

Biomedical Device Innovation I

Course Abbreviation: BIOEN 6801

Designation: Required for Graduate BME students in the BioInnovate track

Course Description:

First semester of a two semester graduate level project based learning class focused on medical device design and documentation within the regulatory framework of FDA QSR, business plan development, and business startup concepts. This course will bring together students in medicine and medical residency, traditional engineering students, and business / law students for a multidisciplinary experience in medical product innovation. The medical device ideas will be produced and refined through a summer clinical immersion course where students are exposed to clinical environments and identify unmet needs through interaction with the environment, clinicians, and patients. During the first semester design input phase, students will design, prototype, and document a medical device using FDA requirements for design control. In order to accomplish this goal, all projects will utilize customer driven inputs to motivate the development of product specifications. Prototypes will then be developed based upon these specifications. In order to provide the training required in device development, two weekly lab sessions will be held to focus on machine shop tools and prototyping. There will also be two lectures per week to introduce concepts including FDA QSR, design documentation, project management, software and hardware tools, and risk management.

Course Prerequisites: Bioengineering graduate status

Number of credits: 3

Instructor: Robert Hitchcock, Ph.D.

Office hours: During lab time or by appointment.

Email: R.Hitchcock@utah.edu

Phone: 585-7741

Class T.A.: Monir Parikh

Office hours: During lab time by appointment.

Email: monir.parikh@utah.edu

Number of lecture hours per week: 2 **Number of lab hours per week:** 6
(hours per week or equivalent number per week for a full semester or equivalent)

Lectures:

Labs:

Course will be offered: Fall

SYLLABI INFORMATION

<u>ASL</u> <u>O</u>	<u>Course Objectives/Student Outcomes</u>	<u>Assessments</u>
1	<p>The student will <u>remember</u> and <u>understand</u> the process of medical device design under FDA regulations.</p> <ol style="list-style-type: none"> 1. Projects will be planned, managed, documented, and executed using FDA Design Control Requirements. 2. Projects will require customer driven inputs to develop product specifications and prototype fabrication. 3. Projects will be implemented using a planned, multidisciplinary team based approach. 	<p>The student will be effectively assessed on each topic listed using assignments such as:</p> <ol style="list-style-type: none"> 1. Development and submission of project plan, requirements, specifications, and weekly progress report documents. 2. Development and of prototype elements. 3. Design review meetings
2	<p>The student will <u>understand</u> how to safely use machine shop equipment in the development of medical devices. The following concepts will be taught:</p> <ol style="list-style-type: none"> 1. Machine shop safety 2. Machine shop tools <ol style="list-style-type: none"> a. Tooling b. Mill, Lathe, Drill press c. CNC machines d. Sanding / Grinding 3. Translating engineering drawings from paper to product 	<p>The student will <u>design</u> and <u>build</u> mock medical device models using the concepts taught in lab.</p> <ol style="list-style-type: none"> 1. Student will <u>design</u> solid models in SolidWorks 2. Student will create engineering specifications for machine shop fabrication 3. Student will use the machine shop to build their models
3	<p>The student will <u>understand</u> and <u>apply</u> prototyping concepts related to medical device design, including:</p> <ol style="list-style-type: none"> 1. Solid modeling 2. Rapid prototyping 3. Electronic assembly 4. Molding and casting 5. CNC machining 6. Fasteners and adhesives 7. Injection molding 8. Design for manufacture and assembly 	<p>The student will <u>translate</u> the design specifications into testable prototype components using the techniques learned in the prototyping lab.</p> <ol style="list-style-type: none"> 1. Student will design and prototype a simple medical device using the concepts and tools learned in prototyping lab.

Delivery Format(s): Lectures, class discussions, design reviews, student presentations, assignments, guest speakers, research / manufacturing facility tours, and hands-on design studio activities.

Required References:

FDA 21CFR820: Title 21--Food and Drugs, Subchapter H – Medical Devices, Part 820 Quality System Regulation (available on the web at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820&showFR=1>)

Design Controls for the Medical Device Industry, Marie B. Teixeira and Richard Bradley, Marcel Decker, Inc. 2002. ISBN:0-8247-0830-X

Tentative Class Schedule

Week	Date	Lecture	Date	Lab	Machine Lab
1		Introduction		bioDesign lab introduction	Introduction
2		Design and Projects Concept Evaluation and Selection		Fundamentals of prototyping	Machine shop safety
3		Project Management		CNC machining	Basic machining tools
4		FDA and Device Design		Molding, casting	Tooling
5		QSR Design Controls and SOPs		Mechanical testing	Milling
6		Intellectual Property		Software / Hardware tools	Milling
7		Marketing Requirements		Electronic assembly	Lathe
8		Product Documentation		Marketing Reqs	Lathe
9		Software Tools		Marketing Reqs	CNC Machining
10		Design Tools		Design Review	CNC Machining
11		Design Concepts and Diagrams		Design Specs	Measurements systems
12		Design Specifications		Design Specs	Measurement systems
13		CAD and Mechanical Drawing		Design Review	Quality Control
14		Prototyping and Testing		Prototype Development	Tolerances
15		Risk Management		Prototype Development	
16		LabView and Hardware		Presentations	
17		Optics		Presentations	

Grade Breakdown

Progress Report	10%
Project Plan	10%
Design Requirements	25%
Reqs Presentation	10%
Design Specifications	25%
Specs Presentation	10%
Machine Shop Model	5%
Prototyping Assignment	5%

Final Grade Breakdown

A	95-100%
A-	90-95%
B+	87-90%
B	83-87%
B-	80-83%
C+	77-80%
C	73-77%
C-	70-73%

Students with Special Needs: The University of Utah seeks to provide equal access to its programs, services and activities for people with disabilities. If you will need accommodations in the class, reasonable prior notice needs to be given to the Center for Disability Services, 162 Union Building, 581-5020 (V/TDD). CDS will work with you and the instructor to make arrangements for accommodations.

Academic Honesty: All honesty and plagiarism policies established by the University of Utah will be upheld in this class. Academic misconduct includes, but is not limited to, representing another's work as your own, collaborating on individual assignments, and submitting the same work for more than one course without the permission of both instructors. Any of these actions will not be tolerated.

If you include information from outside the class or quotes in your written assignments, you must provide citations and a reference list. Avoid the urge to over-rely on quotes; a written assignment that is substantially made up of quoted material will not be considered to be your own work, even if you have used correct citations.

For further information about the University of Utah's policies regarding academic misconduct, please refer to the online version of the Student Handbook and look for "University Code":
<http://www.acs.utah.edu/sched/handbook/toc.htm>

University Drop and Withdrawal Policies: You may drop this class without penalty or permission until January 20, 2010. You may withdraw from the course without permission from January 20, 2010 until March 5, 2010, but a "W" will be recorded on your academic record, and applicable tuition and fees will be assessed. After March 5, 2010, you will not be allowed to withdraw from this course. If you have any questions regarding this policy, please contact the Office of Admissions and Registrar at (801) 581-5808.

Incompletes: In order to qualify for an "Incomplete" in any University of Utah course, you must complete no less than 80% of the course work and be in good standing (i.e., have earned at least a C on all completed work) and receive permission from the instructor. The FCS Department Policy is that students who do not submit work required to resolve an "Incomplete" within 1 year of the posting of the "I" on the student's transcript will automatically receive a failing grade. No exceptions will be made to this policy.

Student Responsibilities: You are expected to...

1. Attend class and participate in class activities and discussions.
2. Complete talks and assignments on time, or make alternate arrangements for completing assigned work with the instructor in advance of assigned due dates.
3. Arrive on time for class and stay the entire class period – arriving late and/or leaving early will be disruptive to group work and class discussions.
4. Treat one another, the instructor, campus staff, and the classroom with respect.
5. Turn cell phones OFF prior to the beginning of class.

6. Seek help from the instructor (and other resources such as the Center for Disability Services or the Writing Center) whenever necessary, and before minor problems become major barriers to learning.
7. Refer to the syllabus and the class web page for important information pertaining to assignments and class policies.

For the full list of student rights and responsibilities at the University of Utah, see <http://www.admin.utah.edu/ppmanual/8/8-10.html>.

Instructor Responsibilities: The instructor will...

1. Be prepared for class.
2. Arrive on time or early for class, and give advance warning if class will be cancelled for any reason. In the case of an emergency, the instructor will contact campus staff to relay a message to students.
3. Use a variety of teaching methods, including lecture, group work, discussion, demonstrations, etc. in an effort to create a stimulating learning environment and accommodate different learning styles.
4. Provide feedback on assignments in a timely manner.
5. Be available for individual consultation whenever possible, or by appointment.
6. Reply to email within 48 hours, not including weekends or holidays.
7. Follow all official University of Utah policies regarding conduct within the classroom, incompletes, and accommodations. Accommodations will be considered on an individual basis and only with the required documentation. No exceptions will be made to this policy.