

AC 2008-2424: DESIGN AND EXPERIMENTAL CAPSTONE: AN INTEGRATED EXPERIENCE

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Design and Experimental Capstone: An Integrated Experience

Abstract

We report on student outcomes across three phases in the development of the BME senior capstone experience. The BME department provides a comprehensive capstone experience to its seniors. All students enroll in a two-course, team-based, device design capstone sequence and a concurrent two-course, team-based, experimental research capstone sequence. The goal of the device design capstone is to advance intellectual property while providing a multidisciplinary design experience. In the first course of the sequence, the teams are presented with a clinical problem and are expected to conceive, design, prototype and evaluate devices with innovative solutions. The course emphasizes information gathering, establishing requirements, concept development, and evaluation. In the second course in the sequence, a verification plan is generated and implemented. The goal of the experimental research capstone sequence is to introduce students to the design and conduct of a pilot study involving human subjects. To this end, students develop a hypothesis, design an experimental protocol to test the hypothesis, conduct an experiment or survey, and use an appropriate statistical analysis of the data. The course also requires students to design an Informed Consent form, adopt high ethical standards for research involving human subjects, and generate a scientific manuscript to report the results.

We found that a close integration between experimental methods of testing/data collection was critical in the initial and final stages of design. Those teams that had an integrated design and experimental capstone experience produced better designs than those teams that had separate experiences.

Introduction

Design Capstone Experience

The University of Cincinnati (UC) Colleges of Engineering; Medicine; Business; and Design, Architecture, Art, and Planning have partnered in the development of the Medical Device Innovation and Entrepreneurship Program (MDIEP). The mission of the MDIEP is to prepare students to be successful entrepreneurs and leaders within the medical device industry. The program creates new intellectual property for commercialization by partnering physician innovators with multi-disciplinary student teams from industrial design, biomedical engineering and business honors academic programs. The multi-disciplinary approach brings together the key knowledge and resources needed to advance early stage innovations. It also educates students in a multi-disciplinary team setting where they learn about the tools and techniques of other disciplines, while collectively learning about the unique requirements of developing medical products in a highly regulated environment.

The MDIEP implements a process that is a subset of the FDA Design Control Waterfall (Figure 1). The design waterfall governs the iterative process of design, design verification, and device validation. The goal of the MDIEP is to create a prototype and verify that the prototype meets the design requirements. Therefore, the elements of the waterfall that deal with the medical device and the validation of the medical device are not implemented in the MDIEP.

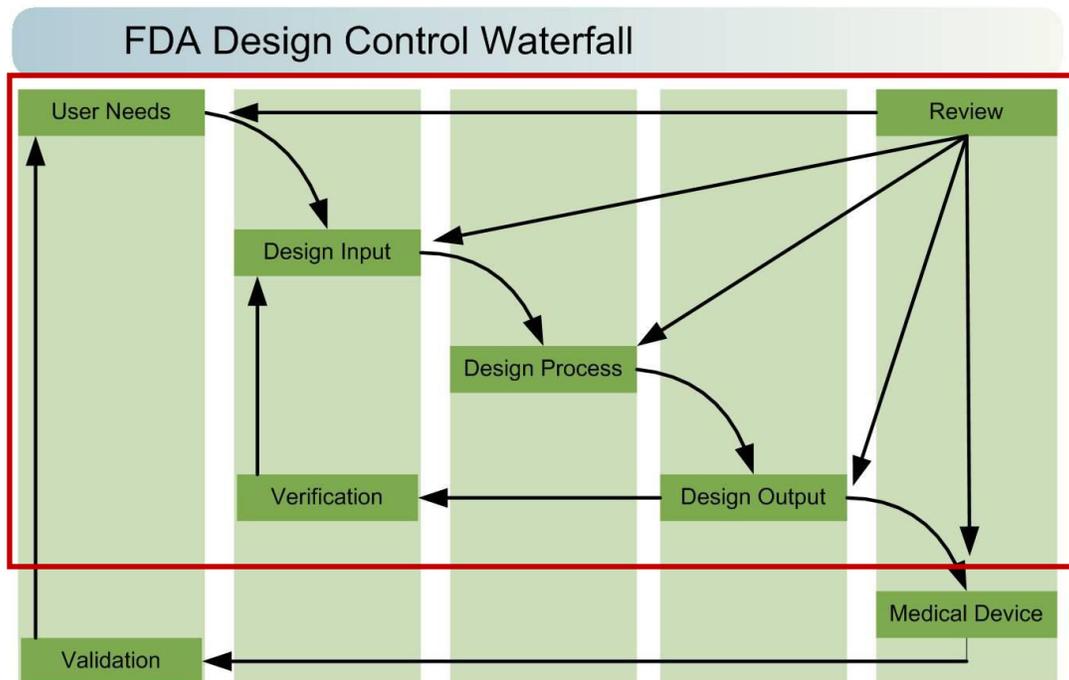


Figure 1. The FDA Control Waterfall. All medical devices must follow the FDA design control waterfall. The goal of the UCBME design capstone experience is to develop a working prototype instead of a completed medical device. Therefore, the capstone experience follows the waterfall to point of Verification (of design requirements) instead of Validation (of the medical device). The red box encompasses the subset of the waterfall followed by the capstone experience.

The student teams participating in the MDIEP are comprised of seniors from biomedical engineering, industrial design, and UC's Business Honors program. Prior to undertaking the innovation courses, all students are required to take an introductory course in medical product development. Course topics include product development and commercialization processes, requirements of successful medical device innovation, professional cultures, and multi-disciplinary teaming. Faculty lectures are supplemented with industry professional presentations and clinical site visits. Upon completion of this course, students have a macro understanding of the challenges and processes which are the basis for successful medical device innovation.

The physician innovators work as part of the design team and the innovation development process is supervised by UC faculty from all participating programs. The innovation development process begins with defining the unmet clinical need and identifying an innovative solution. The physician-innovators meet regularly with the team. They educate the students on the anatomical, physiological, and clinical requirements and provide access to the clinical setting and to allied health professionals. They also mentor the students with regard to appropriate behavior and means of communication within a clinical setting.

The innovation development process is divided into two phases that correspond to quarters in UC's academic calendar year: Concept Generation and Technology Development. In Concept Generation the team is first educated on the disease state and proposed innovation. The team then identifies critical factors for success, available technologies, market potential, and the competitive environment. Concepts are generated and evaluated, and a plan is generated for the

subsequent technology development phase. During the Technology Development phase, the engineering students work collaboratively with design students to generate detailed designs, perform analyses, and conduct experiments needed to demonstrate technical feasibility. Prototypes are fabricated and evaluated. The two phases make up what we call the Design Capstone Experience for the senior biomedical engineering students.

Experimental Capstone Experience

Concurrent with their two-quarter Design Capstone Experience, the same senior-year biomedical engineering students are engaged in a two-quarter sequence that we call the Experimental Capstone Experience. The goal of the Experimental Capstone Experience is to provide the students with the opportunity to design and conduct a pilot study involving human subjects. The approach is for each team of students to develop a hypothesis, design the experimental protocol to test the hypothesis, perform experiments (for example, conduct a survey), use an appropriate statistical analysis of the data. In the process, students must become familiar with the design of an Informed Consent Form and the practice of high ethical standards of research involving human subjects. Finally, the students are asked to compile their experience in the form of a scientific manuscript.

The Development of an Integrated Capstone Experience

The Design and Experimental capstone experiences are required of all senior BME students. In addition, the capstone experiences are held concurrently. Therefore, every senior BME student is simultaneously undergoing their design and experimental capstone experiences. Initially, these experiences were independent of each other. That is, each team in each capstone experience had a separate project and there was no correlation between teams or between capstone experiences. It soon became clear that the techniques that were being developed in the experimental capstone sequence would prove beneficial in the design capstone sequence. In this paper, we report on an ongoing, three-phase program to integrate the design and experimental capstone experiences.

Phase I: Independent Capstone Experiences

In the original design of the curriculum (Phase I), the two capstone sequences were independent. That is, each capstone sequence had its own project and formed different teams (from the same set of students). Once established, a team remained intact for the duration of that capstone sequence. We assessed student outcomes at the end of the first year of the concurrent but independent capstone sequences. From this assessment, we concluded the following:

- the statistical design methods that are used in the experimental research capstone sequence would positively impact the device design outcomes
- experimental testing of existing devices were a necessary part in the requirement definition stage
- verification of the design requirements, as called for by the FDA design controls, involved experimental testing of the prototype
- The experimental capstone involved hypothesis-based experiments. The experiments that were required in the design capstone were not hypothesis-based, but driven by the need to collect the data needed to make sound design decisions.

The faculty concluded that completely independent capstone experiences were not conducive to creating a comprehensive design or experimental capstone experience.

Phase II: Selective Integration of Capstone Experiences

We implemented a pilot study (Phase II) in which two of the design teams were allowed to remain intact for the experimental capstone experience. Furthermore, those teams were also assigned the same project in both capstone sequences. All other students experienced the capstone courses in a manner identical to students in Phase I. We found that the students in the “single-team, single-project” performed at a higher level as measured by quantitative and qualitative assessments versus those students who were part of “two-teams, two-projects”. We found that data generated from the experimental capstone sequence would improve the product design process by a) providing a basis for comparison between different prototypes or a prototype and control devices, and b) providing quantitative data for the specifications/requirements stage of device design.

Phase III: A Single, Integrated of Capstone Experience

We have now moved to Phase III: each team spans both capstone experiences and each team has a single project in both capstone experiences. Although only one quarter of the two-quarter integrated capstone experience has been completed, there is already quantifiable improvement in outcomes. For example, five of six design teams have recently been awarded \$500 stipends toward preparing their designs for entry into the national BMEidea competition. Last year, only one team competed in the design competition.

Lessons Learned

The MDIEP follows a subset of the FDA Design Control Waterfall as shown in Figure 1. There are several points within that waterfall that require the collection of data. Figure 2 expands the FDA waterfall to include the tasks required in each element of Figure 1. To define User Needs, “Ethnographic/ User Research” often requires interviewing or surveying the user (patient, care giver, physician, or medical technician). In addition, verification that the prototype meets the design requirements requires data collection during “Prototype Development & Assessment.” The need for data collection and separate points in the design process necessitates different data collection procedures.

The faculty of the MDIEP found that the quality of a team’s design is directly related to the ability of the team to collect the data necessary for making sound design decisions. However, each team has a different project based on the specific clinical need. Therefore, each team’s prototype will be also different. The data needed to identify the user needs (ethnographic/user needs) and define the design requirements will also be different. The ability of the MDIEP to provide the necessary infrastructure to all teams is critically important to the success of the project.

Projects are selected for inclusion into the MDIEP from a set of projects brought to the BME Department by physician-innovators, researchers, or device companies. There are several factors that influence the decision of acceptance of a candidate project. However, after assessing the outcomes of this three-phase program to integrate design and experimental capstone experiences, one more factor has been added to the requirements list. It has become evident that one of the

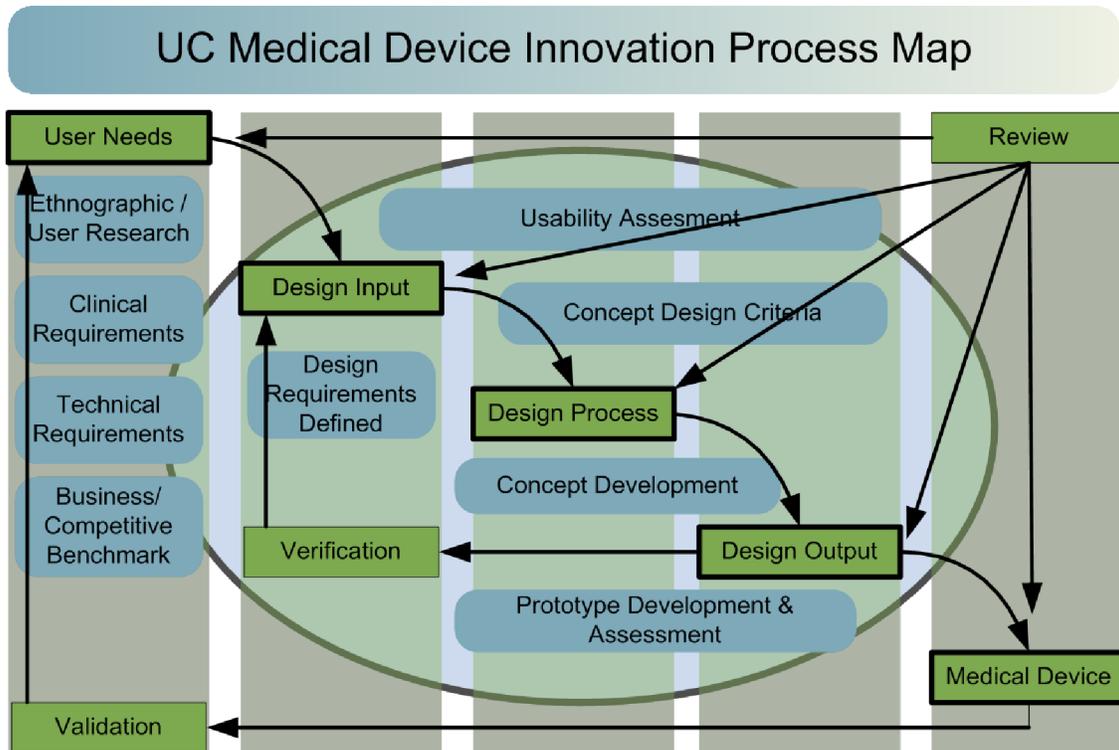


Figure 2. Expansion of the FDA Design Control Waterfall to incorporate the elements of the MDIEP. Testing/Data collection is required in Ethnographic/User Needs and Prototype Development & Assessment.

most important requirements for a project to be included in the MDIEP is that infrastructure exists for collect the data necessary for identifying the user needs and verifying that the prototype meets the design requirements.