Board 5: Work in Progress: Developing Medical Device Evaluation Knowledge in Biomedical Engineering Graduates

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A thorough knowledge of the Food and Drug Administration (FDA) regulations of medical devices and the understanding of a clinical device evaluation process are among the core competencies sought by industry employers in their biomedical engineering (BME) hires. The Bureau of Labor Statistics projected BME to be the fastest growing engineering occupation from 2016 to 2026 with a predicted employment growth of seven percent [1], and the World Health Organization highlighted regulation and standards of medical devices among the BME disciplines required for careers in industry and government [2]. It was also contended that quality engineering concepts that include device regulation, standards and safety engineering may be even more important than product development (design) in BME education [3]. In preparation for an institution-wide curriculum revision, in May of 2014 we conducted our own survey of the BME stakeholders consisting of our program alumni, typical employers, Industrial Advisory Committee and BME faculty members from other institutions to establish the core BME competencies required for successful job placement, career building and differentiation of our graduates. The majority of our stakeholders listed medical device regulation and standards, clinical trial design and statistical analysis among the concepts requiring comprehensive coverage in the modern undergraduate BME curriculum.

In the past, we have been only marginally successful teaching these topics to our students. Due to various curriculum constraints (e.g. a long capstone design course sequence), the coverage of regulatory topics was largely high-level and scattered over multiple courses. Student feedback indicated that these topics had little continuity and lacked the details and specific examples necessary to appreciate their importance in biomedical engineering. During a recent curriculum revision, we shortened our capstone design sequence from seven to four academic quarters [4] and introduced a new course, *Biomedical Device Evaluation*, with emphasis on FDA regulation and clinical device evaluation processes. The course was designed to address the demands for knowledge of regulatory affairs in the medical device industry and to provide our students with a solid framework for understanding and appreciation of these concepts.

Course Description

Biomedical Device Evaluation is a three-credit, required BME course that is offered in the fall quarter of the senior year. The course is offered at the same time as the second capstone design course in which the students continue assessing the feasibility of their design projects, develop their functional design specifications and work toward system-level designs. Thus, the device evaluation course complements the design process topics with those of regulation and device evaluation and allows for course assignments specific to the students' design projects. The course is offered two quarters after the *Professional Topics in Biomedical Engineering* course and builds upon other professional BME topics such as intellectual property, engineering standards, design for manufacturing, healthcare economics, globalization of medical devices,

ethics in medical device development, documentation, and user requirements and design inputs [5]. Together with the capstone design sequence, these courses constitute a comprehensive view of the medical device development process and allow for a fairly in-depth coverage of the medical device regulation process.

The instructional materials for this course were put together from the resources available on the FDA portal as well as the two reference textbooks in [6, 7]. The course also includes at least three guest speaker presentations from regulation experts of the medical device industry and the FDA. This year's presentations covered the topics of international regulations, the FDA De Novo process for medical devices with artificial intelligence subsystems, and FDA compliance audits of medical device manufacturers. To keep the course content current and aligned with the ever-changing regulations, it will be updated annually prior to each course offering. The device evaluation course topics, their sequence and coverage are shown in Table 1. The coverage is based on the course duration of eleven academic weeks with three lecture hours per week (the eleventh week is dedicated to final exams).

Table 1: Biomedical Device Evaluation Course Topics and Coverage

Coverage	Topics
One week	• U.S. history of regulation and FDA • FDA regulation of pharmaceuticals vs. medical devices
One week	• Medical device definition • Classification of medical devices
Two weeks	• Market pathways for medical devices o 510(k) exemption o 510(k) premarket notification o De Novo o Premarket notification (PMA) o Humanitarian device exemption (HDE)
One week	• Regulatory requirements for clinical studies of medical devices o Investigational device exemption (IDE) o Risk management o Clinical studies for insurance reimbursement
Two weeks	• Design of clinical studies for medical device evaluation o Standards and compliance in clinical studies o Statistical methods in clinical studies
Two weeks	• Case study presentations by student groups [6, 7] o Clinical Studies of Prosthetic Heart Valves Using Historical Controls o Role of Device Retrieval and Analysis in the Evaluation of Substitute Heart Valves o Prospective Multicenter Clinical Trials in Orthopedics o Challenges in Conducting Implantable Device Trials o Polyurethane Pacemaker Leads o In Vitro Diagnostics. Design of Clinical Studies to Validate Effectiveness.
One week	• Guest industry and FDA presentations on contemporary regulatory issues.

Course Assignments

In addition to five quizzes and one statistical analysis assignment, the following two major projects are assigned to students throughout the quarter.

Case Study Presentations

To appreciate the complexity and the challenge to apply a "one fits all" regulatory model to different medical devices, the students are placed on teams of 4-5 students and asked to evaluate and present case studies of medical devices that had a major impact on the U.S. and international regulatory processes. The case studies assigned this year are described in [6, 7] and discuss regulation history, clinical evaluation as well as the pre- and postmarket studies of heart valves, orthopedic, left ventricular assist, pacemaker and in-vitro diagnostic devices (Table 1). The student teams were asked to conduct individual research to complement the information discussed in each case study and be sure to present the most current data in class. Each team was given one lecture hour to present their case study and to facilitate a class discussion. In each course offering, it is intended to change or supplement the case study topics with new information or devices to stay current with the device-specific changes in the regulatory field.

Final Project

To connect the clinical study design topics with the students' senior design projects, the students are asked to work with their design teams of 4-5 students to develop and present a bench test protocol for one of their design project's functional specifications. The selected specification must be essential to the performance of their design prototype and must require fairly extensive testing. The teams are asked to develop an experimental protocol as well as the data and statistical analyses plans to test their chosen specification. When possible, the teams are encouraged to present the preliminary results or simulations. This project is assigned at the beginning of the quarter, and the teams are encouraged to work on it throughout the quarter in parallel with their design process. The project results are then presented in class in place of the final exam.

Assessment

In the current academic year, the *Biomedical Device Evaluation* course was taught for the first time (N = 45 students). In May 2019, a survey will be administered to assess the students' perceived knowledge of the regulatory and device evaluation topics, their level of confidence in that knowledge relative to other professional BME topics, and its applicability and relevance to their senior design projects. The same students will also be assessed to investigate the effectiveness of the new design process overall [4], with the data from this study providing the supplementary information in that regard. Furthermore, the survey will investigate whether the knowledge of these topics was helpful during the students' job interview process when seeking employment in industry or government. The assessment survey is currently being developed.

References

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