BME 6018 - Section 2H66 - Class Number 11468

Class Periods:	Tuesday Period 8-9	(3:00 PM - 4:55 PM)
	Thursday Period 8	(3:00 PM – 3:50 PM)

Class Dates: 1/09/23 - 4/26/23

Location: Weil Hall 0234 1949 STADIUM RD GAINESVILLE, FL 32611 Bldg #: 0024

Link to this location: https://campusmap.ufl.edu/#/index/0024

Instructor: Dr. Peter S. McFetridge pmcfetridge@bme.ufl.edu 352-273-9325 Office Hours: TBD

Teaching Assistants: TBD

Course Description

Biomedical engineers are called on to develop practical solutions to various problems encountered in healthcare and clinical practice. In this course, students will be exposed to clinical problems, learn how to identify unmet needs and will devise engineering solutions to address clinical needs. Topics related to clinical translation of biomedical innovations and medical device commercialization will be covered. *3 credit hours.*

Course Pre-Requisites / Co-Requisites

Pre-Requisite: BME 5401 or waiver

Course Objectives

a) Understand various clinical problems and identify significant medical needs.

The best way to learn about clinical problems is directly from the clinicians and healthcare providers that encounter them. Students will attend three "BME Grand Rounds" seminars, where a clinician will describe one or more clinical problems that (s)he encounters on a regular basis. Students are also required to attend 10 grand rounds in clinical departments over the semester, to gain exposure to case studies and clinical problems beyond those covered in the BME Grand Rounds. The course will cover how to generate effective problem and needs statements.

b) Develop engineering solutions to unmet clinical needs.

After each of the three BME Grand Rounds, students will work in teams over 3-4 weeks to develop an original solution to address the clinical need identified. Techniques for effective brainstorming will be covered.

c) Examine the commercialization potential for medical devices/technologies

Course lectures will cover topics related to medical device commercialization, intellectual property, regulatory pathways, and healthcare reimbursement, which are critical to the clinical translation of biomedical engineering technologies. Students will be expected to consider these factors in the development of their solutions and develop a commercialization plan.

d) Communicate ideas to a broad audience in written and verbal formats.

The ideas generated by the teams will be presented orally to the class and clinicians, and written as an NIH SBIR/STTRstyle proposal.

Materials and Supply Fees: None

Required Textbooks and Software: There are no specific required textbooks.

Recommended Materials

Biodesign: The Process of Innovating Medical Technologies Stefanos Zenios, Josh Makower, Paul Yock Cambridge University Press ISBN 978-0-521-51742-3

Course Schedule **Note this is subject to change at instructor's discretion or to accommodate clinicians' schedules**

Week 1	Course overview and clinical overview (Dr. McFetridge) Assignment: Complete Personal Information Form, HIPPA Certification*
Week 2	Needs Finding (Dr. McFetridge) Activity: Begin Attending Weekly Clinical Grand Rounds**
<u>Week 3</u>	Professional communication (Dr. Butler, Department of Linguistics, The William and Grace Dial Center for Written and Oral Communication - <i>to be confirmed</i>) BME Grand Rounds #1
Week 4	BME Grand Rounds #1 Review and Brainstorming Techniques (Dr. McFetridge) GROUP EXERCISE: Develop Problem and Needs Statements for BME Grand Rounds #1
Week 5	Proposal Writing/Review and Specific Aims (Dr. McFetridge) GROUP EXERCISE: Specific Aims Worksheet for BME Grand Rounds #1*
<u>Week 6</u>	Intellectual Property (Office of Technology Licensing - <i>to be confirmed</i>) GROUP EXERCISE: <i>Prior art search and invention disclosure*</i>
Week 7	GROUP PRESENTATIONS #1* BME Grand Rounds #2
<u>Week 8</u>	BME Grand Rounds #2 Review GROUP EXERCISE: Develop Problem and Needs Statements for BME Grand Rounds #2 Report Due: BME Grand Rounds Report #1*
Week 9	Regulatory Pathways Part 1 GROUP EXERCISE: Finding predicate devices
<u>Week 10</u>	Regulatory Pathways Part 2 Assignment: Specific Aims Worksheet for BME Grand Rounds #2*
<u>Week 11</u>	GROUP PRESENTATIONS #2* BME Grand Rounds #3
<u>Week 12</u>	BME Grand Rounds Review GROUP EXERCISE: Develop Problem and Needs Statements for BME Grand Rounds #3 Report Due: BME Grand Rounds Report #2*

<u>Week 13</u>	Healthcare Reimbursement Assignment Due: Peer Reviews*
<u>Week 14</u>	TBD
<u>Week 15</u>	Medical Device Commercialization Quiz (in class) Assignment: Specific Aims Worksheet for BME Grand Rounds #3*
<u>Week 16</u>	GROUP PRESENTATIONS #3 Report Due: BME Grand Rounds Report #3

*Indicate assignments that will be turned in for grading at the end of the specified week (Deadline: Friday by 11:59pm unless otherwise specified)

** Students are required to attend a clinical grand rounds approximately once per week (10 total). For each clinical grand rounds, students must submit a clinical report at the end of the specified week (Deadline: Friday by 11:59pm).

Attendance Policy, Class Expectations, and Make-Up Policy

Excused absences must be consistent with university policies in the graduate catalog (<u>http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#attendance</u>) and require appropriate documentation.

Students are expected to attend course lectures, BME Grand Rounds, and clinical grand rounds, as well as participate in group exercises. If you are unable to attend class, will be coming late or leaving early, then you are expected to inform the instructor or the TA. Students are expected to be in class, prepared to learn, engaged, and overall contributors to the learning environment. Poor attendance in class or absence at BME Grand Rounds will affect your participation grade.

Students who miss class or assignment deadlines for reasons not covered under the UF attendance policy will have 15% deducted from coursework grade per day late and will receive 0 pts for quizzes.

<u>Clinical Grand Rounds and Weekly Reports</u>: Students are required to attend 10 clinical grand rounds over duration of the semester. An approved list of grand rounds across the various clinical departments will be available in Canvas. For each clinical grand rounds, students will write a one page "clinical report" that summarizes the clinical rounds attended and will include the students impressions and thoughts about how engineers may contribute to solving the clinical problems discussed. Note that attendance of grand rounds should be distributed across the semester, as no more than two reports can be submitted in one week. If more than two reports are submitted in one week, only the first two will be graded. The highest professional conduct is expected, particularly in the clinical setting and at grand rounds. When attending clinical grand rounds, please abide by the College of Medicine dress code (no jeans, shorts, sneakers, flip-flops, etc.).

<u>Group Work:</u> Working in groups is an important component to this course and to the BME profession. Each student is expected to positively contribute to group assignments. Peer evaluations will be considered in participation grades.

Background Research: In order to understand and propose solutions to clinical problems, students are expected to independently conduct the necessary background research and review of the literature. This includes anatomy, physiology, state-of-the-art therapies, etc.

Laptops and devices are encouraged for in-class group exercises in order to look up information needed to complete the assigned task. Cell phones and laptops are not to be used during lectures.

This statement is required: Excused absences are consistent with university policies in the undergraduate catalog (<u>http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#attendance</u>) and require appropriate documentation.

Evaluation of Grades

Due to the availability of clinicians and the pandemic– grade assignments/reports etc. (as below) are subject to change. Notice will be given of any changes

Assignment	Percentage of Final Grade	
Clinical Reports (10)	15%	
Quiz (1)	5%	
Proposals (3)	30%	
Presentations (3)	30%	
Assignments (5)	10%	
Participation*	10%	
	100%	

*Participation grade includes class attendance, in-class contribution, group contribution, and peer evaluation

Grading Policy

Percent	Grade	Grade
		Points
90.0 - 100.0	Α	4.00
87.0 - 89.9	A-	3.67
84.0 - 86.9	B+	3.33
81.0 - 83.9	В	3.00
78.0 - 80.9	B-	2.67
75.0 - 78.9	C+	2.33
72.0 - 74.9	С	2.00
69.0 - 71.9	C-	1.67
66.0 - 68.9	D+	1.33
63.0 - 65.9	D	1.00
60.0 - 62.9	D-	0.67
0 - 59.9	E	0.00

More information on UF grading policy may be found at: <u>http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#grades</u>

Students Requiring Accommodations

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, <u>https://www.dso.ufl.edu/drc</u>) 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 professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/. Summaries of course evaluation

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://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-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.

Commitment to a Safe and Inclusive Learning Environment

The Herbert Wertheim College of Engineering values broad diversity within our community and is committed to individual and group empowerment, inclusion, and the elimination of discrimination. It is expected that every person in this class will treat one another with dignity and respect regardless of gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture.

If you feel like your performance in class is being impacted by discrimination or harassment of any kind, please contact your instructor or any of the following:

- Your academic advisor or Graduate Program Coordinator
- Robin Bielling, Director of Human Resources, 352-392-0903, rbielling@eng.ufl.edu
- Curtis Taylor, Associate Dean of Student Affairs, 352-392-2177, taylor@eng.ufl.edu
- Toshikazu Nishida, Associate Dean of Academic Affairs, 352-392-0943, nishida@eng.ufl.edu

Plagiarism

Plagiarism is a common infraction to the UF Honor Code. If you are confused as to what constitutes plagiarism, see here: <u>https://guides.uflib.ufl.edu/copyright/plagiarism</u>. Plagiarism on any of your assignments **will be reported to the Dean of Students as a UF Student Honor Code violation.** Also, note that **copying solutions for any assignment, regardless of the source (e.g. other students, pirated website solutions), will be treated as plagiarism.** If you have any questions or concerns, please consult with the instructor in this class. Note that failure to comply with this commitment will result in disciplinary action compliant with the UF Student Honor Code Procedures.

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: <u>https://registrar.ufl.edu/ferpa.html</u>

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Campus Resources:

Health and Wellness

U Matter, We Care:

Your well-being is important to the University of Florida. The U Matter, We Care initiative is committed to creating a culture of care on our campus by encouraging members of our community to look out for one another and to reach out for help if a member of our community is in need. If you or a friend is in distress, please contact <u>umatter@ufl.edu</u> so that the U Matter, We Care Team can reach out to the student in distress. A nighttime and weekend crisis counselor is available by phone at 352-392-1575. The U Matter, We Care Team can help connect students to the many other helping resources available including, but not limited to, Victim Advocates, Housing staff, and the Counseling and Wellness Center. Please remember that asking for help is a sign of strength. In case of emergency, call 9-1-1.

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

Sexual Discrimination, Harassment, Assault, or Violence

If you or a friend has been subjected to sexual discrimination, sexual harassment, sexual assault, or violence contact the <u>Office of Title IX Compliance</u>, located at Yon Hall Room 427, 1908 Stadium Road, (352) 273-1094, <u>title-</u> <u>ix@ufl.edu</u>

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/.

Other Academic Resources

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

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

Library Support, <u>http://cms.uflib.ufl.edu/ask</u>. 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. <u>https://teachingcenter.ufl.edu/</u>.

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

Student Complaints Campus: <u>https://care.dso.ufl.edu</u>.

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