Delivery and Assessment of the Biomedical Engineering Capstone Senior Design Experience

Dr. Anthony J McGoron, Florida International University

Dr. Anthony McGoron is an associate professor, received his Ph.D. in Biomedical Engineering from Louisiana Tech University in Ruston, La. and post-doctoral training in Pharmacology and Cell Biophysics from the University of Cincinnati. His first faculty appointment was at UC’s Department of Radiology. He joined FIU in 1999 and was instrumental in the development of the academic programs in Biomedical Engineering (BME). He led the design and implementation of the B.S. in B.M.E. program in 2002, its initial ABET accreditation in 2005, re-accreditation in 2008. He served as the founding advisor for the student chapters of the Biomedical Engineering Society (B.M.E.S.) and the Alpha Eta Mu Beta (A.E.M.B.) Biomedical Engineering Honor society. In 2010 he was elected National president of AEMB. He served as the interim chair of BME from 2007 to 2010. The primary focus of Dr. McGoron’s research is drug delivery and molecular imaging, primarily for cancer, and specifically the development of multimodal drugs that simultaneously image and provide therapy. Efforts include the development of tissue or cell specific contrast agents and probes (both optical and radioactive) for noninvasive molecular imaging of cellular and tissue characterization, for monitoring toxicity, for tracking the biodistribution of known toxins and drugs, and image guided therapy. Dr. McGoron is also developing tools for automatic segmentation and registration of organs and tumors to accurately determine tumor functional and anatomical volumes which is required for accurate dosimetry calculations for image guided therapy and Selective Internal Radiation Therapy (SIRT) planning.

Mr. Hamid Shahrestani, Florida International University, BME

Harrid Shahrestani designed and implemented departmental strategic plan in line with organizational goals and vision, resulting in improved efficiency and effectiveness. He also led the development and introduction of complex therapeutic and diagnostic devices for Cardiovascular, Urology, Endoscopy, Neurology, Nephrology, Pain Management, Hemodialysis, Orthopedic and vascular applications. Shahrestani is skilled in developing and executing strategic solutions, which created a competitive edge in the global marketplace. He has strong communication and presentation skills to senior management, executive committees and boards of directors. He also has proven ability to break down complex technical subjects and to communicate effectively to different levels of the organization. Shahrestani earned his M.S. Industrial and Systems Engineering and his M.S. in Engineering Management from the University of Florida in 2001. He earned his B.S. in Electrical Engineering in 1984 and in 1982 Shahrestani earned the A.S. Electrical Engineering, both from the Wentworth Institute of Technology.

Dr. Michael Edward Brown, Florida International University

Dr. James Dennis Byrne, Florida International University

James Byrne earned his Ph.D in Mechanical Engineering from the university of Miami (Coral Gables) in 1984. He designed optical systems and integrated optics and laseris into blow cytometers for Coulter Corporation, later Beckman Coulter from 1984 to 1999. He is the research coordinator for the Biomedical Engineering Department at Florida International University. He teaches undergraduate laboratory courses in Biomedical Engineering and Medical Instrumentation. He has mentored many senior design teams in association with other FIU faculty or FIU’s industry partners since 2006.
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Abstract

The capstone design course is the most important experience engineering students have during their undergraduate academic careers. The capstone design sequence at Florida International University consists of three courses for a total of 7 credit-hours over two semesters. Significant effort by the entire faculty is required for a successful outcome and to ensure that all students receive a “major design experience” and that there is consistency in expectations and outcomes among the students and groups. One of the creative components of the program at FIU is that near the end of the first semester of the senior design course sequence a committee of faculty members reviews each group’s project design written proposal and critiques a 20 minute oral presentation of their proposal during about 40 minutes of questioning. The team’s company sponsor and faculty advisor also attends and participates in the oral proposal defense. The faculty panel then approves the project, does not approve the project, or suggests an expansion or reduction in the scope. Close coordination with the company or faculty advisor ensures that the project meets the curriculum requirements of the program and that the scope of the project is realistic. An assessment tool is completed by each panel member, which is also used to provide input for the students’ grades. In the second semester students complete the project and give a written report and oral presentation to a panel made up of members of the department’s Industry Advisory Board. Students attend weekly lectures by experts on various topics critical to the success of practicing engineers, including regulatory, intellectual property, marketing, prototyping, responsible conduct of research, and others. These sessions also serve to monitor student and team progress. Multiple assessment tools are used to evaluate student learning. Other assessment tools, such as a Self-&-Peer evaluation and a Work Effort Certification are used to assess teamwork. This paper describes the individual topics of the course, the assessment tools used, and the outcomes over the past 6 years.

Introduction

Engineering design is a critical component of every undergraduate engineering program and is specifically required by accreditation agencies, for example the Accreditation Board for Engineering and Technology (ABET). According to ABET, “Students must be prepared for engineering practice through a curriculum culminating in a major design experience based on the knowledge and skills acquired in earlier course work and incorporating appropriate engineering standards and multiple realistic constraints”. It allows students to develop their management skills while learning design and product development. Students apply what they have learned in the previous years, develop their communication skills, as well as their interpersonal and project management skills towards design and product development. The capstone design course prepares students for successful and productive professional careers. Teams must be composed of members with skills needed to successfully complete the project. For complex problems these skills often require knowledge from disciplines outside of their own, and even disciplines outside of engineering. This is true for all engineering disciplines, but maybe more so in Biomedical Engineering. That these skills have been learned by the students must be assessed.
Two points identified in the white paper titled “Design in BME: Challenges, Issues and Opportunities” generated from the 2005 Whitaker BME Education Summit were (1) “increasingly clear mandate from industry for university BME programs to teach design skills, including team-based experiences and (2) expectations that innovation in biomedical technology will be an important driver of economic success and that BME graduates will play a central role in designing these new technologies.”

Identified as necessary components of the capstone senior design experience by participants of the 2005 Whitaker BME Education Summit:

1. Characterizing the Design Need
2. Identifying Attributes of an Ideal Solution
3. Locating, Utilizing and Documenting Quality Sources of Information
4. Creating Multiple Potential Solutions
5. Iterative Prototyping of Design Concepts
6. Understanding the Key Features of Design Implementation
7. Evaluation of Design Solution
8. Technical Communication of Both Solution and Decision Process
9. Project Management

Some programs disperse the design experience throughout the curriculum, and many programs require two semesters of “design” during the 4th year of the curriculum. Often, in the first semester of the design course sequence students form groups, select a project, learn the design process and generate a project proposal. Then in the final semester of the curriculum students complete the project and defend it in both written and oral form.

In 1994 and again in 2005 ABET-accredited engineering programs were surveyed to gather information on their capstone design courses and the results were published at conferences of the American Society of Engineering Education (ASEE) and the Institute for Electrical and Electronics Engineers (IEEE). A number of interesting observations from the survey results were made. Dealing with the way the courses should be presented (lecture component), the duration of the course, number of students on a team, source of ideas for projects, source of funding, level of funding, whether teams are comprised of students from a single department or multiple department, etc. It should be noted that Biomedical Engineering was not included in the survey, possibly because of the low number of ABET accredited BME programs in 1994. To summarize some of the results from the survey: about half responded that they offer class and project courses in parallel while fewer (28% in 1994 and 22% in 2005) responded that their curriculum requires a class followed by the project in successive semesters, as is the case at Florida International University (FIU), another 26% (1994) and 21% (2005) have a project only with no accompanying lecture class; approximately half of the programs have a 1 semester design course, 30%-40% have a 2 semester sequence. The survey reflects an increased emphasis on teamwork and the preferred number of students on a team ranged from 3 to 5; the amount of effort students are expected to expend on the projects also increased from 1994 to 2005; in 2005 71% reported that projects were industry sponsored, 46% reported that their projects were
sponsored by faculty research, and only 15% responded that projects were generated and supported by students (respondents could choose all that apply). The authors of the surveys also note that the results suggest that capstone courses are increasingly incorporating more subject matter with an emphasis on professional skills. This will undoubtedly lead to greater pressure on faculty time. Also noted by the authors was a surge in computer engineering and computer science collaboration in the past decade, reflecting the growing role of computers in engineering design which begs for greater multidisciplinary teams.

A report from the National Academy of Engineering identified the ideal attributes of the engineer of 2020 and recommends ways to improve the training of engineers to prepare them for addressing the complex technical, social, and ethical questions raised by emerging technologies\textsuperscript{26}. The report notes that innovation is the key to the US maintaining its economic leadership and ability to sustain high-technology jobs and that engineering is essential to this task. A growing need to pursue collaborations with multidisciplinary teams of experts across multiple fields was identified as well as the requirement that engineering students learn to use new tools and apply ever-increasing knowledge in expanding engineering disciplines. The attributes of an engineer were identified as strong analytical skills, practical ingenuity, creativity, communication, business and management, leadership, high ethical standards, professionalism, and lifelong learners. These skills should be taught throughout the curriculum, but especially in the capstone design course where students should be able to demonstrate the attainment of these skills. These skills must also be adequately assessed. The question of whether Engineering Design Thinking can be taught at all and as to whether such skill can be adequately assessed were addressed by Dym et al.\textsuperscript{8}. Nevertheless, the importance of appropriate assessment in the capstone design course is evident.

The capstone design course can be used as a primary part of a program’s overall outcomes assessment\textsuperscript{7, 27} since it should test the student’s critical skills and knowledge immediately prior to graduation. ABET requires that a program’s outcomes be adequately assessed to verify that students are learning what they are expected to learn. Several examples of assessment of Capstone Design Courses have been reported\textsuperscript{1, 2, 5, 6, 15, 21, 24, 25}. The assessment described in this paper incorporates many of these ideas.

Assessment is used for evaluating a program to ensure that the program learning outcomes are met (typically for accreditation purposes), but also for assigning grades to individual students in a course. One difficulty that has been identified is how to assign grades to individuals for work done on a team, as the majority of Capstone Design courses are team based. Cooley\textsuperscript{4} has proposed a tool for conducting individual assessment of students working on teams. It requires the direct interaction between the individual students and the instructor, and others directing or otherwise associated with the project. Self evaluation tools are used which ask students to evaluate themselves and their teammates, so-called self-&-peer evaluations. These evaluations serve two purposes. One purpose is to provide the instructor with information on how the students worked together, and the second purpose is to reinforce to the students what are the
expectations of responsible conduct on a team. Formative assessment is a measure of a student’s knowledge and skills during the learning process and should be used to provide timely feedback to the students to help them improve or grow. Gentili et al.\textsuperscript{11} have reported on a survey approach to measure the growth in students’ design skills. Such assessments must be done during the learning process while allowing enough time for the students to learn from their mistakes or shortcomings. Livesay et al.\textsuperscript{17} developed a survey tool to have students evaluate their design skills and assess their actions and attitudes related to the design experience. Such feedback, if provided to the students, can help them improve on their design skills.

Summative assessment is used to obtain a snapshot of a student’s or program’s state at a given time, but does not provide an indication of the improvement of a student’s learning and is not intended to provide feedback to help the student grow. It may consist of a set of tools to measure the overall extent of a student’s knowledge or a program’s effectiveness. These are typically done at the end of the semester (term). The Capstone Design experience can be a convenient opportunity to teach Professional Skills (sometimes referred to as the “soft skills”)\textsuperscript{23} that may not make it into more traditional lecture courses. Engineering design is where these professional skills are most important. These have often been difficult skills to assess. There may be as many ways to offer the capstone design experience as there are engineering programs. To give new programs ideas, groups have reported on the specific elements of their own capstone design courses\textsuperscript{10, 14, 22}.

Assessment tools for evaluating program learning outcomes are freely available\textsuperscript{9, 13, 28} and we in the BME program at FIU have developed our own process and tools for the assessment of learning outcomes for Capstone Design. Outcomes attributes modified from Bloom’s taxonomy\textsuperscript{3} and later adapted by Marzano\textsuperscript{19} provide for a more objective assessment of outcomes to allow attributes to be converted to variables. This makes them more quantifiable so as to provide specificity for evaluating outcomes by ensuring evaluators use identical criteria for scoring their assessments. Rubrics and taxonomies have been designed for our BS program and a very early iteration of our design course sequence has been presented previously\textsuperscript{20}. This paper describes the design courses and assessment at our university that may be of value to other institutions. The process and assessment tools have been developed and refined over the past six years and are be available electronically.

**Methodology and Description of the Courses**

**Description of the 7\textsuperscript{th} Semester Senior Design Experience: BME 4090 and BME 4800**

Our program has a three-course Capstone Design sequence during the 7\textsuperscript{th} and 8\textsuperscript{th} semesters of the eight semester curriculum. The entire sequence was designed to test the students’ attainment of all 8 Program Learning Outcomes (Table 1). During the 7\textsuperscript{th} semester students take two courses for combined four credit-hours on the semester system. The objectives, major topics and course learning outcomes are provided below. Note that there is considerable overlap in the courses’
learning outcomes. These two courses are structured to provide opportunities for learning the
theory of the design process as well as a practical experience with the application of the tools.
Although combining the two classes would not have a significant detrimental effect on the
quality of the learning outcomes, it has been determined that keeping them separate would
provide an affordable opportunity for graduate students or students from majors other than
Biomedical Engineering (elective course) to elect to take the theoretical course without the
practical portion. A second rationale for having two courses instead of a single four-credit
course is so that different grades can be assigned to each course since there are some unique
learning outcomes in each course. Nevertheless, student must pass both courses to continue on to
the Senior Design Project course (BME 4908) in the 8th semester.

<table>
<thead>
<tr>
<th>BME Undergraduate Program Learning Outcomes</th>
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<tbody>
<tr>
<td>1</td>
<td>Ability to apply knowledge of mathematics (including differential equations and statistics), physical and life sciences, and engineering to carry out analysis and design to solve problems at the interface of engineering and biology</td>
</tr>
<tr>
<td>2</td>
<td>Ability to design and conduct experiments, as well as to measure, analyze and interpret data from living systems</td>
</tr>
<tr>
<td>3</td>
<td>Ability to design a system, component, or process to meet desired needs, including systems that involve the interaction between living and non-living materials</td>
</tr>
<tr>
<td>4</td>
<td>Ability to identify, formulate, and adapt engineering solutions to unmet biological needs</td>
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<tr>
<td>5</td>
<td>Ability to use the techniques, skills, and modern engineering tools necessary for engineering practice, including the ability to model and analyze biological systems as engineering systems</td>
</tr>
<tr>
<td>6</td>
<td>Ability to function on multi-disciplinary teams</td>
</tr>
<tr>
<td>7</td>
<td>Ability to communicate effectively</td>
</tr>
<tr>
<td>8</td>
<td>Awareness of the characteristics of responsible professional engineering practice, including ethical conduct, consideration of the impact of engineering solutions on society in a global and contemporary context, and the value of life-long learning</td>
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</table>

Syllabus for BME 4090: Design Project Organization (one credit)

Course Objectives:
This is a one credit-hour design course intended for seniors in the Bachelor of Science program in biomedical engineering. It is the first of two sequential applied learning design courses (the other is Senior Design Project) that are offered as one continuum over two consecutive semesters. These classes are at the pinnacle of the undergraduate biomedical engineering program; they are designed to serve as a venue where the Senior will utilize the knowledge he/she has accumulated throughout his/her academic career toward the design, building and testing of a capstone project. The project aims, among others, at providing students with a hands-on experience and with tools for success in a team-oriented and goal-driven engineering/business environment in a career option of their choice.

Major Topics:
1. Introduction to Device and System Design and Development Process
2. Recognition of Need
3. Introduction to QSR and Design Controls – Design Input
4. Introduction to QFD (Quality Deployment Function)  
5. Creativity and Innovation  
6. Feasibility & Risk Assessment  
7. Project/Product Cost Analysis  
8. Project Management – Organization/Project Plan  
9. Biocompatibility

<table>
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<tr>
<th>No.</th>
<th>BME 4090 Course Learning Outcome</th>
<th>Corresponding BSBME Program Learning Outcome</th>
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<tbody>
<tr>
<td>1</td>
<td>Ability to apply the principles of engineering design from recognition of need to a fully-tested product.</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Ability to organize and manage a design project and work effectively in a team to complete the project.</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Ability to incorporate biocompatibility, regulatory issues, and other considerations and constraints pertinent to medical devices, into the design process.</td>
<td>3, 8</td>
</tr>
<tr>
<td>4</td>
<td>Ability to apply knowledge of natural physiological systems to the design of their replacements, and to devise means to overcome constraints in doing so.</td>
<td>5</td>
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<td>5</td>
<td>Ability to communicate items 1 through 4 in written, oral, and graphical form.</td>
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Syllabus for BME 4800: Design of Biomedical Systems and Devices (three credits)

Course Objectives:
This course is designed to provide the student with an introduction to systems and devices used in the biomedical industry and the basic principles of their design. It is meant to offer the students an application in the biomedical area to the basic theory developed in the lower level course work, as well as an opportunity to learn basic steps and processes involved in engineering design as it specifically applies to biomedical problems.

Major Topics:
1. Recognition of Need/Opportunity
2. Problem Formulation: Design Input
   a. Design in a Regulated Environment: Introduction to QSR and Design Controls
   b. Primary Biomedical Design Input: Biocompatibility
3. Solution Formulation: Creativity and Innovation
4. Feasibility Assessment
5. Project Management
6. Engineering Analysis and Decision Making
7. Detailed Design: Design Output
8. Construction: Prototyping
9. Testing: Verification and Validation
10. Evaluation

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<th>No.</th>
<th>BME 4800 Course Learning Outcome</th>
<th>Corresponding BSBME Program Learning Outcome</th>
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<tbody>
<tr>
<td>1</td>
<td>Ability to apply the principles of engineering design from recognition of need to a fully-tested product.</td>
<td>3, 4</td>
</tr>
<tr>
<td>2</td>
<td>Ability to organize and manage a design project and work effectively in a team to complete the project.</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Ability to incorporate biocompatibility, regulatory issues, and other considerations and constraints pertinent to medical devices, into the design process.</td>
<td>5, 8</td>
</tr>
<tr>
<td>4</td>
<td>Ability to apply knowledge of natural physiological systems to the design of replacements, and to devise means to overcome constraints in doing so.</td>
<td>1, 8</td>
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<tr>
<td>5</td>
<td>Ability to design and conduct tests to verify design input and validate the final product to meet user needs</td>
</tr>
<tr>
<td>6</td>
<td>Ability to communicate items 1 through 4 in written, oral, and graphical form</td>
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These same or very similar objectives and topics most likely appear in every biomedical engineering BS program. The features of our program that may not be incorporated into other programs are (1) the project team selection methodology, (2) some of the courses emphases, and (3) the process for project proposal evaluation, which is done by a Design Evaluation Committee at the end of the 7th semester. Each of these aspects is described in greater detail below. These features were first introduced in fall 2008 and improved on over the years. Formative assessment is provided to the students throughout the semester using the following instruments:

1) Individual and team research assignments in the area of devices, clinical needs and regulatory requirements. Students receive individual and group feedback. If all (majority) of students have the same issues then instructions and feedback are given to the entire class.
2) Multiple presentations in specific device related subject. Written feedback given on their PowerPoint slides.
3) Midterm Exam and Final Exam
4) Peer Evaluations
5) Committee Feedback

In other programs project teams are usually formed randomly or by students selecting their own teammates. In our program, teams are formed by the instructor based on the evaluation of all students, their past experiences and their demonstrated strengths. Individuals are also evaluated based on their performances during the first three weeks of the semester in various areas such as effective research, oral presentations, conflict resolutions, problem solving, and effective communication. As in any team dynamic, individuals on teams may have personality conflicts. When this occurs the instructor and the faculty project advisor tries to mediate to keep the teams functioning. Though rare, it has happened that individual members of teams had to be switched. However, this must be done early. To minimize this problem, students are instructed on the importance of being respectful and considerate of others, as well as the importance of being responsible and dependable. In the vast majority of cases, these problems work themselves out.

In an effort to try to form compatible teams, during the first three weeks of the semester students are evaluated to determine their strengths and weaknesses in the following areas:

- Clinical, Marketing and Technical Research
- Communications (written & Oral)
- Demonstrated Engineering skills such as Drafting, Modeling, Simulations & Analysis
- Technical Problem Solving
• Industry Experience

Evaluations are conducted by the course instructor using various individual assignments and in-class exercises. Students make short presentations on specific subjects. They are required to submit their resume’s as well as a statement of strengths, weaknesses and technical interests in order to ensure balanced teams are formed with complementary skills as well as similar interests. Team members are assisted and encouraged to strengthen their weaknesses during the course to ensure readiness. Supplemental lectures are custom-tailored to assist the students with this objective. This takes considerable effort on the instructor’s part, but we feel that better reflects the industry experience in which employees don’t pick their own team members.

In order to develop students’ presentation skills, specific instruction and guidelines for creation of presentation slides as well as oral presentation are provided. These instructions include recommended font type, font size, number of slides, use of graphs and pictures, etc. Feedback is provided for the numerous (more than 5) in-class presentations to ensure effectiveness of the instructions. Since the students present to the entire class, opportunities for strengthening the individual and group presentation skills is maximized.

The project Design Evaluation Committee is made up of five members of the faculty with complimentary experience in various areas of Biomedical Engineering including clinical expertise. The Committee attends an oral presentation by the group and reads their written project proposal. Each team also has a faculty advisor for its project and most groups have a separate project sponsor who is providing the financial support and technical oversight. If the project is sponsored by a faculty member, then the advisor and sponsor are the same person. The majority of senior design projects at our institution are sponsored by companies. In these cases, the faculty advisor’s responsibility is to monitor the team’s progress, ensure that it remain on track, and ensure that each student meets the learning outcomes from the course and that the final product meets the expectations and requirements of the program. The faculty advisor and sponsor also attend the project proposal presentation and read the written proposals.

A core aspect of our Capstone Design experience is the emphasis on Lean Design and Process Excellence and Six Sigma techniques while maintaining criticality and the importance of functionality. In addition, we include Cost, Reliability, Safety, a Global Perspective, and Regulatory considerations which expands the learning to a true multi-disciplinary level. Another feature that may not be found in most or many Capstone Design courses is the direct industry exposure: In most other programs the school identifies the projects and provides them to the students to pick from. Our students have to solicit their own projects. That's an important step toward identification of the need. Many of our students have received job offers from the same companies that sponsored their project.

During the two 7th semester courses the students develop presentation skills in class. The final oral presentation of the project proposal is limited to 20 minutes, followed by 40 minutes of in
depth questions by the Senior Design Evaluation Committee panel. The faculty advisor and project sponsor also participate in the proposal evaluation session. At the end of the evaluation, the committee makes recommendations regarding the scope and realistic deliverables of the project. Technically the committee can decide that the project is not appropriate, but that has never occurred because the course instructor would have first carefully vetted all projects earlier in the semester so that the group would have time to identify another suitable project if needed. It is more common however that the committee asks the students and the sponsor to reconsider the scope or expected deliverables, either an expansion, or more likely a reduction. The committee members complete an electronic evaluation form that the course instructor uses as part of determining the student’s grade. The form is also returned to the students. The form can be found at the following link [www.bme.fiu.edu]. By the end of the 7th semester the students will have completed all background for their project, identified the user’s needs, translated them into design inputs, completed a risk analysis, identified critical process and project risks and ways to mitigate them, completed a market and intellectual property analysis and developed a preliminary design.

**Description of the 8th Semester Senior Design Experience**

During the 8th semester of the program students complete the engineering design project proposed during the 7th semester. The deliverable is a device or process verified by testing, either experimentally, by modeling, or both, along with all design drawings, a detailed report using a prescribed template, Design History File and Device Master Record (DHF and DMR respectively). The template for the report, and descriptions of DMR and DHF can be found at [www.bme.fiu.edu].

BME 4908 Senior Design Project at FIU contains course learning outcomes that match one-to-one with the program learning outcomes (Table 1 above) with topics most likely similar or even identical to design courses in other biomedical engineering BS programs. Like some other programs our course includes a weekly one hour lecture of invited speakers from industry and the university offices of Compliance and Intellectual Property Management. Students are required to complete an on-line Responsible Conduct of Research course as well as Citi® on-line course on the use of Human Subjects in research. Students also complete on-line training on the use of animals in research. However, few if any projects ever require research on humans or animals in as part of their scope. A list of the most recent topics covered in these lectures appears in Table 2.

<table>
<thead>
<tr>
<th>Table 2: List of Lecture Topics in Spring 2012 BME 4908 Senior Design</th>
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<tbody>
<tr>
<td>1. Required components of the senior design project (Report, evaluations, DHF, DMR etc)</td>
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<tr>
<td>2. Industry-Ready Biomedical Engineering: What does Industry Expect</td>
</tr>
<tr>
<td>3. Principles of DFX – Considerations before the design begins</td>
</tr>
<tr>
<td>4. The Role of Prototyping in Product Development</td>
</tr>
<tr>
<td>5. FDA/Regulatory/Standards (ISO, ASTM etc)</td>
</tr>
<tr>
<td>6. The laboratory Notebook (Assign Responsible Conduct of Research on-line training)</td>
</tr>
<tr>
<td>7. How Products are Approved and Regulated by FDA</td>
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</tbody>
</table>
Students register for the Senior Design Project course with their individual faculty project advisor. All advisors use a common electronic form for evaluating the student’s project and individual participation. The form is also used to tie the performance on the projects to the eight program learning outcomes for accreditation purposes. Students also complete a Work Effort Certification form that is signed by each group member that attests to the participation of each member and finally also completes a confidential Self & Peer evaluation form for themselves and each person on their team. In addition to providing the faculty advisor an assessment of the student’s teamwork, it also provides a tool for students to contemplate their own teamwork but perhaps more importantly to know what is expected of them as professionals. All forms used for student assessment are provided to the students at the beginning of the semester so that they are fully aware of the expectation and how they will be evaluated. All forms used for assessment are available online [www.bme.fiu.edu]. Suggestions and comments on all forms used are welcome.

The faculty project advisor also works with students refining their presentation skills and goes through several dress-rehearsals of their final oral presentation. The senior design experience ends with an oral presentation to a panel of external judges made up of representatives of the department’s industrial advisory board that is open to the public. The judges are provided with a six page executive summary of each group’s project a week before the presentations. Each group presentation is limited to 15 minutes, followed by 10 minutes of questions from the judges. At the end of each presentation the judges score the team on how well the team’s project and presentation demonstrate that they met each of the program’s eight learning outcomes (listed in Table 1 above) as well as their overall opinion of the project and presentation. At the end of the presentations the judges decide on the top two teams for awards. The evaluation form completed by the project presentation judges for each project is also used for program assessment purposes.

Results

We have used this format over the past five years. Students are surveyed anonymously at the end of each semester to determine their own opinions of their attainment of the course learning outcomes. For each course learning outcome the student is asked if they achieved that outcome fully, to a partial degree, or not at all. The responses are assigned 100%, 50%, or 0% and the scores for each learning outcome are averaged. Since the two courses are taught together, and since the course learning outcomes are similar with some overlap, the results of student self-assessment of attainment of the outcomes from both courses are very similar. Results are shown in Table 3. The metric target that we have set for these data is 90%. That is, we want at least 90% of students to feel that they have attained the course learning outcomes in BME 4090 and 4800. It should be pointed out that both 7th semester courses are taught by a Professional Engineer with
Table 3: Average and standard deviation of student responses to surveys on attainment of course learning outcomes in both 7th semester Capstone Design courses. Since no trend versus year was observed the results were averaged over all years from fall 2006 to fall 2012. The program learning outcomes for each course are provided in Table 1.

<table>
<thead>
<tr>
<th>BME 4090 (n=123)</th>
<th>BME 4800 (n=87)</th>
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<tbody>
<tr>
<td>Outcome</td>
<td>AVE(%)</td>
</tr>
<tr>
<td>1</td>
<td>92 ±8</td>
</tr>
<tr>
<td>2</td>
<td>93 ±7</td>
</tr>
<tr>
<td>3</td>
<td>92 ±8</td>
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<td>4</td>
<td>90 ±12</td>
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<tr>
<td>5</td>
<td>93 ±8</td>
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<tr>
<td>6</td>
<td>92 ±3</td>
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The year by year results from the Senior Design External Evaluation of the presentations and executive summaries are presented in Figure 1. Using the assessment form the faculty advisors assess each student based on their experience with the individual student, as well as the team’s project report, oral presentation, the Device Master Record and Design History Files, Self&Peer evaluations, and the Work Certification effort forms. The results of the faculty advisor assessments are shown in Figure 2.

Figure 1: Average (±SD) of the total score (0 lowest to 4 highest) of attainment of program learning outcomes from 2006 to 2012 based on Senior Design Project (BME 4908) presentations and executive summary as determined by Department Advisory Board judges. The senior design external evaluation is based on the entire group. The n values represent the number of groups evaluated by the judges during the final senior design presentations in that particular academic year. Data were collected from the 2006-2007 through the 2011-2012 academic years.
Figure 2: Average (±SD) of the total score (0 lowest to 4 highest) of attainment of program learning outcomes from 2006 to 2012 based on Senior Design Project (BME 4908) presentations and executive summary as determined by the group’s faculty advisor. The senior design faculty evaluation is of individual students. The n values represent the number of students evaluated by the faculty advisors in that particular academic year. Data were collected from the 2006-2007 through the 2011-2012 academic years.

The scoring for the attainment of program learning outcomes is from 0 (lowest) to 4 (highest, 100%). For the program learning outcomes evaluated through the BME 4908 Senior Design Project we expect all outcomes will be achieved at a level of at least 2.5. We have been confident that the students themselves are satisfied with their own attainment of the course learning outcomes. But, we know that student self-assessment is not a reliable indicator that they have actually attained the learning outcomes required. The evaluations by the external judges and faculty, while not perfect, are likely better indicators of attainment of the course learning outcomes. As can be seen from Figures 1 and 2, there appears to have been an improvement in some, but not all, outcomes from fall 2008 when the assessment as outlined in this paper were first implemented. The most recent External Evaluation results for some outcomes seem to have fallen off, but the average is still above 2.5. Due to the large standard deviations, no statistical differences were found and so no firm conclusions can be drawn from this analysis, but we feel that it may provide examples for other programs, especially those in the early stage of their evolution.

Conclusions

The capstone design courses at Florida International University could serve as a model for newer programs that are modifying or just now developing their curriculum. The data presented don’t necessarily show a continuous improvement in student learning outcomes, probably due to the large variability and also since the scores were generally high even in the first year (2006-2007),
but the efficacy of the courses is supported by the assessment data. However, assessing a whole degree program based primarily on the design project courses may not be valid. As with most research surveys there are limitations to the evaluation methods being used. It is difficult to eliminate bias, especially on the part of the faculty advisors towards their own students. The association between the questions on the evaluation survey and the specific program learning outcomes, and the weights assigned are subjective. There is no way to objectively validate the assessment tools themselves. It is impossible to control for many of the variables or to account for all of the factors that may contribute to the results. But the data were collected solely for evaluating our undergraduate program for accreditation and not with the expectation of conducting a detailed analysis in a statistical sense. The number of students, and therefore the number of projects has grown steadily resulting increased working load on the faculty. In the most recent year there were 12 teams and in the 2006-2007 academic year there were 7 teams. The projects all vary in their complexity and scope, and the extent that they actually incorporate each of the eight program learning outcomes. The judges change and while they are provided an evaluation rubric and the project executive summaries, it can’t be assured that they all reviewed the material and thus were evaluating the projects based on the exact same subjective criteria. Finally, there have been numerous other changes to the undergraduate program that we hope would have improved the students overall attainment of the program’s learning outcomes and the senior design projects.

Bibliography