Facilitating Innovation through Regulatory Engineering Education: An Academic Program Overview

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Abstract

In the past 50 years, the medical device industry has been profoundly impacted by significant technological advancements. These new technologies, coupled with the expansion of global regulations, and changes to global regulatory requirements for biomedical products, have dramatically changed the regulatory landscape; creating new complexities affecting the innovation - to - commercialization pathways and timelines. Universities have largely provided the science and engineering curricula and research support driving the technical capabilities and aspirations of delivering these innovations for broad clinical use. However, engineering curricula have fallen woefully short for one particular consideration, namely, the explosion of new or changing regulations, and their impact and application throughout all critical stages of the biomedical product development lifecycle and, holistically, throughout the technical biomedical business. This deficiency grounds the failure of universities to consistently and reliably bridge the gap between what the engineer learns in school and what they must do on the job in a regulated industry, to effectively bring a product to market. This deficit is a global problem that seriously affects our ability to deliver critically needed biomedical solutions in a timely manner. Engineers must be equipped to navigate the increased complexity of this modern regulatory landscape, address the nuances of the biomedical industry, and lead the delivery and preservation of innovative technologies that can withstand intense regulatory scrutiny while satisfying the clinical needs and stakeholder expectations.

Keywords

Regulatory, Medical Device, Engineering, Innovation, Biodevelopment.

Introduction

The medical device industry is a highly diversified industry that produces a range of products using advanced technologies designed to diagnose and treat patients worldwide. New healthcare needs, an aging population, and people living longer, drive a demand for innovative medical products. Regulations define how these products get into clinical use and the scope spans the entire product lifecycle. Having an isolated, point-in-time knowledge of a specific regulation is not adequate. New technologies are outpacing the already dynamic regulations, laws, and regulatory guidance, increasing the volume and complexity of global regulations and the number of regulatory bodies increasing their oversight of biomedical products. Hence, the sophistication of today's technology, the advanced innovation of tomorrow, and the expansion of global regulations have dramatically changed the medical device regulatory landscape. This expansion of global regulations, and innovative technologies that breed new or changing regulations, are having a significant impact on the innovation-to-commercialization process and timelines. This

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impacts efforts in research, as well as in academic and industry environments. The National Institute of Health (NIH) and US Food and Drug Administration (FDA) have drawn the same conclusions.

The NIH National Center for Advancing Translational Sciences posts, in summary, that researcher's nationwide face increased regulatory burdens as a common challenge in clinical and translational research that can delay the development of new devices for patients in need.[1]

The US FDA's Center for Devices and Radiological Health (CDRH), a government branch responsible for interpreting and enforcing regulations, indicates that 'barriers for moving a device out of the research lab into the clinic are navigating the FDA and lack of knowledge and experience with the regulatory process.' [2]

It was concluded that a 'better understanding of regulatory processes will accelerate the delivery of innovative medical devices to patients.' [3]

There has been an increasing number of regulatory education programs developed in response to the growing need by academic researchers, medical device and healthcare industries and regulators. These programs have been independently developed, housed in different departments or schools, and with curriculum content ranging anywhere from a general focus on a broad spectrum of regulated product, to a specific focus on one type of product technology. In 2010 a representative from the University of Southern California invited other representatives from sixteen regulatory programs across the globe to come together and discuss issues of shared concern. This became the first international meeting for graduate regulatory programs aimed at fostering better communication among the variety of programs. Participants agreed to develop and share best practices pertaining to graduate regulatory education.[4]

In 2011, the FDA CDRH launched their Innovation Initiative to help decrease development costs and accelerate regulatory evaluation of innovative devices.[5] This initiative established a Medical Device Technology Forum (MD-TIP), bringing regulators, academic institutions and key opinion leaders together to discuss experiences and identify the academic needs of entrepreneurs, students, and faculty, to share information and to assess how to train and equip the next generation of biomedical innovators. They presented their inputs and discussed the need to develop educational programs specifically in device development and assessment, as well as to enhance academic knowledge and experience with regulatory process. [2]

This initial group of academic stakeholders formalized in 2014 into the Association of Graduate Regulatory Education (AGRE). AGRE was established to promote consistency in the body of regulatory knowledge. They put forth a set of core competencies describing what graduates should know and be able to do from a regulatory science based curriculum and discuss the relationship between these skills and knowledge, and the expectations of potential employers interested in delivering innovative biomedical products.[6]

"The practice of regulation in the healthcare industry is both science and art. The science primarily encompasses healthcare products and the technologies behind them, and verification and validation of safety and effectiveness. The art lies in the interpretation and application of the regulatory requirements and the development of regulatory strategies that meet agency objectives

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and support business goals. MS programs must capture and impart knowledge about both the science and art of regulatory affairs."[4]

Strong multidisciplinary teams who understand the technology, the regulated product development process, the global regulated commercialization pathways, and the business and industry influencers that inform or constrain the regulated product lifecycle are essential to successful innovation-to-commercialization. It is the inherent strength of this team that is often what makes a product commercially viable for clinical use, and sustainable. In industry, these multidisciplinary teams are often led by highly competent engineers. However, employers are in need of engineering professionals with an interdisciplinary background, who understand how to practice their skill in the regulated environment.

While engineering programs focus on instilling the technical skill in students, regulatory knowledge and regulatory science, or the practice of regulation, has not been holistically integrated into engineering curriculums. Delivery of successful medical products is a consolidation of creative and innovative thinking, clinical understanding, business and regulatory compliance knowledge; and the quality and engineering skills needed to create safe, effective, reliable biomedical products that can withstand intense regulatory scrutiny while safely and effectively satisfying the clinical need.

Engineers must be equipped to address the increased complexity of this modern regulatory landscape and the nuances of the medical device industry to enable them to seize the multidisciplinary opportunities of working in this highly exciting and rewarding professional area, in the present and the future. There is an unmet need to educate engineers, researchers, and technical entrepreneurs on the practice of medical device regulation through the critical phases of the product lifecycle. Therefore, engineering academic programs must build the bridge to traverse the gap between what the engineer learns in school and what they must do on the job in the regulated industry to successfully bring a safe and effective product to market, in a timely and cost effective manner, and keep it there.

Biodevelopment Background

Biodevelopment is the term used and believed to be coined by the author in the way as to describe the systematic, multifaceted and regulatory science-centric approach to the strategic use and practice of regulations; throughout the critical stages of the biomedical device translational science continuum, the new product development lifecycle, and the business of medical devices as a whole. The Biodevelopment mission is to reduce or remove regulatory barriers and facilitate and accelerate the development and translation of scientific research discoveries and biomedical device innovation into commercially viable products that can help people in need.

The four-part platform of the Biodevelopment program is depicted in figure 1. It has been designed with three objectives in mind: 1) advance regulatory and translational science in the medical device industry; 2) establish and optimize multidisciplinary research collaborations and clinical operations to accelerate translation of innovative medical devices; and 3) cross train and equip engineering students, clinical researchers, medical device innovators & technical entrepreneurs with: the knowledge, skills and experience necessary to successfully manage the nuances of the medical device industry and address the increased complexity of the modern

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regulatory landscape; and the cross functional knowledge and know-how to facilitate engineering practice along diverse biomedical career paths.

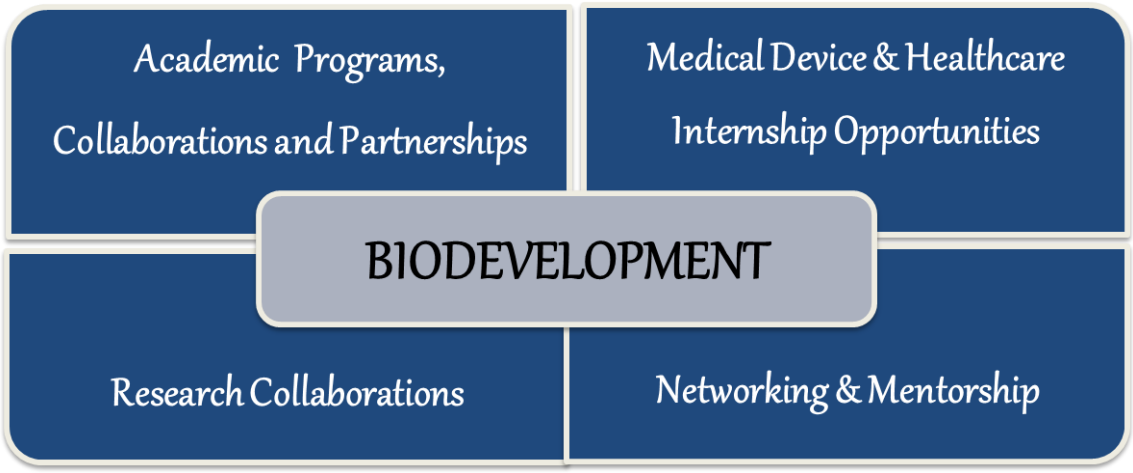

Figure 1 Biodevelopment Four-part Platform

Biodevelopment was originally architected to solve a need repeatedly experienced in the author's industry tenure. That is, a critical need for highly competent engineers and professionals with the understanding of how to efficiently and effectively navigate the regulatory environment and successfully practice their skill in the multidisciplinary, regulated industry. This deficiency was often the culprit for confusion, rework and disharmony that resulted in added complexity, expense, and time delay throughout the product development lifecycle. The needs of the industry haven't been holistically satisfied by academic engineering programs.

Biodevelopment Academic Curriculum Overview

As the regulatory landscape has changed, so have the demands on engineers that practice in this environment. These professionals must develop, in addition to technical skills, the strategic and operational skills necessary to move the technology through the development phases, and beyond. The Biodevelopment educational model has been designed to mirror and complement the product lifecycle. The scope of regulated deliverables spans from preclinical and clinical research to regulatory commercialization strategies, product development, quality, manufacturing, labeling and product approvals, business and product registration, reimbursement, advertising and promotion, distribution of product, post market surveillance, and design changes. This expanse is not a linear one, rather a spider web of interconnected if-then scenarios. Understanding how the design and technology decisions at one stage can critically affect the business activities in a seemingly unrelated stage, and being able to navigate through this fluctuating global regulated minefield of "it depends" pathways is a critical competency. This can dramatically influence the efficient translation and effective commercialization of research and innovation in a timely fashion. It's a unique problem combining the need for practical expertise in engineering, science, regulation and business.

The Biodevelopment academic model overview depicted in figure 2 identifies a series of specific regulatory science-centric courses with concepts and topics that systematically span the product

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lifecycle to holistically and adequately address the unmet need in engineering education. The figure shows the general elements of the product lifecycle, representing the clinical translational continuum and the stages of new product development. Atop a set of core courses centered within the lifecycle, are integrated courses that are germane to the pre and post-market influencers that inform multidisciplinary engineering practice, innovation, and technical entrepreneurship and that impact the delivery of a safe and effective biomedical technology to market, and the ability to keep it there. Beyond this objective, some of these courses are specialized to introduce and support different career paths for engineers while others, represented in lighter text, are suggested electives. In addition to a University's required graduate engineering courses, students would take three core Biodevelopment courses and choose a fourth course pertaining to an interested and more informed career path, e.g. clinical engineering, design and quality engineering, regulatory affairs, manufacturing engineering, etc. Special topics electives in variable areas of emphasis can be offered to accommodate more intense preparation and practice along the desired career path.

The focus of this program is aimed at cross training, equipping, developing and preparing the next generation of engineers, entrepreneurs and innovators with the necessary understanding to effectively address the increased complexity of the modern regulatory landscape, and the cross-functional knowledge to support diverse career paths that can successfully manage the nuances of the medical device industry.

The next level in the Biodevelopment design hierarchy is the curriculum framework. Within this framework are key competency area objectives: Regulations, Clinical, Strategy, Quality, and Communications, with definitions adapted from those established by AGRE. This framework includes a collection of essential, customary, technical, interdisciplinary topics applicable to the various phases of the lifecycle and includes real world deliverables that afford students some industry equivalent experience. The systematic design of the classes and their associated real-world deliverables offer an integrated approach such that outputs of one course may be inputs to another. Courses are intended to be taught by a coordinated team of qualified industry experts, regulators or skilled academics who can bring years of practical experience from the industry to the classroom and keep content current to the global medical device industry. Integration of industry projects, and use of state of the art software tools, case studies, guest lectures, capstone projects and practical hands-on assignments are necessary to reflect current, real world engineering deliverables in the medical device industry.

While the framework offers a standardized academic approach and methodology, there remains the flexibility for universities to tailor the program to accommodate variable degrees programs, different geographic regions, desired delivery methods, and the application of this methodology to other highly regulated fields. This academic framework also offers the flexibility to accommodate different areas of university research interest and expertise, such as with focused case studies, the integration of particular special topics courses, or with specific industry projects, while supporting diverse career paths. The standardized framework also provides consistency for the students between universities and across course offerings and enables the basis for university accreditation compliance.

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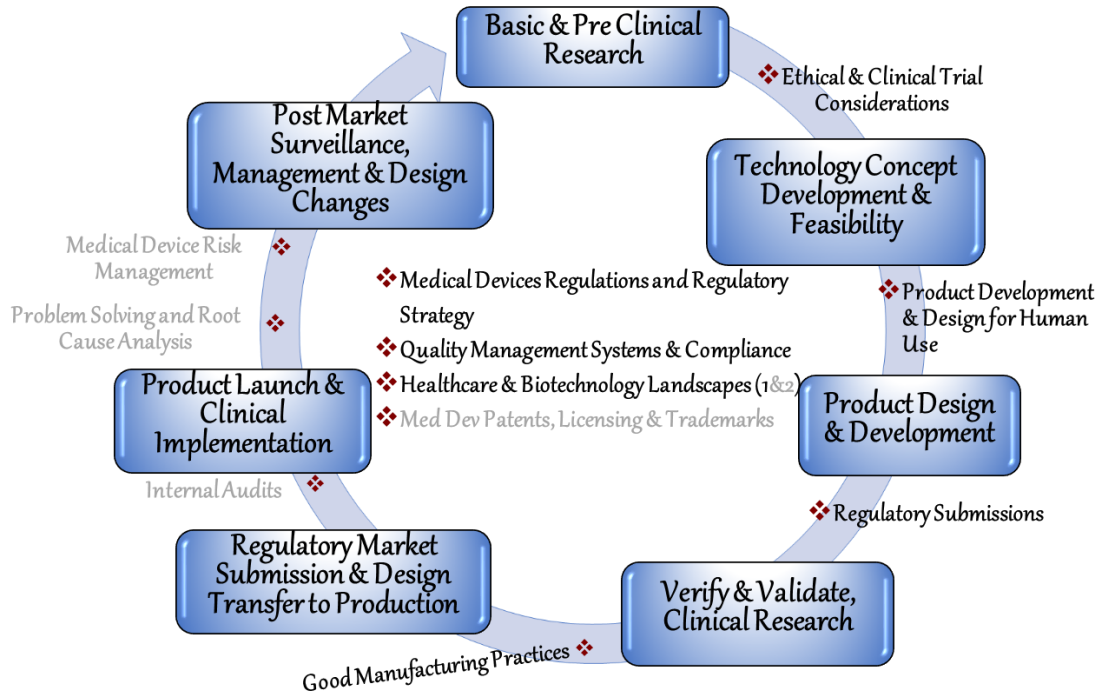

Figure 2 Biodevelopment Academic Model

The proposed academic program is intended to augment the technical engineering education and can be integrated as part of a Regulatory Engineering Masters of Science degree plan, as a traditional engineering Master's degree concentration, as a medical device certification program, and even be offered as standalone professional or medical outreach courses. Various academic tracks, branching off of the common core courses, could be implemented to complement the engineering curriculum with emphasis on support for various roles required of: engineers, researchers, medical device innovators, technical entrepreneurs, and individuals who are currently employed in or wish to enter the medical device industry. Because this globally regulated industry has unique requirements, global university collaborations are recommended, e.g. sharing of best practices, assess unmet needs, develop collaborative programs, student exchange(s),etc.

Conclusion

As we have stated, technologies and expansion of global regulation of medical products have dramatically changed the regulatory landscape. Innovative emerging medical technologies and the changing regulatory requirements create new complexities affecting the innovation-to-commercialization timelines.

The Biodevelopment graduate engineering framework is intended to equip and adequately prepare the future leaders in the medical device industry. It delivers a regulatory science-centric academic approach designed to augment the traditional graduate engineering curriculum with the practice of regulation across critical phases of the product lifecycle, and throughout the medical

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device business as a whole. If deployed as more than a check box education, it can produce critical thinkers, armed with the ability to solve how to address the complexities and nuances of the modern medical device regulatory landscape. These graduates will be able to strategically use regulations in commercialization and business strategy - not passively fall victim to them.

By cross-training and equipping engineers with the interdisciplinary knowledge, tools and skills needed for timely, commercial translation of safe and effective products; acquainting them with the various controlled actions and resulting deliverables required to take discoveries from concept to the market place within the regulatory environment; and understanding how to work in cooperation with the regulatory agencies, the rate at which innovations move forward through the regulatory commercialization pathway can be dramatically increased.

In addition to augmenting an engineering program, this body of knowledge can complement an interdisciplinary graduate curriculum, such as within a Business school, Law school, or Medical school. Target employers for graduates with this type of competency may include a variety of roles within the biomedical industry, regulatory agencies, hospitals, Institutional Review Boards (IRBs), incubators, and consulting firms. This approach can also be ported to other regulated disciplines.

In conclusion, the world's regulatory requirements are forever changing the landscape for many technology industries, particularly in the medical device industry, as well as other product development areas that affect the health and safety of consumers. This ever changing industrial environment is resulting in a revamping of the academic preparation for engineers and scientists who are interested in careers and professional advancement in these disciplines. The program described herein, is an effort to meet these new opportunities; to the benefit of the students, the related industries and research entities, the regulatory agencies, and the consumers.

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