

**BME 4882 Senior Design, Professionalism, and Ethics I**  
Fall 2016 Sections 1A49 & 23C8

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** – BME 4503, BME 4503L, BME 4409, 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
  - (g) an ability to communicate effectively
  - (h) the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context
  - (k) an ability to use techniques, skills, and modern engineering tools necessary for engineering practice

6. **Instructor** – Dr. Stephen Hugo Arce
- Office location: NSC 410
  - Telephone: 352-392-0228
  - E-mail address: sarce@bme.ufl.edu
  - Class Web site: <https://elearning.ufl.edu>
  - Office hours: Wednesdays Periods 4 – 5 (10:40 – 12:30)
7. **Teaching Assistant** – Bijurika Nandi
- E-mail address: bnandi.2103@ufl.edu
8. Office hours: Wednesdays Periods 4 – 5 (10:40 – 12:30)
9. **Meeting Times and Locations** –
- Lecture – Tuesdays, Period 8 (3:00 – 3:55), NZH 112
- Lab/Teams – Mondays/Tuesdays, Periods 2 & 3 (8:30 – 10:25), NSC 407
10. **Class/laboratory schedule** – Weekly Lecture (1 period) & Lab (2 periods)
11. **Material and Supply Fees** – \$129.19
12. **Textbooks and Software Required** –
- Textbook:
    - Biodesign: The Process of Innovating Medical Technologies**
    - Zenios, Makower, Yock**
    - Cambridge University Press, 2009, 1<sup>st</sup> Ed.**
    - ISBN number: 9780521517423**
    - Web:** <http://ebiodesign.org>
  - Resources provided on e-learning course website
  - **Permanently bound and numbered laboratory notebook**
13. **Recommended Reading** –
- Textbook:
    - Product Design and Development, 3<sup>rd</sup> Edition**
    - Ulrich, Eppinger**
    - Boston : McGraw-Hill/Irwin, c2004.**
    - ISBN number: 0072471468**
    - Web:** <http://www.ulrich-eppinger.net>

14. **Course Outline** \*\*Subject to change\*\*

<b>Week</b>	<b>Topic</b>	<b>Assignment</b>	<b>Lab</b>
1	Introduction & Overview	HW: Reaction Essay	No Lab
2	Clinical Needs Finding (1.1 & 1.2)	<b>Project 1:</b> White Paper	Form Teams

3	Professionalism & Ethics (1.3)	HW: Needs Analysis	No Lab Monday (Labor Day)
4	Disease State Fundamentals (2.1 & 2.2)	HW: Treatment Options Review	Mid-month Team Presentation
5	Stakeholders and Markets (2.3 – 2.5)	HW: Needs Filtering	Finalize Need Statement
6	Concept Generation (3.1 & 3.2)	<b>Project 2:</b> 510(k)	<b>Project 1 Due</b>
7	Brainstorming (4.4 – 4.6)	HW: System Designs	Mentor Meeting: Design Inputs
8	Regulatory Issues (4.2 & 5.4)	HW: Predicate Devices Review	Mid-month Team Presentation
9	Intellectual Property (4.1 & 5.1)	Tour: Innovation Hub	Plan Prototype
10	Research and Development (5.2)	<b>Project 3:</b> FMEA	<b>Project 2 Due</b>
11	Risk Analysis	HW: Refine Designs	FMEA
12	Quality Management and Design Controls (5.5)	Guest Speaker: Mike Orrico (Axogen)	Mid-month Team Presentation
13	Clinical Strategy (5.3)	HW: Experiment Design	<b>Project 3 Due</b>
14	Process Management (5.5)	Final Design Report	Verification & Validation
15	Final Design Presentation and Reports Due		

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

16. **Grading** –

- 45% Project Assignments (3 projects – 15% each)
- 20% Homework Assignments
- 5% Peer Assessments of Presentations
- 10% Instructor Assessment
- 20% Final Report & Presentation

17. **Grading 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 by completing online evaluations 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/>.