Incorporation of the Coulter College in Senior Design Coursework at the University of Miami

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Abstract

The senior design sequence at the Department of Biomedical Engineering of the University of Miami consists of three courses, 6 credits (1+2+3), starting in the second semester of junior year. This format was first implemented in spring 2013 and currently is in its second iteration. The course sequence uses cooperative, project based learning of the technical, social, regulatory and business aspects of engineering design.

During the most recent iteration of the sequence, the Coulter College methodology was introduced to the second course of sequence (fall 2014). The teams follow the Coulter College Methodology to identify many unmet medical needs and, using a systematic screening process, they define their design problem. Then they use brainstorming techniques to generate many diverse conceptual solutions that will conduce to a conceptual design after the application of a systematic filtering process. They develop a prototype over which they apply a test ("killer Experiment") that works as a proof of concept. The results of this testing is used to refine the conceptual design and to perform a to plan the implementation and testing phases.

Keywords

Senior Design, Coulter College, Cooperative Learning

Introduction

The Biomedical Engineering BME undergraduate program at the University of Miami has 323 (fall 2014) undergraduate students in four concentrations: biomaterials and tissue, premedical, electrical and mechanical concentration. For students enrolling the department prior to the academic year 2010/2011 the senior design consisted of two courses BME401 (1 credit) and 402 (2 credits). In BME401 the students selected a design topic, a mentor, performed the background information necessary to establish the significance of the project and produce the problem statement and specifications. Additionally the students evaluated many alternative solutions and developed a conceptual design in the form of block diagrams. At the end of BME401 the students presented a formal proposal for the implementation and testing of their design. During BME402, the students implemented their designs and performed a formal testing to verify the fulfillment of the specifications. The senior design strategy worked satisfactorily for many years but the BME faculty identified two main aspects would strength the senior design experience: 1) the students will be performing better in their senior design project if they learn about the whole design process before their senior year and 2) with the recent availability of rapid prototyping tools the whole design experience will improve if the students implement, very early, a first proof of concept prototype (first semester senior year) that will be tested and refined further to allow a second or implementations and testing. The faculty of the BME Department decided to change the senior design sequence for the students enrolled after the academic year 2011/2012. The senior design sequence was expanded to three courses BME401/ BME402/ BME403, starting in the last semester of junior year. The first course (1 credit, junior year) introduces the design concepts while the two senior courses (2credits and 3 credits) are dedicated to the project definition, two implementations and testing. The class of 2014 was the first one following the new design sequence and, currently, the class 2015 will be the second one. The assessment of the design projects of the 2014 class motivated adjustments that are being implemented for the students that will graduate in 2015 and beyond. The most significant adjustment was the inclusion of the Coulter College methodology in the first and second semesters and the strength of the use of engineering standards and biostatistics in the implementation and testing phased on the last semester.

Key Elements of the new Senior Design Coursework

Previous to the new sequence the students worked under the supervision of a BME faculty mostly developing design projects related to the advisor research activity. Typically the students selected their project from a “project catalog” provided by the faculty. In the new senior design coursework, student teams are empowered to identify their unmet needs and to lead the development of their projects; the BME faculty has a facilitator/coordinator role. The coordinator faculty uses the Comprehensive Assessment of Team-Member Effectiveness (CATME) [1] tools for the generation and management of the design teams. The required basic design instruction is provided in the junior year course; during the senior year, the sequence includes unmet need finding, concept generation and two implementations and testing tasks. The design projects have to satisfy the following characteristics:

- Identified by the students using the Coulter College methodology for unmet need finding and screening
- Are feasible, with complexity compatible with the students’ background
- Are suitable to use rapid prototyping tools: i.e. 3D printing, hardware/software sketching
- Are Multidisciplinary, thus requiring expertise from multiple team members
- Require ethical decisions in the design and development processes

First Semester: BME 401: General Bio-Design Instruction

During this course the students learn the basic design skills required later in their design experience. By applying the concepts to case studies common to all the students, the concepts are reinforced. This introductory course includes lectures on topics such: problem identification, brainstorming techniques, FDA regulation, project management, intellectual property, team work and ethics. The students, working in teams, perform in class exercises and homework around a common case study defined by the faculty. At the end of semester the students compile the exercises and write a formal design report that documents the design experience. As example, during spring 2013 and 2014 the *Hospital acquired urinary tract infections problem* was used as the topic to practice the design skills.

For the FDA related instruction the excellent teaching case study repository material produced by the FDA [2] is used. During spring 2014 we successfully used the *“Regulatory Pathways for*

Medical Devices: Choosing the Right One" case study. Nowadays the FDA webpage offers five teaching modules. For the ethics training we use the online program Collaborative Institutional Training Initiative (CITI program) [3]. The BME students are required to pass the modules on animal experimentation (freshman year), responsible conduct of research (junior year) and human subjects research (senior year).

Second Semester: BME 402 First Design Cycle

During the second semester, the students team up and select their design problem. Then they generate many possible alternative solutions, select a conceptual design and implement a first proof of concept prototype. The **Coulter College Methodology** and videos [4] along with the Biodesign textbook [5] were introduced in fall 2014 in BME402 to provide organized framework of activities for the senior design experience. Applying the Coulter College methodology, the objectives of the course can be very well addressed and new realistic entrepreneurial elements that enrich the student learning experience are introduced.

During the first week, teams of students are formed using the CATME Team-Maker tool [6]. The tool is tuned to give the highest weight for the optimization of the team formation algorithm to the time availability (out of class) of the team members followed by the team diversity (GPA, gender, etc) criteria. The College of Engineering allows and encourages the development of senior projects with teams with students from various departments.

Phase I- Need Identification: Students, as individuals identity many medical unmet needs using the Biodesign observation and interview techniques. Then each team brainstorm to produce and document, at least, ten possible unmet medical, dental, veterinary or research instrument needs. They make a presentation where they present, in front of the class, the information about the potential impact of each unmet need in health care and the target population it addresses.

Phase II- Initial Screening: Teams gather additional information about the ten needs to be able to select only three needs as the best fit for the team. They use as selection criteria the perceived feasibility, addressable market size and compatibility with the team background and interests.

Phase III: Additional information gathering: The Coulter College information gathering guidelines are used to obtain deeper information about the three pre-selected unmet needs. For each of the three pre-selected unmet needs the following information is expanded: Observation and problem identification, disease state fundamentals, treatment options and stakeholder analysis.

Phase IV: Unmet Need Selection: the team selects the unmet need that will be developed using a formal design making process that uses as inputs the previously gathered information, the team strategic focus, market analysis and feasibility.

- *Strategic Focus:* The teams define its mission statement, identify its strengths and weaknesses and define a set acceptance criteria for their project.

- *Market Analysis:* For each unmet need (3) the market segmentation, size, dynamics, and needs are investigated by the team. They also elaborate on the stake holders' perceived willingness to pay.

- *Feasibility:* The team members make the case to show that it is possible for the team to find a solution of the unmet need within the time and resources they have. They make his case by referring to scientific evidence (articles) and technological advancements (pre-existing modules, software, etc). They may also refer to the existence of devices that implement similar functions and team members' previous experiences, contacts or special skills.

The teams define a set of decision making criteria and create a decision making matrix. Incorporating all the collected information into the decision matrix the team makes an informed decision of the unmet need to develop in their senior design. The team finishes this selection phase by writing down the set of specifications of the selected unmet need; they use the MoSCoW prioritization technique, used by the software development methodology DSDM [7].

Phase V – Concept Generation and Screening: Using brainstorming techniques the team generates many conceptual designs that are presented in the form of a concept maps and block diagrams. The team then performs a decision making process to produce one concept (or 2) that will be implemented. The technical feasibility of the proposed solution is revisited.

Phase VI – Proof of Concept implementation and Killer Experiment: Using a PARETO analysis of the problem, the team identifies which critical elements of the design should be included in the proof of concept model. The proof of concept is then implemented using rapid prototyping techniques. Test protocols (killer experiment) are then designed to verify the basic specifications of the proof of concept prototype. The achievement of the basic specifications is assessed and the results are used to design an improved prototype in the implementation phase of BME403.

Third Semester BME 403: Second Design Cycle and Validation

The teams develop a second improved prototype and apply systematic device testing in laboratory and with users. They complete a formal design report, a poster, and an oral presentation.

Engineering Standards: In agreement with ABET, the students are required to follow engineering standards in the development of their senior design project. To facilitate this process, lectures on the use of engineering standards in biomedical devices are given by faculty with extensive industry experience. The lectures includes topics such: Risk Management (ISO 14971), Biocompatibility (ISO 10993), Electrical Safety (IEC 60601-1), Mechanical Testing (ASTM) and Software Validation and Testing (IEEE 1012 and IEC 62304).

The students apply the concepts by performing a Failure Mode Analysis (FMEA, ISO 14971) of their device. Once the risks are identified, a risk mitigation exercise that involves the use of the IEC 60601-1 standard is performed. They also work on the regulatory pathway of their device by identifying its potential FDA classification and the required specific standards that the device has to observe in order to obtain the regulatory clearance.

Teams are required to use an electrical safety analyzer to perform the applicable IEC 60601 electrical safety tests of their prototypes. Students who complete senior design projects in the area of biomaterials and tissue engineering will be required to perform cytotoxicity live-dead florescent assay tests, following the standard ISO 10993-5 guidance, if applicable to their project.

Statistics: In order to support the experimental design and data analysis of the device validation task, the syllabus for Senior Design Project III, BME 403 includes refresh lectures on biomedical statistics. The lectures cover topics such: normal distribution and confidence intervals; hypothesis testing; commonly used tests (correlation, regression, t-test, chi-square, ANOVA); introduction to power analysis for sample size calculation and data/results presentation.

Discussion

The inclusion of the Coulter College methodology has benefited the development of the senior design project of the BME students. This methodology offers a framework of activities that promotes the creativity, decision making and team work skills. Additionally, the methodology introduces very realistic entrepreneurial elements that better prepare the students for the industry.

During the first weeks of the course the students resisted the use of the Coulter College methodology because it takes them out of their comfort zone. Very few previous courses in their curriculum confront the students with open problems with multiple solutions. After following a well-structured methodology that includes new tools such brainstorming, strategic focus and decision making matrices the students better appreciate the benefits of the methodology. The iterative character of the methodology that includes activities with expansion of solutions (brainstorming) followed by reduction ones (filtering) seems to produce projects better tailored to the specific background and interests of the teams. The empowerment of the teams to define and manage their projects helps the students to develop their entrepreneurial skills.

Preliminary assessment of the design coursework shows improvement in educational outcomes related societal and economic impact educational outcomes, in addition to the more traditional engineering design ones. The introduction of engineering standards along with realistic constraints and market analysis better prepare the students to industry and strength the compliance with the ABET requirements of the program.

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