

AC 2009-867: JUMPSTARTING THE CAPSTONE EXPERIENCE THROUGH A BIOENGINEERING PRODUCT DESIGN COURSE

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Introduction

Faculty at Florida Gulf Coast University have developed Bioengineering Product Design (BME 4800C) specifically to introduce concepts and skills in bioengineering product design in the semester prior to our capstone experience – thus, jumpstarting students into their senior design projects. Our intent has been to use a reverse engineering, semester-long project to familiarize students with FDA regulations, intellectual property issues, and design with SolidWorks, among other topics, in their junior year so more attention can be paid to the design, development and testing of their chosen project in their senior year. This paper provides a summary of the course structure, content, projects and evaluation of assessment results from the first offering of this course with a discussion of additional topics covered in the second offering.

Overview

Universities across the country recognize the importance of instilling design early in the engineering curriculum. Engineering programs routinely have introductory design courses as first-year experiences to initiate discussion on various important engineering skills, and then the senior capstone design courses focus on individual or team projects where students step through the design process. If elements of the product design process are left until the senior year, there may be too many topics to cover in the design of medical devices, and final projects may fall short of full completion due to the number of skills professors want to instill in their students. To “jumpstart” their design sequence, Bucknell University includes a half semester junior level course in their design sequence that includes topics in device benchmarking, the FDA, and patents and intellectual property.¹ Other programs have developed separate senior level design courses to cover such topics as universal design. Western New England College offers a semester long course in universal design, based on the NISH National Scholar Award for Workplace Innovation & Design.^{2,3} Indeed the importance of biomedical engineering design has launched BME-IDEA, where different university programs come together to “ discuss objectives, challenges, and opportunities for further development of these programs.” Faculty showcase their design programs at day-long workshops to highlight best practices and discuss possibilities for sharing resources and creating web-based tools.⁴

Our program is faced with the additional challenge of offering an interdisciplinary capstone design course with bioengineers, civil and environmental engineers, where we encounter differences in design requirements and important subject matter. Since some of the topics discussed in medical device design are not relevant to engineers in the other majors, the faculty needed to design a course that introduced these topics earlier and that provided a mechanism for the students to appreciate the different challenges in bioengineering product design. The

instructors combined team activities and individual benchmarking projects to reinforce topics of bioengineering product design, such as the steps of the design process, the FDA and regulatory issues, patents and intellectual property, and communication of the design. A description of the first offering of this design experience is the subject of this paper and includes a discussion of the various activities used to introduce topics of bioengineering product design. An assessment of the course provides information on achieving learning outcomes and a perspective from the students now in the capstone design sequence.

Course Content

Topics in bioengineering product design are introduced using in-class activities, most of which focus on the HLPR Chair or the Benchmarking project, detailed on the following pages. The first eight classes introduce steps of the design process as outlined in the text (product planning, customer needs, product specifications, concept generation & selection, and concept testing). The students and instructors approach the design process as a design team tasked with identifying improvements to developing the next generation of the HLPR Chair based on customer needs and previous testing. Once such activity is described in the following section. The next seven classes cover topics in regulatory issues and the FDA along with patents and IP. We have at least two speakers join us for these classes to discuss the importance of these topics in biomedical industry. By this portion of the class, students have their benchmarking device, so class activities on these topics focus on their individual devices. After a midterm, four classes introduce mechanical drawings and Solidworks through in-class activities and work on their benchmarking project. A final five classes wrap up the bioengineering product design with the additional coverage of design for manufacturing, prototyping, economics and human factors. For the course outcomes, at the completion of the course students will be able to:

1. apply the engineering design process in bioengineering from recognition of need to release of a fully-tested biomedical product
2. incorporate regulatory requirements and additional realistic constraints pertinent to medical devices, biologics, and combination products into the design process
3. apply technical knowledge in engineering, mathematics, and the physical and life sciences into the design and benchmarking of bioengineered products
4. use modern engineering software tools in biomedical product design
5. professionally document and communicate their design efforts

Books & Resources

While there are certainly a number of good textbooks available, the first two offerings of this course required Ulrich and Eppinger's Product Design and Development⁵. The textbook Design of Biomedical Devices and Systems⁶ by King and Fries was used a supplemental text for the course though not required by the students. Additional resources included the FDA⁷ and the United States Trade & Patent Office⁸ websites which we utilized through in-class activities and assignments. All classroom computers had SolidWorks software for use by students.

HLPR Chair In-class Activities & Assignments

The instructors of this course first became aware of the Home Lift Position and Rehabilitation (HLPR) Chair (see Figure 1) concept system through an introduction to Mr. Roger Bostelman in the Manufacturing Engineering Laboratory at National Institute of Standards and Technology (NIST). The Intelligent Systems Division at NIST initiated the Healthcare Mobility Project in 2005 to target the challenges facing the healthcare community for patient lift and mobility. While surveying available devices on the market, they discovered the additional needs of (1) rehabilitation to assist patients in gaining independence from a wheelchair and (2) intelligent wheelchairs paralleled previous work with intelligent mobility devices for other industries. Florida Gulf Coast University has partnered with NIST to help further develop aspects of the HLPR Chair, and while the chair has been on campus, the BME4800C instructors have used it as a tool to teach the bioengineering design process. The class design team discussed the following design steps using the HLPR Chair as a benchmark:

- Product Planning
- Identifying Customer Needs
- Product Specifications
- Concept Generation
- Concept Selection
- Concept Testing



Figure 1: Demonstration of the HLPR Chair

For example independently, each student identified a list of user needs (users including patients, caregivers, and healthcare providers) based on a review of the NIST documents and a homework assignment on wheelchair manufacturers (potential competitors of the HLPR Chair). Each need was placed on a sticky note, then the students grouped their independently generated needs on the board under broad subheadings such as, Independence, Cost/Financial, Reliability and Safety. Table 1 is an example of the needs and group rating of the importance of each need. Again, this was another in-class activity where the students used a voting method to independently score the importance of each need, and the sum of the students' scores constituted the group importance. Similar activities probed other steps in the design process, and the class team generated several different concepts based on selected needs in an earlier activity.

Table 1: In-class Activity with HLPR Chair. This is an example of one group of needs and the averaged student rating of each need.

| | Need | Group Importance |
|---|--------------------------------------------|-------------------------|
| 1 | Knows where it is in space | 6 |
| 2 | Intelligently sense and avoid objects | 10 |
| 3 | Self navigation | 7 |
| 4 | Moves quickly enough for common activities | 10 |
| 5 | Turn/maneuver in tight spaces | 15 |

This year students will again include concept and performance testing with the HLPR Chair. One team assignment has the students divided into two groups (competing companies) to advance the rehabilitation function of the chair. They will present their concepts to a group of healthcare professionals on campus based on methods described in their textbook for concept testing. In addition, the students are reviewing ANSI/RESNA standards for testing the performance of the wheelchair. Again in teams the students are writing a protocol for testing a function of the chair, following as close as possible to the procedure described in the Wheelchair standards while still allowing them to accomplish their test in the building.

Benchmarking Project

The purpose of the class-benchmarking project has been to broaden each student's knowledge of product design processes, engineering skill requirements, and regulatory issues associated with bioengineered devices. Students receive a device, available either over-the-counter or from a device company, that they benchmark individually, applying their knowledge of the design process and skills from the class and other courses to their device. For the first offering of this course, devices included a prosthetic hip implant, a blood glucose meter, a pacemaker, a knee brace and a surgical instrument. These products were theirs to keep through the semester which was important for them in creating mechanical drawings of their device. If the product could be disassembled, the students did so for not only for understanding of how the device worked, but also to create more precise SolidWorks models. Students developed a thorough knowledge of their device, and then shared their findings with the team at the end of the semester. The student

presentations, course material and guest speakers provided the students with a broad knowledge of bioengineering product design across a range of devices.

To instill a sense of the documentation required in the medical device development, students created a professional portfolio that documented the work conducted while benchmarking their device. While not a design history file, the portfolio did help them develop an appreciation for the work they may produce at a medical device company. Some of the assignments came through homework and in-class activities as students learned the process involved in product design. The portfolio was a culmination of each project, along with the final poster presentation. Items incorporated into the portfolio included,

1. Introduction and technical summary of how the device worked
2. Company overview including company mission statement
3. Device purpose and targeted users
4. Customer needs and specifications developed from those needs
5. Regulatory review: device classification, device labeling/warnings, pertinent standards, requirements for getting to market, pertinent recalls and/or incident reports
6. Intellectual property review: patent search, IP ownership, patent history
7. Identification of and comparison with competing devices/companies
8. Technical drawings of device/components
9. Discussion of manufacturing requirements including economics
10. Human factors associated with the device
11. Overall summary and conclusions of benchmarking project for the device

Students presented their work midway through the semester with a formal oral presentation to the class and in a final poster presentation to faculty within the School of Engineering (Fig 2). The instructors used grading rubrics created by the engineering faculty for both presentation formats with the expectation that the instructors in the Senior Design course would use the same rubrics; thereby the students would see consistency in presentation format and content.



Figure 2: A student presenting her benchmarking device, a knee brace, to the faculty judge.

Guest Speakers

Several guest speakers joined the class to relate course content to the medical device industry. Arthrex, Inc. has several connections to the school of engineering, including participating on the advisory board and mentoring students in internship positions, so as a local orthopedic company many of our speakers came from Arthrex. Speakers have included the Vice President of Engineering and RA/QA, who spoke about regulatory issues in design control, specifically about the documentation that takes place with any proposed device. The students gain an appreciation of the paperwork, documentation, and team meetings involved with a 510k. A Principal Engineer at Arthrex discussed patents and intellectual property aspects of the design process and again, the importance of documenting all ideas, progress and testing in a design notebook. In addition we had speakers discuss manufacturing and human factors, while another speaker provided a case study on medical device development. The speakers help round out topics discussed from the book with a full appreciation of the “biomedical” aspect of the product design process

Assessment

Program outcome assessment

Assessments of program outcomes were planned prior to the course development as the faculty prepared their curriculum for ABET accreditation. Student achievement of the course outcomes were assessed through the following broader program outcomes: statistics (3a), design, including realistic constraint aspects (3c), identify, formulate and solve bioengineering problems (3e), professional and ethical (3f) and lifelong learning (3l).

Assessment of these program outcomes came primarily from the midterm and final exams and the benchmarking portfolio. Table 2 illustrates the assessment of outcome 3c, design, including realistic constraint aspects. The bioengineering faculty decided to assess at three levels: the percentage of students achieving a minimum score of 65%, 70% and 85%. These were ratings for junior level proficiency of Developing, Competent and Accomplished, respectively. With an N = 5 the instructors recognize the limitations of the assessment, but it does provide a gauge of how well we are preparing our students for senior design. For all but one of the assessment items, four to five juniors performed at a Competent level or better. The instructors will include the Spring 2009 assessment results at the conference presentation.

Qualitative assessment of students

With the first cohort of students taking Senior Capstone Design I and II, the instructors asked the seniors to complete a survey to assess their perception of their preparedness for the course based on concepts learned in the junior level Bioengineering Product Design. This survey was created and posted on the course website in Angel where students’ anonymity was maintained. Table 3 provides a summary of their responses to five questions based on a Likert scale of 4 [1-not at all prepared, 2-somewhat prepared, 3-prepared, and 4-well prepared].

Table 2: Assessment of Program Outcome c - design, including realistic constraints aspects. Points indicate the possible score on the problem/activity. Percent of students indicates the number of students that scored a minimum of 65, 70 and 85%, which relay achievement levels set by the bioengineering faculty.

| Program Outcomes | Points | % of students at | | |
|------------------------------------------------------|--------|------------------|------|------|
| | | ≥ 65 | ≥ 70 | ≥ 85 |
| c - DESIGN, INCL REALISTIC CONSTRAINTS APECTS | | | | |
| Overall/General Design | | | | |
| 1 Mid-term P8 (House of Quality) | 12 | 100% | 100% | 60% |
| 2 Final exam P4 (House of Quality) | 12 | 100% | 100% | 100% |
| 3 Design Benchmarking Proj Portfolio (Overall) | 100 | 100% | 100% | 60% |
| Health & Safety | | | | |
| 4 Final exam P5 (Human Factors Engr) | 10 | 80% | 80% | 20% |
| Economics | | | | |
| 5 Final exam P7 (Production Costs) | 8 | 100% | 100% | 0% |
| 6 Final exam P8 (Manufacturing Costs) | 12 | 100% | 100% | 100% |
| Regulatory | | | | |
| 7 Mid-term P3 (Device Classification) | 10 | 100% | 100% | 80% |
| 8 Mid-term P4 (Regulatory mechanisms) | 14 | 60% | 60% | 40% |
| 9 Final exam P5 (Human Factors Engr) | 10 | 80% | 80% | 20% |
| 10 Final portfolio (Appropriate Reg Review) | 15 | 100% | 80% | 20% |
| IP | | | | |
| 11 Mid-term P6 (IP Strategy) | 20 | 100% | 100% | 100% |
| 12 Final portfolio (Appropriate IP Review) | 10 | 100% | 100% | 40% |
| MANUFACTURING | | | | |
| 13 Final exam P8 (Manufacturing Costs) | 12 | 100% | 100% | 100% |
| 14 Final portfolio (Manufacturing Req Review) | 5 | 100% | 100% | 40% |

Table 3: Survey of seniors' perception of preparedness for their capstone experience based on knowledge gained in Bioengineering Product Design.

| Question | Average Score |
|-----------------------------------------------------------------------------------------------------------|---------------|
| How prepared were you to step through the design process for senior design? | 4.0 |
| How prepared were you to search and recognize the regulatory issues for your medical device design? | 3.0 |
| How prepared were you to create mechanical drawings for your medical device design? | 3.0 |
| How prepared were you to communicate your project with your industry mentor(s)? | 3.8 |
| How prepared were you to document your work as you progressed through the design process for your device? | 3.8 |

The instructors also asked the seniors to comment on what recommendations they would suggest to improve the Bioengineering Product Design course. Below are some of their comments:

1. Additional information about regulatory standards is needed. More information on prototyping and testing would be fun and beneficial...
2. If developing good skills in Solidworks was one of the main goals of the course I would suggest spending more time on that. I learned a little about the program, but would not feel comfortable saying I am have sufficient knowledge if asked by a potential employer. Other than that I feel the class helped a lot with the Senior Design process.
3. Maybe spend more time in Solidworks earlier in the semester to get a better feel. Definitely more exposure to drawings would be beneficial, i.e. tolerances, appropriate dimensions, notes, what's important and what's not.
4. No suggestions for the product design course, it was very helpful. However, given the background we have from this course, it would be appropriate to step up the pace of the first senior design semester (for bioengineers at least)...
5. ...Start the Senior Design Project in Product Design...

Discussion and Proposed Changes

The instructors felt that the outcomes were achieved based on both the assessment through the exams and projects, and also from the response of the seniors. From the program outcomes assessment, 80% (4 out of 5 students) attained a minimum of a competent rating. The intent of the course was to prepare the students for the capstone experience recognizing the continued learning process as the students design their own device and take it forward through the design process. From the comments, we did indeed jumpstart the process, maybe too well since the bioengineers found some of the first semester redundant. In future offerings of Senior Design I, bioengineers will meet separately from their counterparts in the other programs for many class sessions to avoid repetition and provide additional content in the first semester.

The instructors devoted 4 out of 28 classes to SolidWorks, and while this is a limited amount of time to become proficient at the software, there is not sufficient space in this course to develop solid professional skills in SolidWorks. Nor is the intent of the class to be a proficient user of Solidworks. While the instructors feel the students are “prepared” to use SolidWorks for their senior design project, the students clearly would like additional training. We are considering a continuation of a SolidWorks module in Senior Design I based on the survey of the seniors. Likewise, fabrication is not covered in this course, and we are considering an aspect of this in Senior Design I now that the School of Engineering has a machine shop the new building.

Conclusion

The Bioengineering Product Design class sessions focused on technical, regulatory (including FDA design controls), intellectual property, human factors, economic, and manufacturing (including use of SolidWorks for 3D CAD) aspects of medical devices with emphasis on product design, development and commercialization. The class was structured early in the semester such that all participants (students and instructors) were members of a team that was responsible for developing the next generation of the National Institute of Standards and Technology (NIST)

Home Lift, Placement and Rehabilitation (HLPR) Chair concept system. In-class activities and discussions focused on specific elements of the HLPR Chair design concepts and development, often via assigned homework from the previous class. As a group, students finalized each activity with a team statement that represented the goal of the effort moving forward. Subsequent to the HLPR Chair based exercises, each student then carried out a comprehensive reverse engineering and benchmarking project for an existing medical device. The end deliverable for this project was a substantial design portfolio with a poster presentation. Industry practitioners were involved throughout the course to provide additional “real world” perspectives on the design process in the medical device arena. Assessment to date has focused on evaluation of the extent of achievement of the course learning outcomes for each student in the class. Initial assessment of our first seniors advancing through the capstone design sequence indicate that the instructors accomplished a jumpstart to their senior design project, which enabled them to start discussion of biomedical project design with their industry mentors at the beginning of the course. The seniors are on track to have working prototypes and testing of their devices prior to the final presentation of their capstone experience. As a result of early feedback from our seniors, the instructors will consider incorporating a module on mechanical design that includes both advanced Solidworks topics and fabrication experience in the new machine shop.

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