

Senior Design, Professionalism and Ethics II

BME 4882, Sections 1A49, 23C8

Lecture Periods: Monday, Period 3

Lab Periods: Tuesday/Friday, Periods 8-9

Lecture Location: Florida Gym, room 245

Lab Location: Nuclear Science Building, room 408

Academic Term: Fall 2017

Instructor:

Stephen Hugo Arce, Ph.D.

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(352) 392 - 0228

Office Hours: Wednesday, 1pm, Nuclear Science Building, room 407

Teaching Assistants:

Syd Wiggins (*Please contact through Canvas website*)

Course 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. Teams work with a client in the development of projects that incorporate various aspects of biomedical engineering including instrumentation, biomechanics, biotransport, tissue engineering and others. Emphasizes formal engineering design principles; overview of intellectual properties, engineering ethics, risk analysis, safety in design and FDA regulations are reviewed. Part 2 focuses on implementation and testing.

Course Pre-Requisites / Co-Requisites - BME 4503, BME 4503L, and senior standing.

Course Objectives

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

Materials and Supply Fees - None

Professional Component (ABET):

3 credits of engineering topics with a design component

Relation to Program Outcomes (ABET):

Outcome	Coverage*
a. Apply knowledge	High
b. Conduct experiments	Medium
c. Design	High
d. Function on teams	High
e. Solve problems	Medium
f. Professional and ethical responsibility	High
g. Communicate	Medium
h1. Economic impact	Medium

h2. Global, societal, and environmental impact	Medium
i. Lifelong learning	
j. Contemporary issues	Medium
k. Techniques, skills, and tools for degree program	High

*Coverage is given as high, medium, or low. An empty box indicates that this outcome is not part of the course.

Required Textbooks and Resources

- a) Textbook: **Biodesign: The Process of Innovating Medical Technologies**
Zenios, Makower, Yock Cambridge University Press, 2009, 1st Ed. ISBN number: 9780521517423
Web: <http://ebiodesign.org>
- b) **Nuts & Bolts of Great Business Plans:**
<https://warrington.ufl.edu/centers/cei/docs/NutsAndBoltsOfGreatBusinessPlans.pdf>
- c) **Permanently bound and numbered laboratory notebook**

Recommended Materials

- a) Textbook: **Product Design and Development, 3rd Edition**
Ulrich, Eppinger Boston : McGraw-Hill/Irwin, c2004. ISBN number: 0072471468
Web: <http://www.ulrich-eppinger.net>

Course Schedule - **Subject to Change**

Week	Topic	Assignment	Lab
1	Introduction & Overview	HW: Reaction Essay	Meet Mentors
2	Clinical Needs Finding (1.1 & 1.2)	Project 1: White Paper	Assign Roles
3	Professionalism & Ethics (1.3)	HW: Needs Analysis	No Lecture (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)	Project 2: 510(k)	Project 1 Due
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)	Project 3: FMEA	Project 2 Due
11	Risk Analysis	HW: Refine Designs	FMEA
12	Quality Management and Design Controls (5.5)	Guest Speaker	Mid-month Team Presentation
13	Clinical Strategy (5.3)	HW: Experiment Design	Project 3 Due
14	Process Management (5.5)	Final Design Report	Verification & Validation
15	Final Design Presentation and Reports Due		

Attendance Policy, Class Expectations, and Make-Up Policy

Attendance is required for all scheduled lectures unless others noted by an e-learning announcement. Teams may meet outside of scheduled class periods to stay on track with prototyping.

Evaluation of Grades

Assignment	Total Points	Percentage of Final Grade
Project Assignments (3 projects)	15 points each	45%
Homework Assignments	5 points each	20%
Peer Assessments of Presentations	8 points	5%
Instructor Assessment	10 points	10%
Final Report & Presentation	20 points	20%
		100%

Grading Policy

Percent	Grade	Grade Points
93.4 - 100	A	4.00
90.0 - 93.3	A-	3.67
86.7 - 89.9	B+	3.33
83.4 - 86.6	B	3.00
80.0 - 83.3	B-	2.67
76.7 - 79.9	C+	2.33
73.4 - 76.6	C	2.00
70.0 - 73.3	C-	1.67
66.7 - 69.9	D+	1.33
63.4 - 66.6	D	1.00
60.0 - 63.3	D-	0.67
0 - 59.9	E	0.00

More information on UF grading policy may be found at:

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

Students Requiring Accommodations

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, <https://www.dso.ufl.edu/drc>) by providing appropriate documentation. Once registered, students will receive an accommodation letter which must be presented to the instructor when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

Course Evaluation

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu/evals>. 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/>.

University 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 (<https://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.

Software Use

All faculty, staff, and students 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.

Student Privacy

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see: <http://registrar.ufl.edu/catalog0910/policies/regulationferpa.html>

Campus Resources:

Health and Wellness

U Matter, We Care:

If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.

Counseling and Wellness Center: <http://www.counseling.ufl.edu/cwc>, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

Sexual Assault Recovery Services (SARS)

Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or <http://www.police.ufl.edu/>.

Academic Resources

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.
<https://lss.at.ufl.edu/help.shtml>.

Career Resource Center, Reitz Union, 392-1601. Career assistance and counseling. <https://www.crc.ufl.edu/>.

Library Support, <http://cms.uflib.ufl.edu/ask>. Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
<https://teachingcenter.ufl.edu/>.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
<https://writing.ufl.edu/writing-studio/>.

Student Complaints Campus: https://www.dso.ufl.edu/documents/UF_Complaints_policy.pdf.

On-Line Students Complaints: <http://www.distance.ufl.edu/student-complaint-process>.