Work in Progress: Streamlining the Biomedical Engineering Design Process

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Olga has earned her undergraduate degree in biomedical engineering from the Milwaukee School of Engineering in 1999, and a doctorate degree in biomedical engineering and functional imaging from the Joint Functional Imaging program at Marquette University and Medical College of Wisconsin in 2004. Prior to entering academia full-time in 2009, Olga completed a three-year postdoctoral fellowship in anesthesiology at the Medical College of Wisconsin, where she studied the effects of general anesthetic agents on brain function. She then worked at GE Healthcare as a product development specialist in CT and Molecular Imaging with emphasis on post-processing software applications for neurology, oncology, and cardiology. Olga has over twenty peer-reviewed publications and three pending patents. Her professional interests include physiological mechanisms of Alzheimer's disease, anesthetic ablation of consciousness, and applicability of medical imaging in stroke and brain trauma.

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Dr. LaMack teaches full-time in the Biomedical Engineering program in the Electrical Engineering and Computer Science Department at the MIlwaukee School of Engineering (MSOE). His areas of specialty include biophysical transport phenomena, biocomputing, physiology, and engineering design. Dr. LaMack holds a Ph.D. in Biomedical Engineering from Duke University, and he is an alumnus of the Biology Scholars Program of the American Society of Microbiology. Prior to becoming focused on engineering education, his research interests included hemodynamics and the study of how vascular cells respond to fluid forces and its implications in vascular pathologies.

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Dr. Tritt is the past director of the Biomedical Engineering (BME) program at the Milwaukee School of Engineering (MSOE). He has been teaching at MSOE since 1990. His Ph.D. is in Chemical Engineering from the Ohio State University as is his B.S. degree. He holds an M.S. in BME, also from Ohio State. His research interests include BME applications of embedded systems (specifically involving the mbed OS); biomedical mass, heat and momentum transfer; medical product and process modeling; biomaterials; and entrepreneurship, innovation and commercialization in engineering education.

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The Accreditation Board for Engineering Technology (ABET) Criterion 5 states that an ABET-accredited undergraduate engineering program must incorporate a capstone design process to better prepare its graduates for various engineering careers [1]. The most common pedagogical approaches to teaching design focus on a Problem-Based Learning and are centered around a specific problem to be addressed, and include general capstone courses covering relevant professional design topics [2, 3]. This approach aims to provide educational experiences that simulate the real-world industrial design process and encourages creativity, innovation and teamwork among students [4, 5].

For over thirty years, our Biomedical Engineering (BME) program has been successfully teaching design as part of our BME curriculum. Over its lifetime, our design curriculum has seen several significant revisions to address changing industrial practices and to improve the students' educational experience and learning outcomes. In line with the modern industrial design practice, our current curriculum focuses on the systems engineering approach and includes key phases such as project definition, system-level design, prototype development, and verification and validation (V&V). In its most recent revision, our design curriculum was restructured to ensure that the students use their time more effectively to produce a functional prototype by the time they graduate, while alleviating some of the logistical challenges and frustrations commonly experienced by our students. Specifically, we reduced the duration of the capstone design sequence by three academic quarters, and delayed its start to the spring term of the junior year, with system design and prototype building phases to be completed during senior year.

Rationale for Design Curriculum Modifications

The previous design track consisted of seven design courses (13 total credits) taught in seven consecutive academic quarters, with the first course offered in the spring quarter of the sophomore year. This sequence allowed for an extended project definition phase involving thorough market research, potential customer interviews, regulatory and House of Quality analyses, as well as the opportunity to develop more detailed design specifications and theoretical system and subsystem design and simulations. While team- and project-dependent, the initial bench system design and prototype-building phases were typically expected to start in the third quarter of the junior year and continue into the senior year. Various professional BME topics relevant to medical device development (e.g. FDA and international regulatory compliance, medical device standards, quality control in medical device manufacturing, and healthcare economics) were distributed among seven design courses. The design sequence contained two design reviews conducted in the fall and winter quarters of the senior year. During the review, the BME faculty would meet with each design team to discuss their progress and design decisions, and to provide feedback.

The learning outcomes of the design courses along with the students' overall educational experience were routinely assessed using quarterly course evaluations, senior-exit surveys and debriefing. At the time, these data were collected for internal program assessment and

improvement only, and not for public dissemination (no IRB approval). The feedback from the BME program Industrial Advisory Committee (IAC) was also regularly sought to ensure that the design sequence not only met the ABET educational requirements but also provided regular opportunities for industry collaboration and mentorship of student teams and projects. The composite of these data revealed several disadvantages of this track, which served as the motivation for the most recent revision.

1. Sophomore and junior teams experienced challenges proceeding to design and simulations phases without having completed (or being enrolled in) essential engineering courses offered later in the junior and senior years.
2. As the junior year contains the most challenging courses in our curriculum, the teams experienced the most turnover during that time, as some students transitioned out of the program or fell behind on the track. Some teams developed interpersonal problems that seemed to exacerbate over time.
3. Due to the heavy course load in the junior year, the students were often unable to devote as much time to design as necessary, adding to their level of frustration with the process.
4. The extended design sequence made collaborations with the industry challenging. The projects supported by our industrial partners typically require shorter timelines that do not align well with this design track.

New Design Track

The old design sequence was reduced in duration from seven to four design courses (9 credits), with the first course now being offered in the spring term of the junior year. As recommended by the IAC, the new track retained the two design reviews. The professional BME topics were moved from the original design courses to the new course *Professional Topics in Biomedical Engineering* (3 credits). While not specifically associated with the design sequence, this course is offered two quarters prior to the start of design and is intended to introduce the students to the fundamental topics of medical device development. This restructuring resulted in the loss of one credit for the design sequence content. Tables 1 and 2 summarize the two design tracks by courses, major outcomes, topics, and timelines.

Table 1: Old Design Track

Old Design Track
Course 1 (1 credit) – Spring Term, Year 2
• ***Outcome*****:** assignment of teams and projects
• ***Topics:*** project management, literature review, codes and standards, user needs
Course 2 (1 credit) – Fall Term, Year 3
• ***Outcome:*** feasibility analysis
• ***Topics:*** market research, FDA regulation, codes and standards, intellectual property, IRB, design controls, CAD and solid modeling
Course 3 (1 credit) – Winter Term, Year 3
• ***Outcome:*** specifications and system design
• ***Topics:*** interface specifications, system design, funding, biomedical transducers, power budget, technical literature, initial bench design and prototype building

Course 4 (1 credit) – Spring Term, Year 3

- ***Outcome:*** *system design and testing*
- ***Topics:*** bench design and testing, electrical and mechanical safety, design for safety and reliability, electrical noise and interference

Course 5 (3 credits) – Fall Term, Year 4

- ***Outcome:*** completion of design and subsystems testing
- ***Topics:*** medical device evaluation, design for usability, medical device software, professional licensure, technical persuasion.

Course 6 (3 credits) – Winter Term, Year 4

- ***Outcome:*** system integration and testing
- ***Topics:*** design for manufacturing, statistics in device testing, global impact of design

Course 7 (3 credits) – Spring Term, Year 4

- ***Outcome:*** completion of system integration and system-level testing, final documentation
- ***Topics:*** assembly, engineering ethics, biological safety and sterilization processes

Table 2 contains the outline of the new design sequence. Many topics listed in the table are now covered in the *Professional Topics* course and are expected to be applied in the new design courses.

Table 2: New Design Track.

New Design Track
Course 1 (1 credit) – Spring Term, Year 3
• ***Outcome*****:** assignment of teams and projects, market research, project plan
• ***Topics:*** design controls, project management, literature research, FDA regulation, codes and standards, intellectual property, user needs, design specifications.
Course 2 (2 credits) – Fall Term, Year 4
• ***Outcome:*** design specifications, system design and simulations
• ***Topics:*** system diagrams, interface specifications, hazard analysis, university resources
Course 3 (2 credits) – Winter Term, Year 4
• ***Outcome:*** subsystem design, system integration, prototype building and bench testing
• ***Topics:*** power budgets, electrical noise and interference
Course 4 (2 credits) – Spring Term, Year 4
• ***Outcome:*** completion of system integration and V&V testing, final documentation
• ***Topics:*** V&V testing

Assessment

The objective of the latest revision of the BME design sequence is to provide the course structure that enhances the students' ability to develop a functional prototype consistent with the industry requirements, while enhancing the students' overall educational experience and engagement in design. Thus, the assessment is primarily intended to capture the students' perceived knowledge, abilities, and the overall engagement in design upon completion of the design sequence. To ascertain the validity of the assessment results, the following three-pronged assessment approach will be undertaken.

1. The students will complete the senior-exit and professional-topics surveys to assess: (a) their ability to apply a systematic approach to identify design inputs and outputs, and to

verify the attainment of design requirements in the final prototype; (b) their ability to develop a functional prototype appropriate for the level of challenge associated with the project; (c) their ability to apply appropriate research and analyses tools to arrive at their engineering solutions; (d) their ability to work functionally as a team and resolve team conflicts; (e) their ability to stay continuously engaged in and remain enthusiastic about their project; (d) their perceived knowledge and recognition of importance of professional design topics.

2. The same outcomes (a-d) will be assessed by the instructors via individual student performance questionnaires.

3. Student feedback regarding the same outcomes (a-d) will also be sought and documented by the BME program director during the in-person senior-exit debriefing session.

All three assessment approaches will be undertaken upon the students' completion of the senior design sequence. Consistency in responses among the three approaches will be sought as an indication of a valid observation. Currently, 45 seniors are completing the old design sequence, and will participate in the abovementioned assessment plan in May 2018. The cohort of 47 juniors just started on the new design track in March 2018. This cohort will be assessed upon completion of the design course sequence in May 2019.

References

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