



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

Title	Value chain migration from production to product centred operations: an analysis of the Irish medical device industry
Author(s)	Cormican, Kathryn
Publication Date	2006
Publication Information	Dermot Fennelly, Kathryn Cormican, Value chain migration from production to product centred operations: an analysis of the Irish medical device industry, Technovation, Volume 26, Issue 1, January 2006, Pages 86-94.
Link to publisher's version	http://www.sciencedirect.com/science/article/pii/S0166497204001117
Item record	http://hdl.handle.net/10379/4110
DOI	http://dx.doi.org/http://dx.doi.org/10.1016/j.technovation.2004.07.005

Downloaded 2024-05-24T03:35:37Z

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



Fennelly, D. and Cormican, K. (2006) Value chain migration from production to product centered operations: An analysis of the Irish medical device industry *International Journal of Technical Innovation and Entrepreneurship* (TECHNOVATION) 26, 1, pp 86-94.

**Value Chain Migration from Production to Product Centred Operations:
An analysis of the Irish Medical Device Industry**

Dermot Fennelly¹ and Kathryn Cormican^{2*}

¹Abbott Ireland Pharmaceuticals Operations, Manorhamilton Road, Sligo,
Ireland

Tel: + 353 71 9136600; Email: dermot.fennelly@abbott.com

²Digital Enterprise Research Institute, Department of Industrial Engineering,
National University of Ireland, Galway, Ireland

Tel: + 353 91 512292; Fax: +353 91 562894

Email: kathryn.cormican@nuigalway.ie

Key words: Research and Development, New Product Development, Value Chain, Subsidiary, Case Study

* Corresponding Author

Biographic Details:

Dermot Fennelly is a chartered engineer and he holds a degree in mechanical engineering, a master of science degree in operations management as well as an ACCA diploma in accounting and finance. After graduation, he worked as a mechanical engineer in design and engineering management positions with a number of multinational companies in the UK and Ireland. In 1994 he joined Abbott Ireland in Donegal as a project engineer focusing on process improvement and product innovation in their medical devices business. Dermot is currently class A programme manager for Abbott Ireland pharmaceutical operations.

Kathryn Cormican (Ph.D) is a lecturer in the department of Industrial Engineering at the National University of Ireland, Galway. Her research interests lie in the areas of product innovation management and enterprise integration. Kathryn manages a number of European Union and industry funded research projects in this area. She also works with many leading organisations helping them to design, develop and deploy new processes and systems.

Abstract

The medical device industry in Ireland is largely confined to manufacturing operations. This narrow focus limits the competitiveness of the industry in Ireland and consequently poses a threat to development and growth. Economic opinion indicates that more emphasis must be placed on higher value added activities such as research and development (R&D) and new product development. This paper explores the concept of value chain migration in the Irish medical device industry. Specifically, it examines the shift from production to product centred operations in the medical device industry. A significant proportion of organisations that occupy this industry are multinational subsidiaries. Typically, subsidiaries depend on their parent company to develop new products using R&D resources close to headquarters. Few subsidiaries have control of their product development activities and spending on research and development is inadequate. Subsidiaries cannot depend on the benevolent actions of the parent company to secure future viability. This study examines the competitive environment of multinational subsidiaries based in Ireland. The nature and extent of R&D activity in the industry is explored and potential threats and shortcomings are noted. The argument for and against moving towards product centred operations is examined and presented. The findings of this study reveal that the proactive subsidiary is far more responsive to its business environment than an organisation with centralised control. For example, certain initiatives can help to maintain market entry barriers, can help to control the power of suppliers and customers and can help to guard against substitutes. Moreover, subsidiaries must proactively manage the supply of new product developments by securing an adequate share of the output of parent

company R&D. To do this, they must demonstrate solid performance, build local capabilities in new product development and actively manage relationships.

1. Introduction

The Irish medical device and diagnostics industry directly employs some 22,000 people. This figure represents approximately 10% of total manufacturing employment in Ireland. If indirect employees are included the total number of jobs provided within the Irish economy is in excess of 36,000. The employment provided is high quality with 40% of direct employees having a third level qualification. The industry is primarily comprised of manufacturing subsidiaries of multinational companies, most of which originate from the United States. This group produces the greater portion of the industry's output and employs the majority of its workforce. According to the Irish Medical Device Association (IMDA) 13 of the world's top 25 medical devices and diagnostic companies have manufacturing plants in Ireland. Many of these organisations were originally established in Ireland to avail of a cost-effective labour force, favourable tax regimes and its English speaking, European location. Typically these subsidiaries have depended on their parent companies to develop new products using research and development (R&D) resources close to headquarters. The portfolio of products manufactured in Irish subsidiaries has tended to be made up predominantly of mature products. Irish operations have concentrated on cost minimisation through process innovation as the primary means of maintaining their competitiveness.

However, more recently several of the factors that once differentiated Ireland from other potential manufacturing locations have diminished. The cost base in Ireland has risen significantly and there are skill shortages in the Irish labour market. In addition, there are many other regions in the world that offer prospective companies attractive tax regimes. In view of the escalating competitive pressures facing medical device manufacturers in Ireland, many organisations need to rethink their strategies. Traditional approaches that focused on cost minimisation and incremental process innovations are no longer enough to maintain competitiveness (Johannesen et al, 1999; Tidd et al, 1997; Drucker, 1993). Therefore, in order to survive in this new environment companies must move away from traditional manufacturing activities towards more value adding competencies such as research and development (R&D), new product development and/or activities closer to the customer such as logistics, sales and marketing (see figure 1).

Take in Figure 1

Past initiatives aimed solely at product cost, quality, or time-to-market are no longer sufficient to gain market advantage. The focus today is on innovation. Irish companies must differentiate themselves from others and simultaneously remain affordable, reliable, and early to market. However, the scale of spending on R&D by the industry in Ireland indicates that activity is quite limited. Internationally the medical device sector spent approximately 7% of sales on R&D in 1999, the spend on R&D in Ireland was estimated to be a mere 1.5% of

sales. This paper presents a detailed case study of the Irish medical device industry. Particular attention is paid to subsidiaries of multinational organisations. The nature and extent of R&D activity in the industry is explored and potential threats and shortcomings are noted. The competitive environment of these subsidiaries is also analysed and assessed. The case for and against devolving control of R&D to medical device subsidiaries in Ireland is provided. Finally, proactive strategies to facilitate the progression into new product development are identified.

2. Analysis of Competitive Climate

A brief analysis of the competitive climate faced by the medical device industry in Ireland is presented in table 1. The healthcare industry is both large and complex and the myriad of factors that affect its strategic climate is beyond the scope of this study. However, this table provides a context for the discussion.

Take in Table 1

2.1 External Competitive Environment

Porter's five forces model is used to examine the Irish medical devices external competitive environment (see figure 2) (Porter, 1980). These include (a) the threat of new entrants, (b) the bargaining power of customers and of suppliers, (c) the threat of substitutes and finally, (d) rivalry in the Industry.

Take in Figure 2

2.1.1 The Threat of New Entrants: New competitors can emerge from both developing countries as well as from developed countries. Developing economies are intent on moving into higher value added products in order to achieve a higher standard of living. As education standards rise in developing countries such economies become capable of manufacturing high quality medical products while retaining significant labour cost advantages over operations based in mature economies. Manufacturers based in mature economies cannot compete with those in emerging economies if both are making similar products using similar technologies. In this view, it seems that if medical device manufacturers in Ireland are to remain competitive and viable they must make superior products in more efficient ways than their emerging competitors. Therefore, product and process development capabilities are essential to competitiveness.

2.1.2 Bargaining Power of Customers: State funded hospitals are the main purchasing group for medical devices. In many countries healthcare is the largest single use for public money. Consequently, there is pressure on purchasers to keep costs down. Purchasers in hospitals have responded to this pressure by joining forces with other hospitals to increase their purchasing power. The trend of centralised purchasing is expected to increase in the future. The fact that fewer providers are issuing larger contracts for more diverse ranges of products has forced manufacturers to merge in order to provide the volume and variety of products required. Competition between

manufacturers for such contracts is fierce and puts significant downward pressure on margins.

2.1.3 The Threat of Substitutes: Substitute products can emerge from established competitors who develop products that meet customers' requirements more effectively and efficiently. They can also appear in the form of new 'disruptive' technologies (Christensen, 1997). Often patents restrict incumbent manufacturers from copying the new technology. A further form of substitution that is particularly common in the medical industry occurs when changes in regulations make existing products or their manufacturing processes obsolete.

To counteract the substitution threat posed by established competitors, companies must continuously upgrade their product offering and their process technology to surpass those of their rivals. Market leaders may adopt strategies to control the impact of disruptive technologies on the market through direct competition, or they may seek to gain control of the technology by acquiring the innovating firms or by licensing, purchasing or developing the technology themselves. Finally, it may be possible to anticipate the negative effects of regulation changes by adjusting product designs and manufacturing processes to use acceptable technologies.

2.1.4 The Bargaining Power of Suppliers: Suppliers to every industry have a significant influence on competitiveness. If suppliers have power they will use it to increase prices, thereby reducing the competitiveness of the purchaser.

Suppliers may also act as a mere conduit, passing on raw material price increases. If a medical device manufacturer wishes to change supplier for a particular product component it can be a lengthy and expensive process. The new supplier must meet rigorous standards as regards their quality system, manufacturing environment and current good manufacturing practice. This amounts to a very resource intensive, expensive and lengthy process, and as a result most medical device manufacturers try to develop collaborative long-term relationships with their key suppliers. While these relationships provide stability to both the supplier and the purchaser, the purchaser must pay a premium.

Product development initiatives to 'design out' difficult materials and processes can be useful weapons in promoting cost efficient manufacturing inputs. Medical device manufacturers can, by applying new processes and materials in their products, remove supply restrictions that have historically tied them to a single source and forced them to incur excessive input costs.

2.1.5 Rivalry in the Medical Device Industry: Rivalry in the medical device industry intensifies as companies optimise technology, increase quality, reduce cost and promote economies of scale. Where the market for a particular product is declining rivalry is most virulent, here companies must take market share from competitors in order to maintain sales growth rates. On the other hand, in growing segments of the medical device market the race for market leadership, technical excellence and high quality are the primary source of rivalry since such markets are not as price sensitive as the markets for commodity type products.

There has been significant merger and consolidation activity in the medical device and pharmaceutical industries during the last few years. Mergers are often driven by the desire of small innovative companies to expand globally by gaining access to the distribution channels of larger companies. This is matched by the desire of large companies to acquire promising products still in development to bolster their own product pipelines and to gain control of disruptive technologies. Also, by adding appropriate existing products complete with regulatory approval they may rapidly enhance their product portfolios.

This section has explored the external competitive environment of the medical device Industry. Many of the forces active in this environment threaten the viability of manufacturing subsidiaries based in Ireland. The emergence of competitive manufacturing operations in cheaper economies with global marketing, advances in product and process technologies, cost conscious purchasers and demanding consumers all intensify the external competitive environment. In addition, since the Irish medical device industry is primarily made up of subsidiaries of multinational companies, these subsidiaries must also compete within their organisations. The next section analyses this internal competitive environment.

2.2 Internal Competitive Environment

Figure 3 illustrates five internal competitive forces namely, (a) the threat of greenfield sites, (b) the power of downstream functions, (c) the threat of

outsourcing as a substitute, (d) the power of upstream functions and finally (e) rivalry between sister sites.

Take in Figure 3

2.2.1 The Threat of Greenfield Sites: Subsidiaries of multi national companies are mandated to operate to certain standards and within certain constraints (see Williams, 1998; Rodrigues, 1995). This mandate is often referred to as the 'charter' of a subsidiary, and may be defined as '*..The business – or elements of the business – in which the subsidiary participates and for which it is recognised to have responsibility within the multi national corporation*' (Galunic and Eisenhardt, 1996). It is typically a shared understanding between the subsidiary and the headquarters regarding the subsidiary's scope of responsibilities (Birkinshaw and Hood, 1998). Charters are transferable and so subsidiaries are under the constant threat of having their charter reduced in favour of some alternative, more attractive location. The competitive challenges posed by greenfield sites may change as developing economies become more sophisticated and adopt industrial policies that match or exceed the levels of support available to multinational firms investing in Ireland.

2.2.2 Power of Downstream Functions: The effectiveness of the functions downstream of manufacturing (i.e. logistics, sales and marketing) is of paramount importance to the success of the medical device manufacturing subsidiary since they form the route for product to the market and for intelligence from the market. More often than not these functions are not under

the control of the subsidiary, which typically supplies only a portion of the portfolio of products distributed. Products within the overall sales portfolio may have widely varying profit margins, prestige, profile and strategic importance within the organisation. Consequently the energies of the downstream functions will tend to concentrate on the more attractive products. The manufacturing subsidiary must compete for the attention of the downstream functions by raising the profile and increasing the strategic importance of the subsidiary's products within the overall portfolio. In effect, the medical device subsidiary must compete with products from its own organisation as well as those of its competitors.

2.2.3 The Threat of Outsourcing as a Substitute: A subsidiary does not need to be directly involved in all aspects of the business process. Transaction cost economic theory would suggest that business processes should only be internalised if they cannot be undertaken more efficiently in the marketplace. Pre-emptive outsourcing is seen as a useful means of maintaining control of a manufacturing operation that cannot be undertaken efficiently within the subsidiary's own operation (see Linder et al, 2002; Elmuti and Kathawala, 2000; McIvor, 2000; Quinn and Hilmer, 1994). However, some researchers believe that outsourcing can lead to loss of control (Reich and Mankin, 1986). Product and process designs that are efficient in their use of resources are far less susceptible to outsourcing pressures. First of all, the cost imperative to move to a cheaper supplier is reduced to a minimum through production efficiency. Secondly, the efficacy of the product in fulfilling the customer's requirements makes it very difficult to buy in an equivalent. Therefore, the more closely a

product and distribution system integrates with the customer's value chain needs the more difficult it is for the customer to purchase elsewhere and the more difficult competitors (internal or external) will find it to displace the incumbent supplier.

2.2.4 The Power of Upstream Functions: The functions upstream of a manufacturing subsidiary include those involved in the flow of resources (i.e. physical and financial) and those involved in the flow of new products and process development opportunities to the subsidiaries. Subsidiaries must compete against sister sites for the outputs of these upstream functions. In general, the financial resources necessary for projects in multinational subsidiaries must be secured from central corporate funds and the expenditure justified. It is primarily the ability to consistently plan, cost, justify and execute capital projects (particularly new product introductions), with an adequate return on investment that sets subsidiaries apart. Innovative products with attractive revenue and profit streams are crucial to achieving adequate returns on investment.

Research and Development in multinational medical device companies have historically been located at headquarters. Irish medical device manufacturing subsidiaries have in general concentrated their efforts on process innovations aimed at cost minimisation. The success of a cost minimisation strategy depends on a steady supply of new products that may have their production processes optimised. If a subsidiary's portfolio of products remains the same from year to year then its ability to deliver cost reductions diminishes as the

process approaches maximum efficiency. Therefore, new products are an essential input factor for the manufacturing subsidiary. If the subsidiary cannot get enough new products at a satisfactory development cost in a short enough development time then it will be restricted in its ability to perform.

2.2.5 Rivalry Between Sister Sites: Sister sites compete with each other for the power to influence the decisions of the parent company. Through this influence they hope to secure and expand their charters. This influence derives primarily from performance, therefore competition between sister sites to build influence extends across all business activities and performance metrics. In addition to measurable performance other factors such as compliance with industry regulations, management personalities, projected image, credibility and persuasiveness also have a bearing on the influence gained by subsidiaries.

This section has presented an analysis of the dual competitive environments faced by subsidiaries of multinational medical device manufacturers based in Ireland. Some strategies aimed at increasing the competitiveness of these subsidiaries have been suggested. A common thread running through many of these strategies has been the utility of local product development as a competitive weapon. The next section assesses the arguments for and against the devolution of some product development responsibility to the Irish based subsidiaries of medical device multinationals.

3. Devolving R&D Responsibilities to Subsidiaries in Ireland

In today's dynamic environment, it is becoming increasingly apparent that the survivors in this new era of business will be those companies who are rigorous in their pursuit of innovation in order to develop and deploy new products more efficiently (March-Chordà et al, 2002; Shepard and Ahmed, 2000; Cooper, 1999). The Irish Medical Devices Association (IMDA) strategy 2004–2007 specifically sets out the vision of making Ireland *'the location of choice for Research and Development'* (IMDA, 2003). The strategic analysis presented in the previous section has demonstrated that product innovation can contribute to the competitiveness of multinational subsidiaries. It has also shown that Irish subsidiaries must maximise their influence on and control of the product development process in order to manage their supply of new and improved products.

There are arguments for and against the devolution of product development to subsidiaries. In the medical device industry it is unlikely that any parent company will devolve complete responsibility to a subsidiary for reasons of corporate cohesion, medical safety and regulatory control. The parent will invariably retain certain 'reserve powers' (Handy, 1992) such as approval of product release to market, co-ordination of development across the organisation and approval of development budgets. However, local responsiveness can be combined with global efficiency when individual operations are encouraged to specialise around a group of core competencies and to act as a resource for the whole organisation. The question of whether product development should be encouraged and cultivated as a core competency in subsidiaries and in Irish

subsidiaries of multinational medical device companies in particular, is considered.

3.1 The Case for Devolving R&D to Subsidiaries in Ireland

The case for building product development capabilities at subsidiary level in Ireland is strong. From the parent company's perspective, some of the strongest arguments derive from the fact that Ireland is part of the European Union. For example,

- 65% of Irish medical device output is sold in the European market (IMDA, 1998). R&D based in Ireland, close to this market is far better placed to tailor products to fit the European customers' needs. Moreover, it is very difficult for Irish based subsidiaries to persuade centrally based R&D functions to support product development projects for products that will not be released in the home country.
- In a study of product approval times in Europe and the US, higher-risk devices were approved three times faster in Europe than in the US, an average of 240 days compared with 773 days in the US (Magazine, 1997). The same study found that low-risk devices had approval times of 120 days or less in Europe compared with 178 days in the US. Consequently, it seems prudent to relocate technological capacity outside of the US to serve non US markets.

- The availability of extensive and generous national and EU supports and incentives for R&D. Many of these supports are available to subsidiaries of non-European medical device manufacturers.

Other advantages to the parent company of having R&D capabilities based in Ireland include:

- The 2004 Irish Budget, published in December 2003 introduced 'tax credits' for R&D expenditure in Ireland.
- The traditional accountancy treatment of R&D expenditure with regard to tax is open to challenge. Companies can argue that if a new product is developed in Ireland, then the intellectual property rights should accrue to the Irish subsidiary. This means that royalties due to the parent from third parties licensing the newly developed product can be paid to the subsidiary and the subsidiary has no liability to the parent for royalties. Likewise, if an existing product is substantially modified by the Irish operation from the form in which it was originally transferred to Ireland, then the royalties payable to the parent on foot of the original patent should be reduced accordingly. Royalty income from products developed in Ireland is tax free. This alternative treatment of local R&D has the effect of increasing the tax advantage of the Irish operation to the multinational company.

- There is a significant amount of academic research being undertaken in medical related fields in Ireland. Materials Ireland was set up to facilitate the diffusion of such research into industrial application. This is an organisation that acts as a single point of contact for the research services in Ireland. This type of industrial development initiative helps make Ireland more attractive as a location for R&D. Furthermore, centres of academic research and company based research functions tend to have strong unofficial linkages. Randle and Rainnie (1994) call this system of linkages the 'scientific network', and suggest that it is characterised by a significant degree of informal collaboration and information diffusion. By building an R&D capability in Ireland, a parent company may be able to identify new developments in relevant sciences that are being researched in this country. Such developments can be exploited by the whole organisation.
- The co-location of product development with manufacturing in Ireland has been seen to shorten the development cycle and increases speed to market. In addition, the Irish medical device industry has a well-developed service supply sector. There are good opportunities for outsourcing specialist tasks (i.e. process validation and regulatory approval processes). Subcontracting these processes has the potential to allow experienced in-house staff time to use their knowledge and improve their skills in developing products to satisfy customers better.

3.2 The Case against Devolving R&D to Subsidiaries in Ireland

The drawbacks of extending the responsibilities of medical device subsidiaries in Ireland to include R&D are now examined.

- One perceived drawback derives from the low rates of company taxes in Ireland. These low taxes have been very effective in attracting inward investment, particularly in the case of the medical device industry. Ironically they have presented a significant disincentive to the establishment of R&D (and other high indirect cost activities) in Ireland. The current Irish tax rate is 12.5% (compared with 35% in the US) therefore, it is tax efficient for large multinationals with a presence in Ireland to declare the greatest proportion possible of their profits in Ireland. As R&D has traditionally been viewed an indirect expense charged against profits, local R&D would tend to decrease the tax advantage of operating in Ireland.
- The medical device industry in Ireland does not have a long history of product development and the experience that does exist is confined to a limited number of companies. Furthermore, some believe that there are shortages of key people in technology areas. These factors seem to be changing as employment in R&D in the sector rose by 20% between 2000 and 2001 (Nolan et al, 2002).
- The lack of a marketing function in most Irish medical device operations means that the Irish Medical Device Industry is remote from its

customers. In 1998 there were only about 100 people directly employed by the Irish medical device companies in sales and marketing roles, i.e. less than 1% of the total workforce (IMDA, 1998). The development of marketing research skills is identified as crucial for the industry in the IMDA Strategy 2004-2007 (IMDA, 2003). The marketing deficiency of the industry reduces the ability of any proposed product development function to engage with customers' and to satisfy their needs.

Investment in locally based marketing/customer service functions has been limited for reasons similar to those given for R&D, these are indirect activities that incur additional local costs, this reduces the tax advantage of operating in Ireland.

- There is insufficient interaction between medical device manufacturers in Ireland and clinicians. Most new medical devices are based on ideas and needs identified by clinicians. In general, 75% of all successful product ideas come from the customer (Cooper and Kleinschmidt, 1996). On the other hand, the conventional R&D centres near company headquarters will typically have long-established clinical linkages. This shortcoming is specifically addressed in the IMDA Strategy 2004-2007, which calls for the more active involvement of clinicians and physicians in the R&D process and suggests that Irish hospitals should be encouraged to use newly developed products (IMDA, 2003).

- Intellectual property is a major output from R&D processes. Multinational head offices may be reluctant to give control of such a valuable asset to a remote subsidiary.

In order to secure a charter extension to include product development activities, Irish medical device manufacturing subsidiaries need to be proactive in persuading the parent of its merits. There are specific actions that subsidiaries can take to strengthen their case for receiving a product development mandate, these are now discussed.

4. Strategies and Tactics for Subsidiaries

There are two strategic arenas in which the subsidiary can take action to advance its position in moving into product development, the internal environment of the subsidiary and the internal environment of the multinational organisation.

4.1 Strategies for the Internal Environment of the Subsidiary

The first task that must be undertaken in building a new product development (NPD) process is to define a set of long-term product development objectives and plot a step-by-step path towards those objectives. In the medical device industry the appropriate planning period depends on the class of the device being considered, but would typically range from 5 to 15 years. This planning process should include direction setting, product line architecture and portfolio management. The product development objectives must also align with the

strategy for all the organisation's functions (Cormican and O'Sullivan, 2003). The product line architecture (i.e. the evolutionary plan for the firm's product offering) that is most suited to medical device development is likely to place an emphasis on platform products because of the lengthy product qualification process. When the platform products have been qualified, the development and qualification of generations of derivative products is relatively straightforward. According to Woolston, (1996), "*The expanding quantities of documentation and the implications of anything other than minor changes to products or processes mean that incremental product evolution is most appropriate in these industries.*"

The development process should also incorporate following:

- A systematic process that gathers all of the project ideas into the process
- A series of filter stages that separate the less important projects from those with high potential, allowing only the best projects to enter the formal process. This ensures that the development function will not be overloaded.
- Rigorous project evaluations and decision points governing the transition of projects from phase to phase.
- Excellent communications, keeping all relevant personnel abreast of activities. When managers who are required to make 'go/kill' decisions on projects are well informed the time from concept to product launch is reduced.
- Performance measurement of the development process.

It is important to note that the extensive systems development that is involved in building an NPD process in an existing organisation generally involves a radical change to the culture of the organisation. The first element of organisational culture that must change if product development is to flourish is management practice. Management must lead the innovation process by visibly demonstrating their on-going commitment to the company objectives, by encouraging the emergence of new product ideas and input to the decision making process from all quarters of the organisation (Cormican and O'Sullivan, 2004). Recruitment policy must target the competencies that need to be grown. Intrapreneurs, product champions and other internal risk takers must be cultivated and encouraged, a greater tolerance for risk taking must become part of the culture of the subsidiary.

The cultivation of internal resources for innovation can be a lengthy and expensive process, however, external expertise is available. Outsourcing elements of R&D to third parties and liaising with external academic and clinical resources is essential to medical device development. Outsourcing some of the specialised but non-proprietary development activities (e.g. clinical trials, animal studies, sterilisation, and biocompatibility studies) leverages internal resources for work on application specific development (Bassil, 2000).

Subsidiaries can also opt to use the centralised resources of the parent for elements of the R&D. Indeed recent indications from the Irish Industrial Development Authority would suggest that a greater share of the 'development' responsibility than of the 'research' responsibility is being devolved to Irish based subsidiaries. This may suggest that parent companies are recognising

the benefits of local product development, but are retaining the central research function for reasons of cohesion and central control.

Subsidiaries wishing to secure local product development must decide on what products to develop and when (Cooper and Kleinschmidt, 1996), must institute a rigorous development process (Cumming, 1999; Brown, and Eisenhart, 1995) must change the culture of the organisation to foster innovation (Ahmed, 1998) and must secure adequate resources for NPD from inside and outside the organisation (Ettlie, 2000). The relationship between the subsidiary and the parent company is crucial to the success of any effort to secure additional responsibilities for the subsidiary.

4.2 Strategies for the Internal Environment of the Multinational

The internal environment of the broader organisation is the second strategic arena in which the subsidiary can proactively advance its objectives of charter consolidation and extension. This means that the subsidiary's management team must be aware of and active in the internal politics of the organisation. The subsidiary must build its reputation and must establish beneficial relationships and alliances with influential people and groups within the organisation.

Personal contacts and cordial relations throughout the organisation help to grow the influence of the organisation, however charter extension of any kind is primarily built on solid performance. Charter extension to include product development is a gradual process involving confidence building between the subsidiary and the parent. Credibility is built initially by performing the given mandate to a high standard. Sustained high performance is the best source of

security for the subsidiary. Development agencies may also be useful allies in making the best case for devolution of product development from the parent to the subsidiary. These agencies may also be able to offer additional inducements in the way of grant aid or training support. Furthermore, the subsidiary should act to remove the impediments to devolution and to reduce the perceived risks outlined earlier.

A subsidiary moving up the value chain would be well served by a similar move into activities down the value chain such as sales and marketing. Growth that extends the scope of the subsidiary, is valued more highly than growth in scale. Increased scope presents the subsidiary with greater opportunities to develop its strategic importance within the multinational. Also, additional activities such as marketing can help a subsidiary to differentiate itself from sister sites.

5. Conclusion

This paper examined the current state of research and development in the Irish medical device industry and has considered the potential of product innovation as a means of increasing the competitiveness of firms in that industry. The competitive analysis of the industry suggests that a value chain migration strategy is appropriate for Irish medical device subsidiaries to counter the forces of external and internal competition. However, there is much less investment in R&D in the Irish medical device industry than there is in the industry worldwide. Since investment in R&D has a direct effect on output, if output is to be increased then investment will have to be increased proportionately. Primary reasons for this lack of investment by the industry in R&D are perceived tax

disadvantages. However, the fact that royalties on intellectual property developed in Ireland are tax-free and availability of tax credits for R&D expenditure may combat this.

Devolution of some R&D responsibilities to medical device manufacturing subsidiaries in Ireland could be mutually beneficial for both subsidiary and parent. An important advantage arises from the enhanced localisation of products destined for European markets. Another substantial advantage is the relative ease with which product approvals can be obtained under European regulations. Many US medical device manufacturers are now using European development sites so as to get their products on the market quicker than they can at home.

Fundamentally, in order to gain some control of their destinies, subsidiaries must be in a position to influence the decision making process of the parent. Subsidiaries build their influence primarily through solid performance of their given responsibilities, but also through initiative taking and through establishing mutually beneficial relationships with influential groups within the organisation. Local organisations with credible performance records will be perceived by the parent as low risk for the devolution of additional responsibilities. Initiatives that migrate operations from lower to higher value added activities can all contribute to the prosperity and security of the subsidiary, but none more so than initiatives to institute effective local product development.

6. References

Ahmed, P.K., 1998, Culture and climate for innovation, *European Journal of Innovation Management*, 1, 30-43.

Bassil, R., 2000, Removing the decision-making slack from new product development Projects, *Time Compression Technologies*, 8, 2.

Birkenshaw, J. and Hood, N. ,1998, Multinational subsidiary evolution: Capability and charter change in foreign-owned subsidiary companies, *The Academy of Management Review*, October, 773-795.

Brown, S.L. and Eisenhart, K.M., 1995, Product development: Past research, present finding and future directions, *Academy of Management Review*, 20, 343.

Browne, J., Harhen, J. and Shivnan, J., 1996, *Production Management Systems: An Integrated Perspective*, Addison Wesley, Harlow.

Christensen, C. M., 1997, *The Innovator's Dilemma: When new technologies cause great firms to fail*. Boston, Mass.: Harvard Business School Press.

Cooper, R.G. and Kleinschmidt, E.J., 1987, Success factors in product innovation, *Industrial Marketing Management*, 16, 215-223.

Cooper, R.G., 1999, From experience: The invisible success factors in product innovation, *Journal of Product Innovation Management*, 16, 115.

Cormican, K. and O'Sullivan, D., 2004, A critical success factors model for product innovation management. Forthcoming in *TECHNOVATION*.

Cormican, K. and O'Sullivan, D., 2003, A collaborative knowledge management tool for product innovation management, *International Journal of Technology Management*, 26, 1, 53-67.

Cumming, B., 1999, *Understanding Innovation from Cradle to Grave*, Butterworth.

Drucker, P., 1993, *Post Capitalist Society*, Harper Business, New York.

Ettlie, J.E., 2000, *Managing Technological Innovation*, John Wiley & Sons, Inc, New York.

Elmuti, D. and Kathawala, Y., 2000, The effects of global outsourcing strategies on participants' attitudes and organizational effectiveness, *International Journal of Manpower*, 21, 2, 112-128.

Galunic, C.D. and Eisenhardt K.M., 1996, The evolution of intracorporate domains: Losing divisional charters in high technology, multidivisional corporations, *Organization Science*.

Handy C., 1992, Balancing corporate power: A new federalist paper, *Harvard Business Review*, 70, November-December, 59-72.

IMDA, 2003, *IMDA Statement of Strategy 2004 – 2007*, Irish Medical Devices Association.

IMDA, 1998, *The Research and Development Needs of the Medical Devices and Diagnostics Sector in Ireland*, Irish Medical Devices Association.

Johannesen, J. Olaisen, J. and Olsen, B., 1999, How can Europe compete in the 21st century? *International Journal of Information Management*, 19, 263-172.

Linder, J.C., Cole, M.I. and Jacobson, A.L., 2002, Business transformation through outsourcing, *Strategy and Leadership*, 30, 4, 23.

Magazine, A. H., 1997, The Impact of Regulation, *Medical Device Technology*, March.

March-Chordà, I., Gunasekaran A. and Lloria-Aramburo, B., 2002, Product development process in Spanish SMEs: an empirical research, *Technovation*, 22, 5, 301-312.

McIvor, R., 2000, A practical framework for understanding the outsourcing process, *Supply Chain Management: An International Journal*, 5, 1, 22.

Nolan W., Hogan A. and O'Reilly K. , 2002, Irish Medical Devices and Diagnostics industry Economic Impact Survey 2000 – 2003, Irish Medical Devices Association.

Porter M. E., 1980, *Competitive Strategy*, New York, Free Press.

Quinn, J.B. and Hilmer, F.G., 1994, Strategic outsourcing, *Sloan Management Review*, Summer, 43-55.

Randle K. and Rainnie A., 1994, Managing creativity, maintaining control: A study in pharmaceutical research, *Human Resource Management Journal*, 7, 2.

Reich, R.B. and Mankin, E.D., 1986, Joint ventures with Japan give away our future, *Harvard Business Review*, 64, March-April, 78-86.

Rodrigues, C.A., 1995, Headquarters-foreign subsidiary control relationships: three conceptual frameworks, *Empowerment in Organizations*, 3, 3, 25-34.

Shepherd, C. and Ahmed P.K., 2000, From product innovation to solutions innovation: A new paradigm for competitive advantage, *European Journal of Innovation Management*, 3, 100.

Tidd, J., Bessant, J. and Pavitt, K., 1997, *Managing Innovation: Integrating Technological, Market and Organisational Change*, John Wiley & Sons, Chichester.

Williams, D., 1998, The development of foreign-owned manufacturing subsidiaries: some empirical evidence, *European Business Review*, 98, 5, 282-286.

Woolston, R., 1996, The Process of Innovation, *Medical Device Technology*, April.