

Biomedical Device Innovation II

Course Abbreviation: BIOEN 6802

Designation: Required for Graduate BME students in the BioInnovate track

Course Description:

Second 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. During the first semester design input phase, students design, document, and prototype a medical device under the regulations of FDA QSR. During the second semester design output phase, prototypes are refined and tested to ensure requirements are met. In addition to device development, students will develop a business plan around the medical device to understand commercial translation concepts including financials, markets, marketing, sales, competition, risk, and business model. Students will develop business plan requirements and develop a full business plan throughout the semester. Business plans will be entered into business plan competitions and funding sources will be identified for future company formation. This course includes two lab sessions per week, one focused on medical device testing and another on business plan development. Two lecture sessions per week will cover topics including: verification testing, design validation, clinical trials, technology commercialization, ethics, business concepts, and company formation.

Course Prerequisites: Bioengineering graduate status

Number of credits: 4

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: Spring

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, product specifications, prototype fabrication, testing, and evaluation. 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. Creation of verification test plan, testing results, and compilation of final Design History File (DHF). 2. Development and testing of prototype elements. 3. Weekly progress reports 4. Design review meetings 5. Compilation of Design History File (DHF)
2	<p>The student will understand testing techniques, tools, and methods, including</p> <ol style="list-style-type: none"> 1. Mechanical testing 2. Wear testing 3. Electronic testing 4. Tolerance testing 5. Customer driven testing 6. Functional testing 	<p>The student will test specific components of the medical device prototype, driven by a verification test plan.</p> <ol style="list-style-type: none"> 1. Perform applicable tests on device 2. Produce verification test results 3. Integrate data into final Design History File (DHF)
3	<p>The students will <u>understand</u> and <u>develop</u> a business plan for a medical device venture.</p> <ol style="list-style-type: none"> 1. Students will understand basic business concepts, including: <ol style="list-style-type: none"> a. Intellectual Property b. Markets c. Competition d. Sales & Distribution e. Business Development f. Operations/Management g. Financials 	<p>The student will <u>develop</u> a business plan document using a template provided by the instructors.</p> <ol style="list-style-type: none"> 1. The business plan will contain the following elements: <ol style="list-style-type: none"> a. Executive Summary b. Business Description c. Product/Service d. Market Strategies e. Competitive Analysis f. Design/Development Plan g. Operations/Management Plan h. Financial Components

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

Business Development book

Tentative Class Schedule

Week	Date	Lecture	Date	Testing Lab	Business Plan Lab
1		Verification Testing		Mechanical testing	Business Plan Requirements
2		Design Validation		Electronic testing	Business Plan Requirements
3		Clinical Trials		Tolerance testing	Business Plan Requirements
4		Design For Manufacture and Assembly (DFMA)		Human Ergonomics	Business Plan Requirements
5		Technology Commercialization		Wear testing	Business Plan Requirements
6		Ethics		Functional testing	Business Plan Development
7		Fundamental Business Concepts Management, Product/Technology, Marketing/Sales Competition		Prototype refinement	Business Plan Development
8		Fundamental Business Concepts Financing, Risks, Business Model		Test plan review	Business Plan Development
9		Business Plan Components		Verification testing	Business Plan Development
10		Business Plan Components		Verification testing	Business Plan Development
11		Business Plan Components		Testing results	Business Plan Development
12		Funding		Results incorporation	Funding Sources
13		Business Sustainability		Final DHF	Attracting Investors
14		Company Formation		Presentations	Business Plan

					Competition
15		Attracting Investors		Presentations	Business Plan Competition

Grade Breakdown

Progress Report	5%
Verification Test Plan	15%
TestingResults	5%
Verification Testing Pres	10%
Business Plan Reqs	15%
Business Plan	25%
Business Plan Pres	15%
Final DHF	10%

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.