Go west  

Boston Scientific’s CPD strategy wins new product site for Galway

Boston Scientific Galway is the overall Engineers Ireland Continuing Professional Development (CPD) Company of the Year 2010. This exclusive profile outlines the key role its CPD strategy played in the establishment of Boston Scientific’s Galway facility as the new product development site for the next generation drug eluting stent project (PROMUS Element).
Boston Scientific Corporation is one of the world’s largest medical device companies dedicated to less-invasive medicine. For more than 30 years, Boston Scientific has advanced the practice of less-invasive medicine by providing a broad and deep portfolio of innovative products, technologies and services across a wide range of medical specialties. These less-invasive medical technologies provide alternatives to major surgery and other medical procedures that are typically traumatic to the body. In less-invasive procedures, devices are usually inserted into the body through natural openings or small incisions and can be guided to most areas of the anatomy to diagnose and treat a wide range of medical problems.

Boston Scientific has three facilities in Ireland — Galway, Cork and Clonmel. Thanks to its almost constant evolution, Galway is Boston Scientific’s largest plant worldwide, producing a range of products for coronary, vascular, urology and endoscopy procedures. Galway is central to the company’s global leadership in the drug-eluting stent (DES) business. In excess of 12m Boston Scientific stents have been implanted worldwide, and many of these have been manufactured in Galway. The site is currently involved in developing and manufacturing the fourth generation of drug-eluting stents. While Boston Scientific may be the driver of any innovation that takes place in the plant, it is the employees themselves who are pivotal to the success of the site. In 2006, Boston Scientific acquired the Guidant Corporation and gained access to new interventional cardiology technologies, specifically the Everolimus DES technology, and adopted a dual drug DES strategy (Paclitaxel and Everolimus products). This provided the opportunity for Boston Scientific Galway to create a product development strategy for new technologies.

The development of this type of technology / product is key to the long-term success of the company, especially the Boston Scientific Galway site due to its co-location of R&D and manufacturing. Boston Scientific Galway seized this opportunity by carrying out the following key activities:

- the creation of a product development plan to leverage pre-existing skills and knowledge, while allowing for significant new knowledge and skills to be introduced to the Irish site; and,
- the creation of a financial development proposal with the IDA for Boston Scientific’s first Everolimus DES product development project involving a significant R&D investment of greater than $50m.

**Business context**

The objective was to establish Galway as the new product development site for this next generation DES project (PROMUS Element project). Boston Scientific Galway, as a combined R&D and manufacturing site, developed a business plan that was based upon existing R&D, process development, manufacturing infrastructure and skill-sets in Galway. However, this included a number of significant developments...
development opportunities for the site and its staff, in order to develop and commercialise an Everolimus coronary stent system in Ireland. The key components of this were:

- staff competencies / development potential;
- demonstrated knowledge / technical acumen;
- Boston Scientific Galway new–product development performance and track record; and,
- Ireland-specific financial R&D incentives (IDA support).

The project started at Boston Scientific Galway in 2007 with the project objective being to develop and launch the PROMUS Element product to maintain Boston Scientific leadership within the DES market. The product development plan was to transfer the Everolimus technology acquired through the Guidant acquisition and apply this to new Boston Scientific technologies in the field of coronary stents and stent delivery catheters. The following activities were key to the success of the programme:

- Novel combination and leverage of Boston Scientific technologies and processes, based upon the combination of Platinum Chromium Element stent design and Element catheter and Everolimus DES technologies;
- parallel product and technology development; and,
- upskilling of the new-product development group (R&D and manufacturing).

**Project management approach**

The project plan for the PROMUS Element project was developed on best practices of project management based on internal Boston Scientific product and technology process and application of techniques from the project management body of knowledge (PMBoK).
Pipeline Industries Guild - Irish Branch
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Technical Paper Prize Competition
Call for Technical Papers from Recently Qualified Engineers

The Irish Branch of the Pipeline Industries Guild is pleased to invite the submission of technical papers related to any aspect of the pipeline industry. This invitation is confined to engineers with less than three years postgraduate experience as of 31/12/2010 and who are current members of Engineers Ireland.

The judging panel will draw up a shortlist of three papers and the authors will be invited to attend the Pipeline Industries Guild (Irish Branch) Annual Dinner on Friday 11th February 2011 where the overall winner will be announced. There will be a prize of €1000 for the winning author. The winner will be required to present the paper at a subsequent technical meeting of the Guild. Papers, which should not exceed 3000 words in length, should preferably be illustrated. While there is ample opportunity to choose from a very wide range of topics within the pipeline industry, favourable consideration will be given to papers which would be of interest to a broad spectrum of the industry and the content of which would have practical application.

The closing date for the receipt of papers is 14/01/2011. Papers should be submitted in both hard and soft copy format to Mr. Des Maguire, Secretary, Pipelines Industries Guild, c/o Tech Skills Resources Ltd., 25 Merrion Square, Dublin 2. email: des@techskills.ie
The project had a defined scope statement defining the project cost/project schedule/project and product performance metrics:
- cost broken down between R&D, clinical trial and capital requirements;
- project schedule broken down by geographical region due to regulatory/clinical requirements; and,
- project/product performance – primarily based on product performance and customer requirements based upon pre-defined metrics, i.e. product safety, efficacy (based on clinical outcomes) and ease of use.

The initial phase was a technology transfer and development phase and the project was configured around the key required technologies for the product and broken down into technical work streams. After this initial phase of the technology/product, the new product development project was managed through Boston Scientific’s product development process with the initial focus on European product approval and product launch. The project subsequently achieved all of its major milestones.

Firstly, the project performed on plan to the original project schedule developed in 2007 (examples of key project dates are shown below):
- technology transfer and concept selection, 2007;
- global clinical trial (PLATINUM) start, Q1 2009;
- European-CE Mk approval and product launch, Q4 2009;

Secondly, as anticipated in the pre-defined market specifications, the product has met its market projections in terms of product performance (ease of physician use and specifically product deliverability) and its performance is perceived as equivalent or improved to its nearest competition within the EU markets.

Thirdly, the project met all of its pre-defined cost criteria: operating and capital expense, and manufacturing standard costs.

At the presentation of the CPD Company of the Year Award 2010 to Boston Scientific Galway were (l-r): Tánaiste Mary Coughlan TD, Karen Brennan and Terry Vick of Boston Scientific Galway, and John Power, Director General, Engineers Ireland.
Key CPD activity

The development of a DES product such as PROMUS Element typically takes in the region of five years to get from project/technology development to EU launch. For the PROMUS Element stent this development process was targeted to launch in the EU market within three years. This project had to take a different approach and concentrated on achieving this through a focus on its human resources – the project team. The Galway-based team was composed of staff from the following disciplines: project management, R&D and process development manufacturing engineering, quality and analytical and manufacturing.

In order to achieve the project schedule and eventual product launch in 2009, the ‘internal bar’ was raised which included reviewing some processes including:

- **Product development process (PDP)** – focused on investigational device exemption (IDE – release to clinical trial), CE approval, PMA (US approval), PMDA path (Japan approval), design development, test method development, process development, regulatory path and commercialisation;
- **Key test methods improvements/changes** – extensive test method development/ validation was required as this was a different technology from the TAXUS Stent;
- **Key process technology improvements/changes** – process development/optimisation/validation required for all process steps balloons – catheter – DES – packaging was required as this was a different technology from the TAXUS Stent; and,
- **Technology development objectives** – assessed current technologies, carrying out gap analysis and identified what technologies we could leverage from and new technologies that needed to be developed to meet the project requirements.

There were several initiatives involved in making this happen, the three key CPD programmes were: new product excellence essentials (NPE); process development essentials (PD); and knowledge driven...
product development (KDPD).

The NPE and PD essentials are part of a series of ‘essentials’ best practices frameworks for key business and manufacturing fundamentals. NPE and PD essentials are primarily focused on the development and commercialisation of new products and processes. NPE essentials define an approach to enable and sustain flawless, predictable, commercialisation of the new product pipeline, using standard tools and methodologies. PD essentials defines an approach to managing the development of new processes and products that meets product performance and operational requirements through effective planning and execution.

KDPD is a set of principles and methodologies that enables the capture and leverage of technology and product performance knowledge to reduce development costs, resources and time to market.

NPE and PD essentials
The principles behind the NPE and PD essentials are to:
• define and document best practices, tools and templates in a structured reference guidebook available to all relevant support staff;
• collate these best practice tools and templates (with golden case studies) in a single easily accessible location (e.g. intranet);
• provide an overview to all people involved in the New Product Development Process on these best practices and tools;
• train NPD practitioners in usage of each of the individual tools and templates outlined in the guides and accessible on the intranet; and,
• provide mentoring in developing expertise on usage of these best practice tools.

The essentials programme sets the framework for new product excellence and product development where the KDPD programme covers knowledge management and mentoring.

KDPD
KDPD is a set of principles and methodologies that enables the capture and leverage of technology and product performance knowledge to reduce development costs, resources and time to market. It enables the effective redistribution of new product development resources for proactive, predictive technology and product development. Knowledge can be broadly classified into two knowledge types – explicit and tacit.

Explicit knowledge:
• is transmittable in formal, systematic language – words, numbers;
• can be disseminated using IT (e.g. Goldfire); and,
• can be learned in structured, managed specific processes.

Tacit knowledge:
• possesses a personal quality;
• is hard to formalise and communicate;
• is not easily visible or expressible as it manifests in ‘know-how’, beliefs, ideals and value; and,
• can be learned by encouragement, but requires the input of
the right people under the right circumstances. It is important to consider which type of knowledge is being created/shared when deciding on the process/systems to deploy the knowledge, as the optimum mechanism for each knowledge type differs. See Figure 1 for the mechanism currently in operation at Boston Scientific Galway. This model is composed of four quadrants:
- individual mentor to mentee – face to face interaction;
- site-wide mentor group – common goal of a team dynamic facilitates tacit to explicit knowledge conversion;
- inter-site KDPD council and knowledge sharing – organisational structure and systems allow explicit knowledge to be disseminated across the corporation; and,
- principles and training/methods and tools – allows individuals to internalise explicit knowledge.

There is a formal mentoring process in place to support such knowledge transfer through the organisation. This ensures quick learning and standardised processes creating consistency across the network.

**Employee development**

The Boston Scientific employee development strategy drives programmes across the site to sustain training activities to support employee requirements. The Boston Scientific further education programme sponsors key individuals to undertake MBAs, Masters in Bio-Medical Engineering and a host of relevant courses to support the learning necessary to sustain competency requirements. Development assignments are important to this programme, as these enable individuals to perform in a learning capacity in a role and facilitate key learning on the job.

The company’s site employee development strategy is based on a ‘3E’ strategy where: education = 10 per cent, exposure = 20 per cent and experience = 70 per cent. This is a supporting strategy that operates in conjunction with the company’s performance management process. It encouraged employees to plan out their own individual development planning.

**Business benefits**

In conclusion, this project has been a major success within both Galway and the wider company. The initial step of seeking funding from the IDA for R&D projects has been a valuable lever to influence Boston Scientific to situate projects such as PROMUS Element in Galway. This process, together with the progress made on this project, has increased Boston Scientific Galway’s credibility and enabled it to be seen as a strong product development site within Boston Scientific. Iterations to the PROMUS Element product and technologies are developing throughout Boston Scientific and the knowledge development in the staff at Galway enables Galway to be attractive for future R&D projects. The introduction of the PROMUS Element product has transformed the Galway site from a single-drug to a dual-drug manufacturing facility. Technical development roadmaps and work streams; focused endpoints and technical deliverables; NPE and PD essentials; and the KDPD programme will ensure continuous improvement for Boston Scientific new product development in the future. This new product has resulted in a very strong commercial performance, which has led to strong manufacturing demand in Boston Scientific Galway. It is expected to be a key product line for Galway in the future, contributing to the overall profitability of the company.