AC 2007-668: UNDERSTANDING THE MEDICAL PRODUCT DEVELOPMENT PROCESS: CONTINUING PROFESSIONAL DEVELOPMENT FOR LIFE SCIENCE PROFESSIONALS

Rogelio Rodriguez, UC Irvine

Rogelio C. Rodriguez, M.S. Director, Engineering and Science Programs University of California Irvine Extension

Continuing Education professional with 12 years experience in the planning, development and implementation of advanced professional development education. Has led continuing education development efforts in the areas of engineering, science, and life sciences. ASEE member, 2006–2009 commissioner for University Continuing Education Association (UCEA) Leadership and Management Commission, and 2006-2007 President for Association of Analytical Chemist (AOAC) Southern California Section.

Understanding the Medical Product Development Process: Continuing Professional Development for Life Science Professionals

Abstract

Navigating the medical product development maze from concept to market can result in a challenging experience. The life science industry is a highly regulated industry and depending on the medical product and classification (device, pharmaceutical, or biologic) the approval process can be complex and lengthy. Unlike high-tech products such as consumer electronics which may have a relatively short time-to-market cycle, medical products can take anywhere from 3 to 7 years before they make it to the market.

Modern technology has made many inroads in the advancement of medical technology and engineers and scientists are playing a key role. As students make the transition to becoming professionals and professionals seek to enhance their careers, continued education and skills enhancement is taking center stage. This paper describes the development of a continuing education certificate program in medical product development for both professional development and workforce development. Various disciplines may be involved throughout the development cycle from marketing to engineering to regulatory affairs. Possessing a thorough understanding of medical product design and manufacturing increases the level of expertise needed to enhance the safety and quality of medical products. A common development cycle for medical products is presented with explanations of the various phases within the product development cycle.

The Medical Product Development Certificate program has been designed to provide core knowledge of the medical product development process. Through evaluated learning and competency-based courses, students increase their knowledge of clinical and regulatory compliance, good manufacturing practices, and quality assurance.

Influential factors in the global need for life sciences are growing population and changing demographics. The global patient base is currently estimated to be 6 billion people and expected to grow to approximately 8 billion people by 2025. The aging population is growing with the 60+ group as the fastest growing group. Changing disease burdens add to the global need for life sciences by 2020 and 75% of all projected deaths are age-related, chronic conditions. As economies improve, global governments are placing more resources into healthcare.[1] In the United States, there are approximately 6,000 medical technology companies generating an estimated $77 billion in revenue. These companies develop pharmaceuticals, biologics, or devices.[2] California has one of the largest percentages of life science companies in the U.S., as reported by CHI 2006 California Biomedical Industry report, 2,700 companies and approximately 46% of those companies have 100 or less employees.[3]

Industry dynamics are driving the formation of new business models with distinct characteristics. Globalization, R&D, innovation breakthroughs, and volatile capital markets have influenced companies to move more towards specialization, outsourcing, collaboration, and establishing strategic networks. As a result, there has been a decoupling of traditional value chain activities leading to specialized business activities. Traditionally an integrated company would be associated with many of the activities involved with the product development lifecycle: research; product development; pre-clinical-testing; clinical trials; manufacturing; and marketing. It is now common to have product development involve many distributed companies, including clinical research organizations (CROs), clinical research managers (CRMs), manufacturing, and testing services. With many more distributed companies coming into the product development lifecycle, a variety of concerns arise – FDA regulatory practices and compliance, issues related to intellectual property protection, customer demand for cost-saving or cost-effective technology, and Medicare coverage and reimbursement requirements.[4]

Increased organizational complexity for companies can have implications on managing the product development lifecycle. To remain competitive and agile to global competition, there is a greater role and need for the number of professionals to oversee external service providers and manufacturers. These professionals are required to understand and comply with various regulations for different product development stages and company types. There are a variety of regulations that Life Science companies must comply with and the most common are ISO, FDA, HIPAA, and JACHO. There are three regulatory centers under the FDA that medical products fall under, Center for Devices and Radiological Health (CDER), Center for Drug Evaluation and Research (CDER), and Center for Biological Evaluation and Research (CBER). Each of these centers has specific regulations and compliance measures for medical product approvals. Of particular importance is current good manufacturing practices (cGMPs), quality systems regulations (QSR), and design controls.

Current good manufacturing practice (cGMP) requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.[5]

Quality system regulations (QSR) refer to compliance practices related to the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.[5]

Design controls are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements, and discrepancies between the proposed designs and requirements, are made evident and corrected earlier in the development process. Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use. [6]

Medical product development from concept to market requires a considerable amount of knowledge at different job levels. Various disciplines may be involved throughout the development cycle from marketing to engineering to regulatory affairs. Possessing a thorough understanding of medical product design and manufacturing increases the level of expertise needed to enhance the safety and quality of medical products. The medical product development process can be described by three stages: early stage, development and approval stage, and commercialization stage.

In the early stage the key considerations are concept and innovation, market research, product definition, and product reimbursement. From a conceptual point of view the product needs to satisfy a medical need with a thorough understanding of the end user or innovative new ways to address existing practices. Marketing research can provide further insight on the level of need for the product and define requirements for the product. Reimbursement by Medicare and other third-party payers is critical to the market success of many drugs and medical devices.

During the development and approval stage the key considerations are clinical and regulatory planning, product design, and design and process validation. It is important to determine what clinical research will be required early on and which regulatory pathway is required for the product – pharmaceutical, device, or biologics.

If clinical trials are required, the general process is described below:

- Early Research and pre-clinical testing – Identify pre-clinical type, protocol, and design
- Phase I: Preliminary Safety Evaluation Studies – compliance with good clinical practice.
- Phase II: Efficacy Evaluation and short-term safety studies – validation of clinical data.
- Phase III: Results used in regulatory approval application for market approval – release clinical trials results.
- Phase IV: Post market studies, approval, and outcomes research.

Once the product is at the commercialization stage the key considerations are market evaluation, post market reports, vigilance, and safety. Medical product misuse, adverse effects, and clinical evaluations often require FDA reporting.

Based on the information that has been presented the Medical Product Development program has been design for a wide variety of Life Science professionals in biomedical, biotech, and clinical arenas who need either specific knowledge of the medical product development process or a broad understanding of the products they use or market. The program can benefit engineers, research scientists, product managers, regulatory professionals, quality managers, non-technical managers, manufacturing professionals, clinical professionals, and other healthcare professionals. The curriculum addresses the breadth of the development process, including a thorough understanding of FDA regulations and compliance, quality engineering for improved performance, how to mitigate commercial and financial risks, and building marketing success.

Jobs range from conducting research at Universities, or private-sector companies, manufacturing, clinical trials, regulatory affairs, to marketing. In many of these environments managers are constantly challenged with attracting and maintaining a skilled workforce to sustain their companies' competitive advantage. A continuing education program such as this can be instrumental in developing an effective workforce that is viable to the success of a Life Science organization.

The curriculum for the Medical Product Development certificate program at the University of California Irvine Extension consists of the following courses:

Required Courses (9 units)

- Medical Product Lifecycle Management (3 units)
- Regulatory Requirements for Medical Devices (3 units)
- Regulatory Requirements for Pharmaceuticals (3 units)
- Medical Product Quality Systems (3 units)

Elective Courses (choose 6 units)

- Medical Product Manufacturing (3 units)
- Fundamentals of Clinical Trials (3 units)
- Application of Good Clinical Practices (3 units)
- Intellectual Property Law for the High Tech Industry (1.5 units)
- Medical Product Reimbursement (3 units)
- Process Validation for Medical Products (3 units)
- Medical Device Design and Evaluation (3 units)
- Medical Device Risk Management (3 units)
- Software-Controlled Medical Devices (3 units)
- Medical Device and Pharmaceutical Combination Products (3 units)

The certificate program was initiated in 1998 with a series of stand-alone courses associated with regulatory affairs. Based on the peaked interest in this type of courses, an advisory committee was formed including life science industry representatives, consultants, faculty, and FDA representation. Initial recommendations were made to address the medical device industry but that would leave out addressing the needs of the pharmaceutical industry. Thus, the title of the certificate was agreed upon to be Medical Product Development, implying that the medical product can be either a device or pharmaceutical. The program has gone through three revisions with each revision the make up of the program has been changed to meet the changes in the

market place. The essence of the program is to provide core knowledge of the medical product development process. Key to the success of the program is having experienced instructors who specialize in the areas they teach. It is through their industry experiences that applied and practical knowledge can be established that is relevant for the students' professional development and workforce development for industry. Convenience of schedule is also important as well as effective marketing strategies.

Establishing credibility as a provider of regulatory training can be a daunting task when competing with life science associations or independent regulatory training providers that offer seminars, workshops, or short courses. It is through competency-based courses and evaluated learning, which enables students to increase their expertise in the areas of clinical and regulatory compliance, good manufacturing practices, and quality assurance.

Since 1998 to the present, 550 students have enrolled in various courses in the program. Some students have taken only those courses that are the most relevant to them while many others have decided to complete the entire certificate program. 90 students have graduated from the Medical Product Development program and there are currently 52 students who have declared candidacy for the program. Students have represented over 120 companies ranging from life science companies to hospitals to university medical centers. Although the majority of the students have been from Southern California there is a representation of students from other states as well as international students. On-line courses have been added which has expanding the opportunity to offer distance education to students outside our geographic area and also to companies in lieu of on-site courses.

Most recently UC Irvine Extension and the Keck Graduate Institute of Applied Life Sciences have entered into an agreement where graduates from the Medical Product Development Certificate Program, upon formal admission to the Keck Graduate Institute of Applied Life Sciences, can transfer course credits towards their Masters of Bioscience Program. This brings an added value to our certificate graduates who seek to further advance their education.

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