

BE 694 Biomedical Needs Finding

BE 695 Advanced Biomedical Design and Development

COURSE DESCRIPTION:

Course	BE 695/BE 694
Semester	Fall 2021 – Spring 2022
Hours	Mondays and Wednesdays 2:30-4:15 PM (Lectures); TBD (Design Reviews)
Location	LSE B03 (24 Cummington Mall, downstairs)
Credits	BE 694 = 1 Credit (F21 only) BE 695 = 8 Credits (both F21 and S22 required)
Course Director	Prof. Mario Cabodi, Director of BME Masters Programs, cabodi@bu.edu
Co-Director	Mr. Marc Gillette, Director, International Strategy, Boston Scientific Corporation, gillettm@bu.edu
Office	ERB 331, 44 Cummington Mall Zoom only
Office Hours	by appointment only

COURSE DESCRIPTION AND APPROACH

BE 694 is a one-credit, one-semester class taught in conjunction with BE 695. In this course, student teams will work with their Clinical Advisor, a clinician practicing at Boston Medical Center, in their selected clinical specialty, to observe first-hand how technology is applied to the diagnosis and treatment of their patients. Detailed and comprehensive observation logs will be maintained by each student recording their visits to the clinic. Opportunities for improving the current standard of care through technology and new product development will be explored through the “Clinical Needs Finding” process.

BE 695 is a two-semester project-based design course that provides graduate engineering students with an intense, immersive, experiential opportunity to develop professional-level skills in biomedical product design and development.

The course is divided into four modules: *Discovery*, *Design*, *Development*, and *Deployment*.

During the *Discovery Module*, students will directly observe clinical practice related to their selected clinical specialty. Teams will identify technology-related clinical challenges, explore the relevant anatomy, physiology, and pathology and select their own project. Classroom instruction will include introductions in formal needs finding, intellectual property, regulatory, and safety methods. Clinical requirements will be developed during this Module.

During the *Design Module*, many alternative design strategies will be explored and compared in the context of Competitive Analysis, intellectual property strategies, preliminary market trends, and economic variables. An optimized solution strategy will be proposed as the final presentation for this Module.

During the *Development Module*, students will establish engineering specifications, build working prototypes of key components of their engineering solution, incorporate Design for

Manufacturing considerations, and develop risk mitigation strategies. Validation testing will be used to evaluate design feasibility.

During the *Deployment Module*, students will create a full business model canvas, evaluate reimbursement and intellectual property feasibility. Packaging, labeling, and sterilization considerations will be included in the business model analysis.

Biomedical research and industry leaders will be invited to present cases that illustrate both technology successes and failures from their own experience, and discuss trends for the future of medical innovation.

For BME Master of Engineering students, BE 695 is a required course and fulfills one technical and one leadership requirement towards completing the Biomedical Masters of Engineering degree program at Boston University. Students are required to take both semesters to receive graduate credit for the course.

REQUIRED MATERIALS

Individual and Team Observation Logs and Design Journals

Each member of each Team will keep and maintain a comprehensive log of their clinical observations. A standard template is provided. Each student will also maintain a journal that will record the preparation, analysis, critiques, and novelty related to each idea generated during observations, discussions, meetings, and in class. These will be incorporated in the “Binder” as part of the Design History File. The team member will maintain minutes for each team meeting and assemble the Team Log. The Logs will be maintained and assembled on a suitable server (Google Drive or Dropbox). This personal Journal can be prepared on paper, but should be routinely scanned into an appropriate server file.

Not required, but a useful reference:

Biodesign: The Process of Innovating Medical Technologies. Yock, Zenios, Makower. 2nd Edition. Cambridge University Press (ISBN: 978-1107087354)

Additional Reading Materials will be provided in advance of lectures, guest lectures, current event discussions, including articles, texts, videos, and websites.

EXPECTATIONS AND REQUIREMENTS

Clinical Observations: Each Team will be responsible for working with the scheduling coordinator for your specialty to select and schedule procedures appropriate for your observations. Most Operating Rooms are very crowded places, and the senior clinician in charge of that room sets the rules for how many observers can be present, for how long, and how often. Teams will often have to rotate through longer procedures, take notes on a section of the case, and then combine and analyze the full experience in

Team Meetings. In general, each student and each team will want to take the fullest possible advantage of this unique experience. On average, each student should aim for at least 50-100 hours of observations during the year, with much of that time scheduled during the first semester.

Attendance: Each week of this course will include a variety of activities: lectures on engineering topics, invited lectures by professionals working in the medical device field, hands-on prototyping, discussions, and presentations from your fellow classmates. We expect you to attend every class and you must let us know in advance (via email) if you plan to miss a class; everyone gets a single excused absence (*no questions asked*), and, of course, please do not come to class if you are ill. Please note that having previously-arranged travel or vacation plans is *not* a reason to miss class.

Smartphone/electronics policy: We all know how intrusive and distracting phones/smartwatches/tablets/laptops can be. There will be times when I specifically ask you to read a case study online, complete a worksheet, or look up relevant information for an activity; outside of these times, *please do not spend time on your gadgets during lecture*. I will mention ahead of time when I would like you to use your electronics. Please respect these requests, and we will all get more out of class; your grade will be affected by non-compliance with these requests.

Practera site: All course documents, assignments, and announcements will be available on the Practera course site. Submit all assignments and evaluations to the Practera site. Just to be clear: submit all assignments and evaluations to the Practera site. Do not email them to us. It is your responsibility to ensure that submissions are completed and accepted by Practera.

Presentations recording: All design reviews will be recorded for the benefit of external mentors who are unable to attend live sessions (either in person or remotely). Recorded sessions will be made available to registered students ONLY via their password-protected Practera account. Students may not share these recordings with anyone not registered in the course and may not repost them in a public platform.

Students have the right to opt-out of being part of the design review recording. Please contact your instructor or teaching assistant to discuss options for participating in the course while opting out of the class recording.

No student may record any classroom or other academic activity (including advising sessions or office hours) without my express written consent. Unauthorized use of classroom recordings – including distributing or posting them – is also prohibited. If you have (or think you may have) a disability such that you need to record classroom activities, or need other assistive services, you should contact Disability & Access Services to request an appropriate accommodation.

Academic Honesty: Plagiarism of ANY KIND will not be tolerated. Any assignment that exhibits plagiarism, copying, cutting and pasting, teamwork when teamwork is precluded will result in an F (zero credit) on that assignment. Depending on the seriousness of the offense, an F in the course may result. The Academic Conduct Code is available at <http://www.bu.edu/eng/current-students/ugrad/faq/>. All quoted text must be properly cited.

Disability Accommodation: Reasonable accommodations for eligible individuals will be provided in accordance with Boston University policies:

<http://www.bu.edu/academics/policies/disability-accommodation/>

Please make the Instructors aware of any required accommodations at the earliest possible time.

Re-Grading: Requests on exams and assignments must be submitted in writing within one week of grades being returned and only after the solutions are posted. A rationale for re-grading should be included. Points will only be changed for errors made in calculating final scores or grading that did not follow the grading rubric for that assignment.

Official BU Policy on Re-Grading: “This policy provides a means for a student to contest a final course grade received in a credit-bearing Boston University course when that grade is alleged by the student to be arbitrary. Grading is the prerogative of the faculty and is based upon a student’s performance against a clearly articulated set of assignments, expectations, and standards.

Arbitrary grades are defined as those:

- assigned to a student on some basis other than performance in the course; or,
- assigned to a student by resorting to unreasonable standards different from those which were applied to other students in that course or section of the course; or,
- assigned to a student on the basis of criteria that are a substantial, unreasonable, and unannounced departure from the instructor’s previously articulated standards.

Issues that do not meet one or more of these criteria of arbitrariness are not appropriate bases for a grade appeal under this policy. Only final course grades may be formally appealed.”

Due dates: All assignments should be submitted by 11:59 pm EST on the day that they are due on the Practera site. In the unlikely event that Practera should fail, you may email the assignments to all Instructors.

Any assignment handed in late without prior approval for extra time will lose 10% after one day, 25% after two days, and will not be graded after three days.

ASSESSMENT (GRADING) BE 694

Clinical Observation Volume (25%)

Total individual observation time and frequency.

Clinical Observation Quality (25%)

Care, completeness, detailed descriptions, questions and insights. Individual and team.

Clinical Observation Problem Synthesis (30%)

Quality and quantity of proposed clinical challenges. Presentations and discussion leading to final selection of Clinical Challenge for the Team. Meeting deadlines and deliverables. Individual and team.

Clinical Etiquette (20%)

Observed protocols, professional decorum, respect and appreciation. Individual.

ASSESSMENT (GRADING) BE 695

Your final grade for BE 695 will not be recorded until the end of the Spring semester. A special no-penalty incomplete "J" grade will be recorded at the end of the Fall semester. Your BE 695 final grade will be determined by a combination of individual and group assignments:

Individual Assignments (25%):

Design journal entries, current events postings, individual writing assignments, and individual contributions to the Binder will be graded and privately posted on Practera. Each assignment will have written expectations, deliverables, and grading rubrics posted when the assignment is opened.

Team Assignments (20%):

Team Meeting minutes, research plans, team and team presentations will be graded and periodically posted privately to the Team.

Peer Evaluation (10%):

Peer teaching and mentoring, constructive group dynamics, outreach to other teams, supportive critiques during presentations, as reported by classmates.

Class Participation (15%)

Attendance, contributions during class discussions, case studies discussions.

Clinical Evaluation (5%)

Each student and each team will be evaluated by their Clinical Advisory Team on their adherence to clinical protocol, their courteousness, and their curiosity quotient.

Binder (25%):

Overall completeness, organization, insights, analysis, planning, and conclusions.