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Process Development and BSCI's Wayne Operations

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Boston Scientific, a producer of less-invasive medical devices for hospitals and surgeons, was founded in 1979. In the period from 1979 to 2005, the company showed tremendous growth with sales increasing from \$2M to over \$6B. Boston Scientific achieved this growth through innovation and acquisition. The firm acquired the Wayne, New Jersey plant in the late 1990's. Wayne focuses primarily on vascular grafts, which are invasive textile products that are either knitted or woven, and are implanted within the body. Quality is Boston Scientific's most important goal because of the nature of its products and is reflected by BSCI's individually-centered quality policy: "I improve the Quality of Patient Care and all things Boston Scientific." As Ted Weir stated, "If you are going to put something like [a vascular graft] in someone's body, it had better be right." Weir compared Boston Scientific's overall business strategy to the ancient Parthenon, with a foundation that is based on three quality steps - defect prevention, total employee involvement and customer requirement. Its overall vision is "to be the best medical device producer in the world."

BSCI's success is driven by clear goals and clear directions that create synergy with all of its plants while at the same time addressing each plant uniquely. Because of the nature of its business, Boston Scientific has to comply with many regulations. New product development is a difficult process, requiring simultaneous attention to process and product development. "The process development function is a bridge from the other functions into manufacturing," said Weir, "the link between product concepts and production." Firms must incorporate both process and product design in order to make certain that a new product idea is feasible from its conception. Boston Scientific uses a stage-gate process in order to successfully develop new products: (1) proposal, (2) definition, (3) development, (4) validation and scale-up, and (5) commercialization and launch. During the proposal stage the project and its goals are agreed upon. In the definition stage the product is designed and technology assessments are made. The product's performance is verified in the development stage and the firm begins to move into full-scale process development. Next, product design and processes are validated during the validation and scale-up stage. Finally, the product is commissioned during the commercialization and launch stage.

Boston Scientific uses a wide variety of tools to measure process development: Technology Assessments, Event Charting, Process Flow Charts, Design of Experiments (DOE), Process Failure Modes and Effects Analysis (PFMEA), Design Capability Matrix (DCM) and Test Method Validation. The company also integrates Six Sigma and Lean into the core of their thinking. In addition to process development measurement tools, Boston Scientific also uses communication tools including Yield Analysis, New Product Acceleration Meetings, Operations Technical Reviews and DCM.

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According to Weir, the DCM is the foundation of information about product and process development. The DCM is essential because it is performed before the product design is frozen so that necessary modifications can be made. DCM is a color-coded scorecard that can be described with a series of four questions that structure thinking about product and process development. The DCM is reviewed regularly by the vice president of operations and senior plant management to ensure these questions are being answered:

- What product features are important to your customers?
- How much can your specifications vary and not impact your customers?
- Do you have a method to effectively evaluate if you are meeting your customer's requirements?
- Can your manufacturing process consistently meet your customer's requirements?

Use of DCM includes these benefits: realistic product specifications, high process capability with reliable and repeatable test methods, cross-functional ownership, increased communication, clear expectations, performance measures and a demonstration of manufacturing risks.

Having such a clear strategy for new product and process development has helped Boston Scientific's Wayne plant with product introductions such as Taxus™, which was one of the most successful launches in the company's history.