

BME 4882 Senior Design, Professionalism, and Ethics I
Fall 2013 (Section 1A49)

1. Catalog Description (3 credit hours) – Design of custom strategies to address real-life issues in the development of biocompatible and biomimetic devices for biotechnology or biomedical applications. Student teams will work with a client in the development of projects that incorporate various aspects of biomedical engineering including instrumentation, biomechanics, biotransport, tissue engineering and others. Formal engineering design principles will be emphasized; overview of intellectual properties, engineering ethics, risk analysis, safety in design and FDA regulations will be reviewed. Part 1 focuses on design.

2. Pre-requisites – BME4503, BME4503L, and Senior standing **Co-requisites** – None

3. Course Objectives

- Apply the design process in a project resulting in a prototype medical device, circuit, system, process or algorithm with commercial potential
- Learn the methods of identifying unmet clinical needs
- Demonstrate the process of inventing, designing, and commercializing new medical devices and instruments
- Learn to give effective, objective, and clear presentations
- Learn to communicate design through efficient and effective technical writing
- Understand the larger FDA regulatory framework for medical devices
- Understand the professional and ethical obligations of a biomedical engineer

4. Contribution of course to meeting the professional component

3 credits of engineering topics with a design component

5. Relationship of course to program outcomes

The following ABET EAC Student Outcomes are covered in this course:

- (a) an ability to apply knowledge of mathematics, science, and engineering
- (c) an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability
- (d) an ability to function on multidisciplinary teams
- (e) an ability to identify, formulate, and solve engineering problems
- (f) an understanding of professional and ethical responsibility
- (k) an ability to use techniques, skills, and modern engineering tools necessary for engineering practice

6. Instructor – Dr. James F. Schumacher

- a. Office location – NSC410 Telephone – 352-392-0228
- b. E-mail address – JSchumacher@bme.ufl.edu
- c. Class Web site – E-learning (gatorlink login)
- d. Office hours – Weekly by e-learning announcement or by e-mail appointment

7. **Teaching Assistant** – Emily Hester, emilyhester@ufl.edu
8. **Meeting Times** – Lecture Period – Thursday, Period 3 (9:35 – 10:25), MAEB211
Laboratory/Team Period – Thursday, Periods 4 – 5 (10:40 – 12:35), NSC406
9. **Class Schedule** – Class topic schedule, assignments, quizzes, and exams are managed via the e-learning class site
10. **Meeting Location** – MAEB211 (Period 3), NSC406 (Period 4 – 5)
11. **Material and Supply Fees** – None
12. **Textbooks and Software Required**
- Textbook
Title: Biodesign: The Process of Innovating Medical Technologies
Author: Zenios, Makower, Yock
Publication date and edition: Cambridge University Press, 2009, 1st Ed.
ISBN number: 9780521517423
 - Resources provided on e-learning course website
 - Permanently bound and numbered laboratory notebook**
13. **Recommended Reading** – supplemental material assigned and provided via e-learning course site
14. **Course Outline** – subject to change and re-arrangement, check e-learning course site for updates

****Schedule subject to change, check e-learning for updated schedule**

****Lecture and Lab Assignment due dates are coordinated through e-learning**

Date	Topic and Pre-Work	Assign/Activity	Lab
Aug 22 nd	Introductions & Overview	Student Bio	No Lab
Aug 29 th	Clinical Needs Finding (chap. sect. 1.1 and 1.2)	Needs Topics	Bio Present. Team Form.
Sept 5 th	Clinical Needs Finding (chap. sect. 1.3)	Project 1 (Clinical Need)	Needs Analysis
Sept 12 th	Clinical Needs Screening (chap. sect. 2.1 and 2.2)		Team Presentation
Sept 19 th	Clinical Needs Screening (chap. sect. 2.3 – 2.5)	Project 2a (Concept Ideation)	Concept Generation
Sept 26 th	BMES – No Class		
Oct 3 rd	Concept Generation (chap. sect. 3.1 and 3.2)	Project 2b (Concept Generation)	Customer and Product Requirements
Oct 10 th	Concept Selection (chap. sect. 4.4 – 4.6)		Intellectual / Competitive Landscaping

Oct 17 th	Intellectual Property (chap. sect. 4.1 and 5.1)	Project 3 (Prelim. Designs)	Team Presentation
Oct 24 th	Regulatory Issues (chap. sect. 4.2 and 5.4)		
Oct 31 st	Research and Development Strategy (chap. sect. 5.2 and 5.3)	Risk Analysis	FMEA (Failure Mode Effects Analysis)
Nov 7 th	Research and Development Strategy (chap. sect. 5.2 and 5.3)	Project 4 (Design Review and Prototyping Plan)	Prototyping
Nov 14 th	Quality and Process Management (chap. sect. 5.5)	Quality Plan and Testing	Product Verification
Nov 21 st	Quality and Process Management (chap. sect. 5.5)	Final Design Report	
Nov 28 th	No Class - Thanksgiving		
Dec 2 nd - 11 th	Final Design Presentation – Time/Place to be Determined		

15. Attendance and Expectations – attendance is required for all scheduled lectures unless others noted by an e-learning announcement.

16. Grading –

- Project Assignments (Written and Presentations) – 40%
- Peer Assessments – (10 – 20%)
- Instructor Assessments – (0 – 10%)
- Final Design Report & Presentation – 20%
- Quizzes, Individual Assignments & Participation – 20%

17. Grading Scale – the standard grading scale is included below. Grades may be curved at the discretion of the Instructor but not to the dis-advantage of any student that earns a higher grade based on the provided standard scale.

A	A-	B+	B	B-	C+	C	C-	D+	D	D-	E
≥92	90- 91	87- 89	83- 86	80- 82	77- 79	73- 76	70- 72	67- 69	63- 66	60- 62	< 60

“A C- will not be a qualifying grade for critical tracking courses. In order to graduate, students must have an overall GPA and an upper-division GPA of 2.0 or better (C or better). Note: a C- average is equivalent to a GPA of 1.67, and therefore, it does not satisfy this graduation requirement. For more information on grades and grading policies, please visit: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

18. Requirements for class attendance and make-up exams, assignments, and other work are consistent with university policies that can be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

19. **Honesty Policy** – UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” The Honor Code

(<http://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Note that failure to comply with this commitment will result in disciplinary action compliant with the UF Student Honor Code Procedures.

See <http://www.dso.ufl.edu/sccr/procedures/honorcode.php>

20. **Accommodation for Students with Disabilities** – Students Requesting classroom accommodation must first register with the Dean of Students Office. That office will provide the student with documentation that he/she must provide to the course instructor when requesting accommodation.

21. **UF Counseling Services** –Resources are available on-campus for students having personal problems or lacking clear career and academic goals. The resources include:

- UF Counseling & Wellness Center, 3190 Radio Rd, 392-1575, <http://www.counseling.ufl.edu/cwc/Default.aspx>, counseling services and mental health services.
- Career Resource Center, Reitz Union, 392-1601, career and job search services.

University Police Department 392-1111

22. **Software Use** – All faculty, staff and student of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

23. Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.