

Clinical Correlations in Biomedical Engineering

BME 6018 Section 2536

Class Periods: Tuesdays, Periods 8 and 9, 3:00pm-4:55pm; Thursdays, Period 8, 4:05-4:55pm

Location: Benton 0328

Academic Term: Fall 2021

Instructor:

Blanka Sharma

blanka.sharma@bme.ufl.edu

352-273-9329

Office Hours: Tuesdays and Thursdays 1-2pm

Teaching Assistants:

N/A

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 "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 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/STTR-style 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 speakers'/clinicians' schedules****

<u>Week 1</u> (8/24)	Course Overview and Clinical Overview
<u>Week 2</u> (8/31)	Needs Identification
<u>Week 3</u> (9/7)	Professional Communication (Dr. Butler, Director, The William and Grace Dial Center for Written and Oral Communication) BME Grand Rounds #1 (Thursday 9/9)
<u>Week 4</u> (9/14)	Problem and Needs Statements, Brainstorming Techniques
<u>Week 5</u> (9/21)	Proposal Writing/Review and Specific Aims
<u>Week 6</u> (9/28)	Intellectual Property
<u>Week 7</u> (10/5)	Regulatory Pathways Part 1
<u>Week 8</u> (10/12)	GROUP PRESENTATIONS #1*
<u>Week 9</u> (10/19)	Regulatory Pathways Part 2 BME Grand Rounds #2 (Note: Thursday 10/21)
<u>Week 10</u> (10/26)	Career Paths in Regulatory Affairs (Dr. Dang, Senior Manager of Regulatory Affairs, Abbott Medical)
<u>Week 11</u> (11/2)	Healthcare Reimbursement and Business Models
<u>Week 12</u> (11/9)	Healthcare Reimbursement and Business Models
<u>Week 13</u> (11/16)	Medical Device Commercialization and Product Development (Laleh Tamhidi, Senior Engineering Director, Therapy Delivery Systems – Neuromodulation, Medtronic)
<u>Week 14</u> (11/23)	TBD (Week of Thanksgiving)
<u>Week 15</u> (11/30)	GROUP PRESENTATIONS #2
<u>Week 16</u> (12/7)	Medical Device Commercialization

* Students are required to attend a clinical grand rounds once per week. Students must submit at minimum of 10 clinical reports at the end of the specified week (Deadline: Friday by 11:59pm).

Online Course Recording

Our class sessions may be audio visually recorded for students in the class to refer back and for enrolled students who are unable to attend live. Students who participate with their camera engaged or utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. The chat will not be recorded or shared. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

Attendance Policy, Class Expectations, and Make-Up Policy

Excused absences must be consistent with university policies in the Graduate Catalog (<https://catalog.ufl.edu/graduate/regulations>) and require appropriate documentation. Additional information can be found here: <https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/>

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. 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.

Clinical Grand Rounds and Weekly Reports: 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.).

Group Work: 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.

Evaluation of Grades

Assignment	Percentage of Final Grade
Clinical Reports	15%
Quizzes	10%
Proposals	30%
Presentations	30%
Assignments	5%
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	A	4.00
87.0 - 89.9	A-	3.67
84.0 - 86.9	B+	3.33
81.0 - 83.9	B	3.00
78.0 - 80.9	B-	2.67
75.0 - 79.9	C+	2.33
72.0 - 74.9	C	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: <http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#grades>

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the disability Resource Center by visiting <https://disability.ufl.edu/students/get-started/>. It is important for students to share their accommodation letter with their instructor and discuss their access needs, 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.ua.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.ua.ufl.edu/public-results/>.

In-Class Recording

Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor.

A “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or lecturer during a class session.

Publication without permission of the instructor is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons),

including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor Code and Student Conduct Code.

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 Conduct Code (<https://sccr.dso.ufl.edu/process/student-conduct-code/>) specifies a number of behaviors that are in violation of this code and the possible sanctions. 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
- Jennifer Nappo, Director of Human Resources, 352-392-0904, jpennacc@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

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

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 umatter@ufl.edu 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: <https://counseling.ufl.edu>, 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 **Office of Title IX Compliance**, located at Yon Hall Room 427, 1908 Stadium Road, (352) 273-1094, title-ix@ufl.edu

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/>.

COVID-19

- You are expected to wear approved face coverings at all times during class and within buildings even if you are vaccinated.
- If you are sick, stay home and self-quarantine. Please visit the UF Health Screen, Test & Protect website about next steps, retake the questionnaire and schedule your test for no sooner than 24 hours after your symptoms began. Please call your primary care provider if you are ill and need immediate care or the UF Student Health Care Center at 352-392-1161 (or email covid@shcc.ufl.edu) to be evaluated for testing and to receive further instructions about returning to campus.
- If you are withheld from campus by the Department of Health through Screen, Test & Protect, you are not permitted to use any on campus facilities. Students attempting to attend campus activities when withheld from campus will be referred to the Dean of Students Office.
- UF Health Screen, Test & Protect offers guidance when you are sick, have been exposed to someone who has tested positive or have tested positive yourself. Visit the [UF Health Screen, Test & Protect website](#) for more information.
- Please continue to follow healthy habits, including best practices like frequent hand washing. Following these practices is our responsibility as Gators.

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://career.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://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-code/>; <https://care.dso.ufl.edu>.

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