

BME 4883 Senior Design, Professionalism, and Ethics 2
Spring 2014 (Section 12D8)

- 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 2 focuses on implementation and testing.
- 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** – TBD
- 8. Meeting Times** – Lecture Period – Wednesday, Period 7 (1:55 – 2:45), WEIL0273
Laboratory/Team Period – Wednesday, Periods 8 – 9 (3:00 – 4:55), NSC406
- 9. Class Schedule** – Class topic schedule, assignments, quizzes, and exams are managed via the e-learning class site
- 10. Meeting Location** – WEIL0273 (Period 7), NSC406 (Period 8 – 9)
- 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**
****Project/Presentation due dates are coordinated through e-learning**

Date	Topic and Pre-Work	Project/Presentation/Activity	
Jan 8th	Introductions & Overview	Design Competition	No Lab
Jan 15th	R&D Strategy (5.2)	Prototyping (all semester)	
Jan 22nd	R&D Strategy (5.2)	FMEA (Failure Mode Effects Analysis)	
Jan 29th	Risk Analysis	Fabrication Lab Orientation	
Feb 5th	Intellectual Property Strategy (5.1)	Disclosures and Claims Generation	
Feb 12th	Intellectual Property Strategy (5.1)	Competitive Landscaping	
Feb 19th	FDA Design Controls	Product Validation	
Feb 26th	FDA Design Controls	Product Verification	

Mar 5th	No Class – Spring Break	
Mar 12th	Clinical Strategy (5.3)	Clinical Studies
Mar 19th	Regulatory Strategy (5.4)	510(k) or PMA Drafting
Mar 26th	Regulatory Strategy (5.4)	
Apr 2nd	Quality and Process Management (5.5)	Quality Plan and Testing
Apr 9th	Quality and Process Management (5.5)	
Apr 16th	Marketing Strategy (5.7)	Marketing Product Claims
Apr 23rd	Investor / Business Planning (6.2)	
Apr 30 th / May 1st	Prototype Presentation – 4/30 3-5PM or 5/1 10AM - Noon	

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 Poster & Prototype 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/>.