innovation management practices in the Irish medical devices industry. We analyse key determinants to assess the nature and level of innovation management practices relative to published literature in ten small medical device organisations. A two staged research method was employed. First a structured survey was conducted to empirically assess the level of management in the participating organisations. Qualitative interviews were then employed to elicit deeper insights and experiences. The research found that managing innovation was not a priority in the organisations surveyed, failure tolerance was low and SMEs encountered issues with intellectual property rights when dealing with research institutes. This paper thus addresses a gap in the literature as it articulates the relationship between prescribed best practice and implementation in a specific context. It also provides a series of recommendations to managers that can guide performance improvement.

## Keywords

Innovation, management, measurement, audit, SME

## 1 Introduction

There has been a paucity of research in innovation best practices in relation to Small and Medium Enterprises (SMEs). This is a worrying imbalance because research has shown that the majority of break-through innovations are developed by small firms and not by market leaders who spend the most on R&D. Small, agile companies can capture innovations quickly and explore them with minimal bureaucracy. The majority of failures in technological innovation can be attributed to weaknesses in the innovation management process [Ulrich and Eppinger 2008], [Tidd, et al 2009]. Therefore attention should be paid to understanding, improving and optimising these processes in order to guide small companies wishing to improve their innovative capability. Our research aims to redress this imbalance. This study targeted small firms who work in R&D and focus on designing innovative new medical device products in Ireland. A purposive sample of 10 small firms was surveyed. We developed a systematic protocol to analyse the nature of innovation management in responding companies using both quantitative and qualitative techniques. The contributions of this research are twofold; an evaluation of best practice relative to the literature that is informed by real industry experience and a series of recommendations for similar organisations interested in effective innovation management.

We found that little attention is paid to measuring innovation activities. Success rates are not tracked and measured and most companies do not manage their product portfolios to ensure adequate diversification. Most worryingly we found that participating organisations do not tolerate failure and they do not have a process in place where they can learn from mistakes. The

research also found that intellectual property (IP) protection policy is a serious challenge for SMEs and often prevents them from collaborating. The remainder of this paper is organised as follows.

First, the literature on best practice innovation management is synthesised and analysed. Second, the research methodology employed in the study is presented. Third, findings from the study are presented. Fourth, the findings are discussed and analysed. Fifth, a series of recommendations is provided and finally we conclude by identifying some important limitations to our study and suggestions for further research.

## 2 Literature and related theories

### 2.1 Innovation management

Theories of innovation management have been developed and used to various extents to identify the factors that facilitate innovation in organisations. These theories differ in scope and they analyse innovation from many different perspectives such as the level of innovation (e.g. policy, sectorial and firm level) the type of innovation (e.g. incremental, radical, technological, service) and the application area (e.g. SMEs, multinational, virtual enterprises). It is clear that there are many factors that affect innovation management. Therefore we synthesised the literature and identified best practice factors that are consistently found to enable innovation in SMEs.

#### 2.1.1 New product Strategy

Without a clear innovation strategy, tactical or operational decisions guide behaviour. On the other hand, creativity can be stifled a strategy a strategy is too rigid [Tidd, et al 2009]. Research suggests that the innovation strategy must be aligned to the business strategy [Davila 2006] [Cormican and O'Sullivan 2004]. Innovation strategies should aim to balance incremental and radical innovation in order to support a diversified portfolio. SMEs should consider strategic partnerships; outsource models and virtual enterprise models as they require significantly less resources in the early phases of development.

#### 2.1.2 Clear New Product Development (NPD) Process

SMEs need to have a well-defined and managed product development process in place, and the innovation team must know how to progress an idea through the system in a manner that produces consistent results. This process must allow for time to be spent on the initiation period as these up front activities help to ensure that the right products are developed that meets the needs of the market [Van de Ven 2008] [Ulrich and Eppinger 2008]. A well-defined process ensures all ideas receive fair treatment and a chance to move through the system. Cooper [2008] outlines a revised 'Stage-Gate' innovation process for new product development (NPD) management.

#### 2.1.3 Senior Management Support

The CEO is directly responsible for implementing the infrastructure, strategy and culture that feeds an innovative enterprise [Davila, et al 2006]. Trust, recognition, support and funding are four key areas which CEOs should use to instil creativity and innovation [Wei, et al 2012]. The correct environment is a positive, supportive atmosphere where success is praised and failure is acknowledged as contributing to the organisation's knowledge base.

#### 2.1.4 Failure Tolerance

Failure is fundamental to innovation [Van de Ven 2008]. Organisations need to develop a system for managing innovation where failure is not criticised but rather seen as integral to innovation. Financially motivated intervention of managers and/or investors can result in premature product launches. Pressure to produce results can lead to a situation whereby engineers present results that are deemed adequate, but are not innovative. Van de Ven [2008] defines this as '*impression management*' which has the ability to cloud decision making processes as a result of '*sugar-coated*' information.

#### 2.1.5 Dedicated Teams

The innovation process is characterised by intricate interdependencies among many functions so it is necessary to integrate knowledge and skills from various disciplines. Cross-functional teams are increasingly used to develop new processes and products [Edmondson and Nembhard 2009]. McDonagh [2000] found that the increased use of cross-functional teams in new product development is related to higher project success. Sethi and Sethi [2009] also documents similar findings. These teams must be specifically tasked to manage innovation; they must have dedicated roles and share R&D and organisational support responsibilities.

#### 2.1.6 Motivation

Motivation theory suggests that individuals respond positively to stimuli that reward achievement and performance. Motivation and reward systems are key elements in aligning the interests of employees to that of the organisation [Kandemir and Acur, 2012] [Wei et al 2012b]. They can be adjusted to encourage the desired behaviour from all staff. Therefore, if organisations wish to encourage they must design motivation and reward systems that incorporate these activities.

### 2.2 Measurement

Effective measurement is crucial to assess an organisation's propensity for innovation and many researchers have proposed models, frameworks and indicators to facilitate this process [Tidd, et al 2009] [Cormican and O'Sullivan 2004]. However measuring innovation management practices concisely and in a repeatable way is very difficult and fraught with challenges. SMEs can measure success or failure from many different perspectives. The following factors have been identified in the literature and are known to correlate strongly with effective innovation measurement practices in SMEs.

#### 2.2.1 Product Success

Research suggests that a product's success rates should be tracked for several years after launch to assess how well the investment is working out. Return on investment (ROI) rates should be monitored for each product/technology on an on-going basis. The criteria for assessment should be clear and communicated to all in order to focus effort.

### 2.2.2 Diversified Portfolio

Effective product portfolio management is essential [Heising 2012] [Petit 2012]. An organisation should seek to have a diversified portfolio that comprise a mix of small and large, safe and risky as well as low and high value projects in their portfolio [Petit 2012]. In light of this, specific indicators should be developed and used to help SMEs assess the nature of their product portfolios relative to their strategy and known best practice.

### 2.2.3 Lead Users

Capturing the voice of the customer and translating that into the product concept is essential for a product to succeed in the marketplace. Therefore, more and more organisations are forming close relationships with lead users so that they can identify their needs (both articulated and latent) and design products and services to meet those needs. Developing prototypes, fine-tuning continuous iterations and capturing feedback from users is known to be very effective and consequently it should be incorporated into the process [Martínez Leóna 2013] [Bingjian, et al 2013].

### 2.2.4 Culture and Values

Research suggests that promoting a culture that is conducive to innovation is crucial for organisations [Kahn, et al 2012] [Wei, et al 2012]. However, concepts such as culture and values are intangible and elusive and consequently very difficult to orchestrate. While there is much debate surrounding these concepts in the literature there is some consensus that organisational culture can be described in terms of values, norms and beliefs. Therefore SMEs should aim to understand the hopes, fears and aspirations of each team member and try to align performance indicators that link with both individual goals as well as team targets.

## 3 Research Method

Case study research is about *‘interpretation, subjectivity and meaning’* [Ryan, et al. 2004]. It uses multiple sources of evidence to better understand a particular issue in a specific context [Baxter and Jack 2008]. A mixed method strategy was employed in this study to reduce the impact of *‘method effect’* [Lance, et al. 2010] and increase the trustworthiness of the research findings [Lewis, et al. 2009].

A structured survey was constructed to empirically analyse best practices about metrics, techniques, culture and management of innovation in medical technology SMEs. It is based on the guidelines set out in the Oslo manual for gathering and collating innovation data [OECD 2005]. 10 themes were identified and 47 measures were developed based on a synthesis of the most recent literature to ensure that data reflected the most up to date research findings. Likert scaling techniques were used to assess the extent to which the organisation implemented an innovation practice. The questionnaires were completed in the presence of the researcher to ensure consistency of approach and to clarify any ambiguities that arose. In depth qualitative interviews were then conducted to allow for additional information to be gathered and to probe more deeply into specific aspects that the interviewee wanted to discuss.

Ten organisations employing no more than 75 employees operating in medical device R&D sector were purposefully selected to ensure homogeneity in the sample (see Table 1). All of the companies chosen are high potential start-ups (HPSU) and all are less than ten years in business. All interviewees were directly involved in the management of medical device R&D, either at the early concept stage, the product development stage or the marketing and realisation stage. These selection criteria helped to determine relevant small young firms (in line with the county’s norm) that demonstrate a clear intention to innovate.

	<b>Number of Employees</b>	<b>Number of R+D Employees</b>	<b>Years in Business</b>
Company A	36	10	10
Company B	70	6	7
Company C	10	6	3
Company D	10	5	10
Company E	7	5	4
Company F	10	7	1
Company G	8	6	4
Company H	14	6	6
Company I	4	1	5
Company J	48	9	3

Table 1: Profile of Responding Organisations

## 4 Findings

### 4.1 Quantitative Data

Table 2 presents findings from our quantitative analysis. The mean value is a statement of the strength of each score across the organisations in the sample. The higher the result, the better the companies performed in implementing these important features. The standard deviation indicates the variation between the organisations and their relative ability to implement the measures identified. A larger standard deviation indicating that some organisations are much better at implementing the measures than others.

The results from the innovation audits showed that the four innovation *measurement* activities (7-10) suffer from poor attention across the range of management disciplines. There is little attention paid to product tracking or success rates and most of the companies do not manage their product portfolios to ensure adequate diversification. The mean score for measurement activity across the ten companies is 59% and this suggests that innovation measurement as a discipline should be improved. The spread from 41.7% to 95.8% for engaging lead user shows that some organisations do not appreciate the usefulness of being driven by customer needs. Second-guessing which products or innovations to deliver to market is risky as it requires competitor data to ensure another company is not working on a similar product. Tying individual aspirations to organisational goals (management of team values) varies from 0.0% to 91.7% across the range of companies, with an average score of 51.7%. This tying of goals was acknowledged during the interviews to be an administrative challenge for an SME, however Company N which scored 91.7% had a simple employee review process for assessing motivations and linking these to employee responsibilities. While the levels of the six innovation *management* activities fared better than the measurement activities they varied greatly across the ten companies. Failure tolerance, which is critical for morale and performance of innovation teams, was low for most companies. In a traditional industry or manufacturing business model, it could be expected that

mistakes and failures are directly linked to expense and waste. However, in innovative companies which are designed to harvest knowledge and develop novel concepts, failure should be seen as an opportunity for learning.

<b>Innovation Audit Scores</b>	<b>Mean</b>	<b>Standard Deviation</b>
Management		
1. NPD Strategy	77.5	22.5
2. Clear NPD Process	68	19.9
3. Senior Management Support	71	14.5
4. Failure Tolerance	53.2	19.6
5. Dedicated Teams	56	15.2
6. Motivation	55.7	12
Measurement		
7. Product Success	55.4	12.8
8. Diversified Portfolio	51.3	18.8
9. Lead Users	72.5	17
10. Culture and values	51.7	30.9
<b>Innovation Measurement Score</b>	<b>59.2</b>	<b>9.3</b>
<b>Innovation Management Score</b>	<b>63.7</b>	<b>12.6</b>
<b>Innovation Activity Score %</b>	<b>61.8</b>	<b>10.4</b>

Table 2: Findings from Quantitative Analysis

## 4.2 Qualitative Data

We posed a series of questions regarding the organisations strengths and challenges in managing innovation. Nine key themes emerged and they are discussed briefly below.

### 4.2.1 Senior Management Support

The attitude and direction of the CEO is a dominant factor in innovation in all companies. Almost all of the respondents described both positive and negative behaviours from senior management. Three companies described their CEOs as leaders who gave clear direction and total support to innovation, while one manager described the CEO as being closed to innovation beyond the scope of the project in hand, and that the only way to improve the innovation capability of the organisation was to, “*replace the CEO*”.



#### 4.2.2 Access to Lead Users

Just four of the ten SMEs surveyed have lead users involved in the development process. These four companies have established medical review boards to carry out prototyping and product development. The remaining six companies depend on a 'technology push' to establish product specifications, using industrial designers to produce enhanced versions of existing products.

#### 4.2.3 Research Institute Linkages

Three of the ten companies have a direct link to the Royal College of Surgeons. Two of the companies have strong links with a local academic research institute; one company has links with more than two colleges and was funding/partnering breakthrough research at both. All of the companies have made contact with a college at one time or another but found progress to be slow. Many respondents highlighted the importance of protecting intellectual property. For example Manager 7, Company H, "*Our IP is our soul and we are not prepared to share that*" while Manager 5, Company E noted that "*It is unworkable that a college should share IP in a venture that is funded by investors.*"

#### 4.2.4 Government Agency Linkages

All of the ten SMEs interviewed have contact with the development agency Enterprise Ireland with most attesting to a strong relationship or financial support. All of the companies stated that the networking and business support provided by Enterprise Ireland is invaluable. Manager 7, Company H is particularly impressed with the work of Enterprise Ireland in establishing foreign links: "*Enterprise Ireland has a function which is often overlooked when they are judged as just a provider of local finance [...] we benefited greatly from links which EI through their strategic offices, particularly in the USA made into the US National Institute of Health*".

#### 4.2.5 Strategy

Seven out of the ten managers are unclear about the overall company strategy in relation to the organisational goals. Innovation strategy or innovation management do not feature in the strategic plans of any of the companies investigated. A statement from Manager 9, Company L highlights some of the ambiguity surrounding what is classified as strategic innovation: "*Strategically, innovation is very important to us but we don't specifically call it 'Innovation' and although it is inherent in everything we do it is not actively managed*". Manager 5, Company E echoed the findings of the quantitative data for his company (79.3% on Innovation Activity) when he said, "*We are very clear on our innovation strategy – it is something we work very hard on. It is part of what constitutes our value proposition and is central to it*". Conversely, one R&D manager claimed that there is no innovation strategy at all at his organisation and his attempts to introduce it were resisted by senior managers: "*It wasn't so much that there was little interest, there was absolutely no interest and there was no attempt to change*".

#### 4.2.6 Culture

The relative size of an SME, as opposed to a corporation, means that its culture is difficult to define. Most of the managers when asked about the culture in their organisations, described the atmosphere and the business model. Manager 6, Company G pointed to the size of their company "*[...] We have to do things differently to the way a large multinational companies do them and it is innovative in nature how people think on their feet and effect change quickly to deliver value to the company and its shareholders...we don't have the bandwidth a larger*

*company has available to them*” (Manager 6, Company G). Manager 10, Company N expressed a lack of an innovation culture at the company despite its claims to be an intensively innovative organisation: *“There is a hard-working ethos in the company but beyond the R&D group there is no focus on innovation”*.

#### 4.2.7 Failure Tolerance

Failure tolerance is the topic that drew the greatest amount of discussion from the R&D managers interviewed. Almost all of them admitted that they have not implemented a formal process to capture, evaluate and review information about failures during the development process. Interviews supported the quantitative data, with most companies saying that they do not tolerate failure well, and in no instances was failure viewed as positively contributing to the knowledge base. Three of the managers admitted that they rely on traditional project planning techniques and simply adjust the timelines when a failure results in a delay. Another manager attested to the natural aversion to risk in a smaller company stating: *“For an SME, the opportunity to be successful is a long and narrow path which doesn’t allow for alternative directions”* (Manager 9, Company L).

#### 4.2.8 Diversified Portfolio

Manager 1, Company A described their efforts to find new and radical uses for their core technology, stating that it fell under marketing, rather than innovation strategy: *“We have a fundamental technology which we want to exploit and we have an advanced development group which constantly searches for new applications for it, but we probably don’t manage it as pure innovation management – it is a marketing function.”* Manager 5, Company E attested to the need to tie innovation to strategy: *“We explore ideas widely [through] analysing, modelling and prototyping, even though they might seem unlikely in order to learn something about them. There is usually a tangible link between the idea and what we work on, otherwise it results in a lack of focus; otherwise these ideas could be called ‘Blue-Sky’”*.

#### 4.2.9 New product Development Process

Of the managers interviewed, only three described the NPD process as a robust and well managed aspect of the organisation. These three were very clear about where new ideas came from (lead users and marketing contacts), but also what ‘go/kill’ decisions the idea would encounter during the process.

## 5 Discussion

The interviews showed that none of the managers interviewed had ever carried out or participated in an innovation audit of their organisation. Furthermore, they do not use suitable metrics to measure innovation. Managers expressed resistance to spending time measuring innovation and one interviewee went as far as to regard it as *‘a waste of time’* (Manager 8, Company K). Similarly, the interviews show that very little actual innovation management takes place, and failure is understood in an entirely negative light. All of the managers admit to finding challenges with delivering innovative solutions with the triple constraints of time, cost and quality. Of the companies who claimed innovation as a core competence, further analysis suggests that these are individual incidents of innovation as opposed to long-term organisational habits.

The most innovative companies have CEOs who are involved with innovation on a daily basis. A small proportion of companies are deeply involved with their customers; and the others who are still in the early development phase of R&D have not considered the positive influence of engaging lead users. Given SME start-up success rates, depending on market sector, of between 10% and 50%, an innovation strategy from an early stage is crucial. Innovation plays a significant part in developing diversification strategies, partnering with other companies or selling to Original Equipment Manufacturers (OEMs) for the purpose of assembling a kit of products. Limited resources (human or financial) to develop diversification strategies mean that opportunities for alternative uses for core technologies are not being explored. Several of the managers were able to recall completing innovation audits as part of investor due-diligence reports and they understood the value of them. However, few of the managers feel that they have the adequate resources or necessary support from senior management to implement an innovation management system in the near future.

## 6 Recommendations

### 6.1.1 Involve Lead Users

Companies who involve lead users at the earliest stage of product development are more likely to be successful in the long run. Several of the companies in this study have invested in building strong relationships with global lead users, identifying them and engaging them in the processes. One distinct advantage of early involvement of lead users is that they often wish to invest in the company. Their belief in the value of the technology provides both finance and knowledge at the development stage. Companies who rely on their marketing managers or CEO to provide concepts for the product pipeline are operating at a disadvantage, confining their company to incremental innovation and not actively searching for radical uses for their technology.

### 6.1.2 Front-end Innovation

Spending twice as much time on the fuzzy front end of product development delivers a better product and a more innovative solution in the long run. This phase is the least expensive to finance and efforts in the initial stages provide a repository of data should problems arise during the next stages. Once a design is frozen, the danger is that innovation will end and the organisation loses the advantage it may have because of its size and flexibility. The major difficulty for SMEs in transitioning from early to mid-stage development comes in sourcing funding. SMEs rarely get a second chance once the development process derails and while there is no doubt that companies learn from failure, they do not always survive it.

### 6.1.3 Company Culture

Companies who formalise innovation teams, train their employees in the necessary skills and spread a message that innovation is of primary importance are better at delivering innovative solutions. Empowering cross-functional teams with the sole purpose of delivering innovative solutions, not just the R&D group, is critical. An atmosphere of trust, openness and common sense of purpose will nurture innovative activity.

### 6.1.4 Business Model Design

Most Irish medical device SMEs use a traditional manufacturing business model. The majority of companies in this study are arranged for an R&D phase which transitions to a manufacturing phase with insufficient resources available to run both concurrently. Two of the companies operated 'outsource' business models that utilise strategic partnerships to carry out many of the

non-critical aspects of the business. These companies contracted their manufacturing, testing, logistics and support services (calibration, maintenance, facilities) to carefully chosen external companies. This has kept up-front costs low and allowed them to concentrate finance in the R&D.

## 7 Conclusion

This study found that there are varying levels of innovation activity across organisations polled. The quantitative data found that each of the companies has certain aspects of innovation management behaviour incorporated into its routines but few displayed excellence. The qualitative data found that innovation management is at best an aspirational aspect of organisational management, with a lack of resources and senior management resistance being cited as the main reasons behind non-observance of best practice. The study found that intellectual property ownership is the primary reason that SMEs do not engage with universities and colleges. Innovative success requires a company-wide focus and it comes about when there are clear methods for measuring it, tied to techniques for managing it. This study has shown that a contingency approach to measuring innovation is best applied. An innovation audit based on the business model of the company is the optimal solution as it allows for longitudinal as well as cross-sectional study. Once data is gathered, a balanced scorecard or other suitable framework should be used to present the data and allow it to be acted upon. It is crucial that the data is actually used, and not forgotten once the audit is complete. In most cases, simply drawing attention to innovative practices on a regular basis will have a positive effect on the innovation activity at the company. It is clear that innovation management requires a balanced approach whereby care is taken not to dis-incentivise innovation. Excessive planning, analysis and bureaucracy in the early stages of a start-up company can take away its agility and delay market entry. On the other hand prematurely launching a product without due diligence can result in product failure.

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