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Career Development of Biomedical Engineers in Medical Device Industry

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Abstract—**With concerns of the current health care system, biomedical engineers have expertise, opportunity and responsibility in developing innovations that may improve cost, coverage and quality of health care delivery. This paper reviews the product development process in the medical device industry, and the associated training and experience required for biomedical engineers involved at each stage of the process. This paper also provides personal perspectives of some of the differences between established device companies and start-ups in the product development process and career paths for biomedical engineers.**

I. Introduction

Biomedical Engineering (BME) is unique in its interdisciplinary approach to training and offers capability to deliver solutions in the complex medical device industry. Our health care system is in critical condition. It accounted for 16 percent of America's GDP in 2007 and consistently ranked lower than other developed nations in outcome. A disruptive solution for the health care crisis can come from medical innovations that improve quality, accessibility and affordability by changing the way hospitals and doctors work [1]. BME education has progressed in recent years with increased recognition of industrial career development. Biomedical scientists and engineers can play important roles in shaping the future business models of health care delivery.

II. Technology and Product Developemnt Process

Both large sized and or early stage medical device companies follow a variation of the stage-gate process [2] for their technology or product development. The process divides a new-product project into distinct stages separated by decision gates. The project team must successfully complete a prescribed set of tasks and meet requirements prior to a gate review and can only proceed to the next stage of development with management approval. In the medical device industry, the typical process consists of four stages: concept evaluation, development, clinical evaluation and product launch.

Concept evaluation is the beginning stage for a new product. In this stage, unmet clinical needs are evaluated, customer inputs are collected, and ideas are captured. A small team may perform discovery work, such as a pre-clinical or clinical feasibility study for proof of concepts. Research departments in many large sized device companies may establish a stage-gate process within the concept evaluation phase to select projects for funding and staffing. The marketing department is involved in this stage to collect customer needs and requirements, a process often referred as "voice of customer". At the completion of concept evaluation, a decision is made if the project can proceed to the next stage for development, typically requiring commitment of larger resources. Medical device start-ups are often initiated in the various phases during concept evaluation. Once inventors or entrepreneurs have completed work that attracted financing, a company can be formed to complete prototyping, pre-clinical evaluation, and sometimes a feasibility clinical study. For the implantable medical device industry, it is common to conduct a feasibility clinical study with external systems, and complete the concept evaluation with a phase one study of an implanted system. Prototypes or early generations of new products are used to gather preliminary safety and effectiveness of the therapy or technology not intended for commercial launch.

The development stage in the medical device industry varies based on the complexity of the product. For example, a new generation of an implantable cardiac pacemaker, may take multiple years and several stages within the development process before completion. The initial stage of development focuses on engineering requirements, first at the system level and then at individual functional levels, such as electrical, mechanical, and software. These requirements need to align with customer input and project objectives established at concept evaluation. The development team often uses project management approaches to plan, organize, prioritize and manage resources among cross-functional teams to meet corporate level schedule. Typical constraints are scope, time and budget. In order to optimize resource allocation and integration the engineering teams may be organized in a matrix structure with each area of expertise residing in individual functional areas relying on a project manager for integration In contrast, smaller start-ups often utilize an integrated approach, in which the project is allocated with dedicated personnel throughout the development phase. A start-up has a very similar development stage to cover all key disciplines with similar constraints regarding scope, time and budget. More than often the start-ups have less sufficient resources throughout their development stages to meet yet more critical (company success or not) objectives

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in a short period. This requires a compact and dedicated team of managers/engineers to function with no redundancy but high versatility (i.e., "wearing multiple hats") to get the job done.

Clinical evaluations are often required for regulated medical products for approved labeling. The evaluation results are submitted for pre-market approval on products without precedence or a 510 (k) filing for products with "substantial equivalency" to the current market products. The purpose of these clinical studies is to demonstrate the safety and effectiveness of a product. In the US, FDA categorizes medical device clinical studies into investigational device exemption (IDE) or non IDE, significant risk study or minimum risk study, depending on study endpoints and risks involved. The development and execution of clinical studies are carried between the sponsor (companies) and investigators (doctors and hospitals). This usually takes dedicated efforts from a group of various scientific and clinical experts. Many established device companies have dedicated personnel working directly with investigators, while start-ups often utilize clinical research organizations (CRO) for clinical trial management.

Product launch can only occur after regulatory approval is received after clinical evaluation. In the implanted medical device industry it is very common to have dedicated sales representatives working closely with hospital staff for implant coverage and device follow-ups. For a start-up a successful product launch will increase the probability for a successful initial public offering or integration with a larger company. Reimbursement policy can play an important role in distribution of new therapies and technologies. Obtaining reimbursement coverage for a new product or therapy from major insurers, such as CMS, requires significant effort from the company to demonstrate its benefit to patients.

III. ROLES OF BIOMEDICAL ENGINEERS

Concept evaluation relies on biomedical engineers and scientists often affiliated with a research department for discovery work and intellectual property development. Biomedical engineering, with its multi-disciplinary curriculum in training, is well suited for developing careers at this stage. The needs for understanding human physiology and clinical issues, generating hypotheses, designing and conducting experiments are all important in preparing careers for the medical device industry. Established device companies often have dedicated facilities for prototyping and pre-clinical studies, while start-ups need to rely more on vendor services and independent problem solving skills of their limited staff. One particular challenge many graduates with an advanced degree may face is the need to adapt to the ever changing company directions and market demands.

In the development stage, system or architect level engineering, an interdisciplinary field of engineering, can also be well suited with biomedical engineering training. A system engineer translates customer requirements into engineering requirement. This is no small task with a complex medical device that may involve hardware, firmware and software. A solid understanding (if not experience yet) of the major engineering disciplines is important for the role and a real career advancement factor is an intimate understanding of the clinical application of the product.

Clinical engineering, sometimes considered a specialty within biomedical engineering, is responsible for implementing medical technology in clinical evaluation and often health care delivery itself. Many device companies have dedicated field clinical engineers (FCE), who work closely with hospital staffs in all phases of clinical evaluation. Problem solving skills as well as interpersonal skills are particularly important in working in this dynamic clinical environment.

Sales and marketing professionals involved at the product launch stage can also come from a background in BME training. In addition to other important factors for being a successful sales and marketing professional, the BME training may offer greater depth and understanding of the medical technology in addressing clinical needs. After all, audiences are often physicians, medical doctors or related professionals.

IV. SUMMARY

The medical device industry presents many opportunities for a biomedical engineering graduate to develop a successful career. The global demand for access to cost-effective and high quality medicine will continue to make medical technologies and innovations the engine of growth in future decades.

REFERENCES

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