Senior Design

preparing students for capstone design

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The senior capstone design course is the culmination of the previous three years of the undergraduate curriculum. The goal of this course is to develop students' communication (oral and written), interpersonal, teamwork, analytical, design, and project management skills through a team-based design experience. Students learn about the product-development process and gain experience solving open-ended problems. Capstone design courses give students insight into what it is like to work as an engineer.

Many students begin the capstone design course with several weaknesses. First, for some students, the senior design project may be their first team-project experience. They may lack the teamwork skills needed to successfully complete a team project, are used to having more control over project outcomes, and are not used to depending on the performance of others (teammates) for their grades in the course. Second, project management concepts and tools such as developing and using a work breakdown structure, managing a project by using a schedule, and dealing with cost and budget constraints may be new concepts for them. Third, students often lack time management skills and knowledge on how to run effective project meetings. They typically lack experience in leading a project team and motivating fellow team members. Fourth, unless students have work experience through internships, summer jobs, or co-op positions, they are typically unfamiliar with the product-development process and the standards and regulations that affect how the products are developed. Fifth, since a vast majority of engineering students have never taken a business or management course, they often lack knowledge of economics, finance, and marketing. They are unfamiliar with concepts such as time value of money, methods for determining return on investment, new product-development project portfolios, and cost/benefit ratios.

To make the most of the capstone design experience and improve learning outcomes, students can be better prepared for the course if the previously described weaknesses are addressed prior to the senior year. Two approaches can play a major role in accomplishing this. First, students should be encouraged to take advantage of co-op and internship experiences in industry. This will give them experience in working as an engineer and seeing what engineers do on a daily basis. They learn what issues are the most important and with what areas they need to become familiar. Co-op and internship students often become very familiar with standards and regulations that impact how products are developed and tested. Second, design should be incorporated into more than just the senior year. Many biomedical engineering programs are expanding their design curricula into

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Importance of Design Controls

The title of my column appearing in the January/February 2009 issue of *IEEE Engineering in Medicine and Biology Magazine* was ''Design Verification in Capstone Design Courses.'' It should have read ''Design Validation in Capstone Design Courses.'' The terms *validation* and *verification* were used incorrectly in the column. According to ISO 9000:2005, verification (Section 3.8.4) is defined as ''confirmation, through the provision of objective evidence, that specified requirements have been fulfilled,'' and validation (Section 3.8.5) is defined as ''confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled'' (1). Validation has more to do with meeting customer needs (making the right product), and verification has more to do with the processes used to produce the product (making the product right). In comparing the two definitions, the differences between specified requirements and requirements for a specific intended use or application are ambiguous. This contributes to the confusion present in the literature (and in my column) regarding the interpretation and use of these definitions. In most situations, verification occurs upstream of the final product, where validation involves the final product design. There are situations where verification and validation occur simultaneously on the final product. The ISO 9000 family of standards is flexible enough to allow this approach. What is most important is that an organization completes both phases.

The purpose of my column was not to provide readers with an overview of design controls but to show fellow educators how they can incorporate design controls into their capstone design courses. My ultimate goal was to convince fellow educators of the importance of design controls in producing safe medical devices and the need for their students to understand design-control requirements to better prepare them for their careers. I apologize for confusing the two terms and want to thank Dr. George Samaras for bringing this error to my attention.

Reference

(1) *Quality Management Systems—Fundamentals and Vocabulary,* ISO 9000:2005.

other years. For example, at Marquette University, the freshman *Introduction to Biomedical Engineering Methods I and II* courses include four design challenges (design of an algorithm for analysis of ECG waveforms, design and testing of an imaging phantom, design of a wound-care material, and design of an assistive technology/rehabilitation device) that introduce basic design and product-development concepts. Students work in teams, learn about design constraints, convert performance requirements into design concepts, and build and test prototypes. In the junior year, students can take *Clinical Issues in Biomedical Engineering Design*, where they observe procedures in the clinical environment and learn to identify problems in need of technical solutions. This course focuses on the first phase of new product development (problem identification) and helps students learn how technology is used to solve medical problems. Problems identified through visits to the operating room and other clinical areas can be used as the basis of a capstone design project. In the senior year, students take the capstone design course, where they go through the entire

Capstone Design Conference

The Second Capstone Design Conference will be held in Boulder, Colorado, 7–9 June 2010. The goal of the conference is to provide a forum for engineering and applied science faculty to share ideas about improving design-based capstone experiences. The primary conference theme is capstone course pedagogy; the secondary new frontier theme is international teams. To foster discussion, the conference will include panel sessions, interactive poster presentations, short courses, and working groups. Abstracts are due by 15 January 2010. More information is available at http://www.capstoneconf.org.

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design process from project definition and identification of customer needs to prototype construction and validation. They learn about the medical device industry, testing for safety and efficacy, standards and regulations, risk management, project scheduling, intellectual property, and a variety of design issues (industrial design, green engineering, and universal design for accessibility).

Another way to incorporate design into the four-year curriculum and prepare students for the senior capstone course is to include components of design and opportunities for skills development into nondesign courses. Many courses can include a design project as a way for students to be more hands-on and learn about practical applications of the course material. Team projects can provide additional opportunities for students to develop their teamwork skills. Oral presentations and written assignments allow students to develop communication skills. By including a discussion of the regulatory and clinical issues associated with the technologies presented in their classes, faculty can help students learn about some of the regulatory and clinical constraints of design.

Offering courses in specific knowledge areas such as project management, engineering economics (time value of money, return on investment, etc.), and manufacturing operations can help prepare students for the senior capstone design course too. At Marquette University, an entire course is being developed for the sophomore year that covers the technical, legal, regulatory, financial, environmental, ethical, and cultural/social/political constraints of medical device design. If students can become familiar with these design constraints prior to the senior year, then they will be better prepared for the senior capstone design course and their team projects.

In summary, there are several strategies that can be used to strengthen areas where students tend to be weak and better prepare them for the capstone design course. Students can be encouraged to participate in internships and co-ops, components of design can be incorporated into courses throughout the four-year curriculum, and entire courses covering specific knowledge areas needed for the capstone design course can be offered. The more opportunities the students have throughout the four-year curriculum to practice and develop their communication, time management, design, analytical, teamwork, and project management skills, the better prepared they will be for not only the capstone design course but also for their careers.

Please send your comments, opinions, and feedback to jay.goldberg@mu.edu.

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