



Introduction

1. Course Information

Course Name	<i>Advanced Biomedical Design and Development</i>
Institution	<i>Boston University</i>
Course Number	ENG BE 695
# credits	8 (must enroll for 2 semesters)
Meeting times	F: Thursday 630pm – 815pm; S: Thursday 630pm-80pm
Is this a required course?	YES for
Pre-requisites	(?)
Target audience (e.g. 1st, 2nd year):	Students in BME Master of Engineering Program
Textbook	NA(?)
Course Website (if it exists)	https://www.bu.edu/academics/eng/courses/eng-be-694/

2. Course Description

In the space below, “paste” the description of the course. This can be the actual description listed in the syllabus from the course.

This two-semester 8-credit course is a required sequence for students enrolled in the BME Master of Engineering program. Students will work with leading clinicians to observe and identify unmet clinical challenges, design and develop innovative engineering solutions to those challenges, and explore the regulatory, intellectual property, and reimbursement pathways that will ultimately advance the standard of patient care through the deployment of their innovations. During the first semester, students will qualify for Medical Observer Status and the Boston Medical Center and project teams will conduct formal Needs Finding protocols, select projects, and design alternative solutions. During the second semester, project teams will develop their designs, and make multiple prototypes. Formal Design Control, Life Cycle, Risk Analysis, Project Management, and Intellectual Property Strategies will be introduced. Using formal Product Develop Protocols, students will prepare a detailed regulatory and implementation pathway analysis for completing the commercialization process needed to eventually bring their innovations into clinical practice. 8 credits over 2 semesters - must enroll for both semesters

3. Course Learning Objectives

In the space below, “paste” the course learning objectives if explicitly stated.

4. Fundamental Tools and Skills

In the space below, describe the fundamental tools and skills that are addressed in the class. For example, labview, arduino's, the design process etc.

Design Process
Exploration of regulatory, IP, and reimbursement pathways
Needs Finding
Formal Design Control, Life Cycle, Risk Analysis, Project Management, and Intellectual Property Strategies
Product Develop Protocols
Writing business models

5. Exercises or Experiential Projects of Interest

Exercise/Project	Project Overview	Learning Activities and Assessments	Required Resources for Project Completion
<i>EXAMPLE</i>	Students make pulse oximeters.	Learning Activities <ul style="list-style-type: none"> • Students will use resistors and a bread board to ... • In a short essay assignment, students explain... Assessment <ul style="list-style-type: none"> • Students complete a laboratory report that explains ... 	Function generator, resistors, oscilloscope....
1	Observation Reports		
2	Clinical Observation		

Exercise/Project	Project Overview	Learning Activities and Assessments	Required Resources for Project Completion
	and Problem Presentations		
	Comparative Attribute Analysis		
	Marketing Specification -User/ Clinical		
	Requirements, and Functional Specification		
	Design Presentations		
	Peer Review		
	Project Design History file		
	Prototype I Presentations - Design and Prel. Risk		
	Presentations - Prototype II		
	Business Model presentations		
	Clinical Feedback and VOTC inputs-Focus Groups		
	Documentation		

Exercise/Project	Project Overview	Learning Activities and Assessments	Required Resources for Project Completion
	Checklist and Organization		
	Final Presentations		

6. Additional thoughts

If you have any other thoughts about this course, but have not been able to reflect it elsewhere in the document, please feel free to do so here.

Emailed Professor. Hopefully, I will be able to expand if he replies.

Similar to our graduate design class, but different elements: clinical needs finding in the front-end portion, business models and IP/reimbursement regulatory towards the end.