

BME 3012: Clinically-Inspired Engineering Design

Spring 2020

Day	Block	Time	Location
Tuesdays	8 & 9	3:00 pm – 4:55 pm	TUR L005
Thursdays	9	4:05 pm – 4:55 pm	

Instructor

Jennifer A. Nichols, Ph.D.
Assistant Professor
J. Crayton Pruitt Family Department of Biomedical Engineering
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Office Hours: Thursdays 2:30 – 3:30 pm
Office Location: NEB 355

Supervised Teaching Student (STS)

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STS Office Hours: TBD
STS Office Hours Location: NEB 325

Course Description

In this course, students will be exposed to real clinical problems, thereby learning to communicate with medical professionals in order to (1) identify unmet needs, (2) develop prototypes and initial concepts for clinical problems, and (3) critically evaluate potential solutions for clinical problems.

Course Pre-Requisites / Co-Requisites

Pre-requisites: BME 3060 – Biomedical Engineering Fundamentals (minimum grade of C)

Co-requisites: BME 4409 – Quantitative Physiology

Course Objectives

By the end of this course, students will be able to describe how the engineering design process can be applied to address clinical problems. Students will specifically learn how to:

- Identify medical needs through interactions with healthcare professionals.
- Define engineering, regulatory, and economic constraints for the engineering design process in the biomedical industry.
- Develop risk, reliability, and safety assessments.
- Understand cost evaluation for potential designs.
- Evaluate critical legal issues in intellectual property protection.
- Identify, discuss, and resolve potential ethical issues in the development of medical technology.

Relation to Program Outcomes (ABET)

Outcome	Coverage ¹
1. An ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics	Low
2. An ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors	High
3. An ability to communicate effectively with a range of audiences	High
4. An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts	High
5. An ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives	High
6. An ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions	
7. An ability to acquire and apply new knowledge as needed, using appropriate learning strategies	High

¹Coverage is given as high, medium, or low. An empty box indicates that this outcome is not part of the course.

Required Textbooks and Software

Required Textbooks

Title: Biodesign: The Process of Innovating Medical Technologies
Author: York, Zenios, Makower, Brinton, Kumar, Watkins, Denend
Edition: 2nd Edition
Publisher: Cambridge University Press
ISBN #: ISBN-13: 978-1107087354 and ISBN-10: 9781107087354

This textbook is **available online for free** through the UF Library. To access, search for the title through the library catalog or use this link: <https://ebookcentral.proquest.com/lib/ufl/detail.action?docID=5120125>

Required Software

OnShape will be used to teach computer-aided design (CAD). OnShape is a cloud-based, CAD software system that is freely available for educational purposes. To access OnShape, you should set-up an account through OnShape Education (<https://www.onshape.com/products/education>; account set-up is accessed by clicking on "Getting Started"). Please use your University of Florida e-mail address and actual student ID number when signing up so that the system can verify your student status and university affiliation. For the "What are you using OnShape for?" question, please write "BME 3012 an undergraduate course at the University of Florida on clinically-inspired design."

For the CAD project, you may use either OnShape or Solidworks. As a UF engineering student, you have access to Solidworks through UF Apps or by following the directions below. Directions on how to download Solidworks will be posted on the Canvas site.

Course Schedule

Note: The course schedule is subject to change. Please refer to the course website for current schedule.

	Date		Topic	Assignment Due Date
Section 1. The Design Process				
1	Tues.	Jan. 7	Intro to Design & Ask: Needs Finding	
	Thurs.	Jan. 9	Ask: More Needs Finding & Design Constraints	HW #1
2	Tues.	Jan. 14	Project 1: Guest Speaker (Reb) & Stakeholders	
	Thurs.	Jan. 16	Project 1 Workday	HW #2
3	Tues.	Jan. 21	Imagine: Brainstorming	
	Thurs.	Jan. 23	Imagine: Concept Selection	HW #3
4	Tues.	Jan. 28	Team Dynamics & Clinical Communication	Quiz #1 – Design 1
	Thurs.	Jan. 30	Project 2: Guest Speaker (McCarrel)	Project 1
5	Tues.	Feb. 4	Project Management & Create: Prototyping Simulating	
	Thurs.	Feb. 6	Experiment: Experimental Design & Testing	HW #4
6	Tues.	Feb. 11	Project 2 Workday	
	Thurs.	Feb. 13	Improve: Risk, Reliability, and Safety	HW #5
Section 2. Drafting: A Useful Design Tool				
7	Tues.	Feb. 18	Introduction to CAD & Multiview Drawings	
	Thurs.	Feb. 20	Geometric Dimensioning & Tolerancing	HW #6
8	Tues.	Feb. 25	3D Printing & Assemblies	Quiz #2 – Design 2
	Thurs.	Feb. 27	CAD Applications	Project 2
9	Tues.	Mar. 3	Spring Break	
	Thurs.	Mar. 5		
Section 3. Regulations & Economics				
10	Tues.	Mar. 10	Project 3: Guest Speaker (Diabetes Panel)	
	Thurs.	Mar. 12	Scientific Writing & Project 3 Workday	HW #7 & #8
11	Tues.	Mar. 17	Regulatory: FDA History & Pathways	Quiz #3 – CAD
	Thurs.	Mar. 19	Regulatory: Drugs vs. Devices	
12	Tues.	Mar. 24	Economics: Market Analysis	
	Thurs.	Mar. 26	Economics: Commercialization	HW #9
Section 4. Ethics & Law				
13	Tues.	Mar. 31	Ethics: Primer & Historical Cases	
	Thurs.	Apr. 2	Ethics: Ethical Analysis & Applications	Quiz #4 – Reg. & Econ.
14	Tues.	Apr. 7	Law: U.S. Legal System & Intellectual Property	CAD Project
	Thurs.	Apr. 9	Law: Case Studies & Engineering Applications	HW #10
15	Tues.	Apr. 14	Presentation Skills & Project 3 Workday	
Section 5. Conclusion				
	Thurs.	Apr. 16	Summary: The Design Process Revisited	Quiz #5 – Ethics & Law
16	Tues.	Apr. 21	Project 3 Presentations	Project 3

Note: Class periods with guest speakers will be held in Communicore C1-11.

Course Policies

Attendance Policy, Class Expectations, and Make-Up Policy

Class & Participation: Students are expected to attend all scheduled class sessions. Attending class is critical for understanding the course material. Class sessions will regularly include presentation of new material, solving sample problems, answering homework questions, group discussion, and team work. The highest total grades in the class are regularly earned by students who come to class having read all assigned materials and are prepared to actively participate in classroom activities and discussions.

Reading: Reading is an opportunity for students to learn and review course material. Reading also provides a perspective on the course material that is different than that provided by the instructor. The required textbook is a very good and widely used engineering design text. Many students actually find the textbook enjoyable to read! The assigned textbook readings (outlined on each homework assignment) are designed to help students be prepared this course, and also be prepared to excel in senior design. Additional readings pertinent to specific topics will also be assigned with the homework. Students are expected to complete all assigned reading.

Homework: Homework assignments provide students with an opportunity to apply concepts learned in class and affirm their understanding of the course material. All assignments are due by 11:59 pm on the date indicated on the course schedule (refer to course website for most up-to-date deadlines). All assignments should be turned in electronically via the course website. Please use the following convention when naming your homework files: LastName_HW_X.pdf (replace “LastName” with your last name and “X” with the homework number). Assignments turned in late will not be graded, except under extreme circumstances at the discretion of the instructor (not the STS, TA, or graders). Students are encouraged to work cooperatively on assignments. However, each student must individually submit assignments consisting of his or her own work. This means that students are encouraged to discuss the solution process for problems. However, copying another student’s work (or allowing a student to copy your work) will be considered a violation of the University honor code.

Clinical Design Projects: The design projects are an opportunity to learn, practice, apply, and master the engineering design process. There will be three group projects. For each project, groups will be assigned by the instructor. Each project will be based on a clinical problem presented in-class by a guest speaker. Being present and attentive for each guest speaker’s lecture is critical for successful completion of each project. All projects will involve written deliverables and one project will involve in-class presentations. Accommodations for missing an in-class presentation will only be made for student who provide appropriate documentation of an excused absence. Excused absences must be consistent with University policies in the undergraduate catalog (<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>). Further project details will be discussed in class and distributed on the course website.

CAD Project: The CAD project is designed to provide each student the opportunity to practice and receive feedback on their computer-aided design skills. This project also acts as a mechanism to widen the course’s grading scheme because it is a major individual (instead of team-based) project. Further details on the project will be discussed in class and distributed on the course website.

Quizzes: Quizzes allow the students and the instructor to assess understanding of current course material. They also act as a mechanism to widen the course’s grading scheme (i.e., lower the stakes of each project and include individual, instead of team-based, grades). Quizzes will occur approximately every three weeks (refer to course website for most up-to-date schedule). If circumstances do not allow a student to take a quiz on the scheduled date, the student must notify the instructor with enough advanced notice to make arrangements to take the quiz before the scheduled date. Make-up quizzes will only be permitted in exceptional circumstances. The lowest quiz grade will be dropped.

Re-Grade Policy: If a student feels that an assignment was graded incorrectly, they should return the assignment and a written description of the grading error to the instructor (not the STS, TA, or graders) within 5 business days of receiving the graded assignment. The instructor will evaluate the request and adjust the grade

if an error was made. Any request for re-grading where the student has altered the assignment after it was returned to gain a grade benefit will be considered a violation of the University honor code.

Changes to the Syllabus: Occasionally, course policies may need to be changed due to unforeseen circumstances or to improve the course. The instructor reserves the right to make necessary changes. Additionally, if a student or group of students have a suggestion on how to revise the course and the instructor agrees that the revision would improve the course, the proposed change will be put to an anonymous vote by the entire class. If the majority of the class agrees to the change, it will become part of the syllabus.

Announcements, Communication, and Office Hours

Canvas Course Website: The course website will be used to post lectures, course material, assignments, and grades. Students are expected to regularly check the course website and are responsible for ensuring that the grades posted on Canvas match those on returned assignments. If there is a discrepancy between the posted grade and the grade you received on the assignment, please send the Instructor a message through Canvas.

Slack Workspace: A Slack workspace has been created for this course (bme3012spring2020.slack.com). Directions on how to join the workspace will be distributed in class and posted on Canvas. Students are encouraged to use this workspace to engage with the Instructor, Supervised Teaching Student, and their peers. This workspace will be used for some in-class activities. In class, we will also discuss how to use this workspace to effectively communicate with your project team. The public Slack channels are the preferred method of communication for general questions regarding homework, projects, quizzes, and course content. This public discussion board allows all students to benefit from the questions that are asked and answered. Both the Instructor and STS will regularly check the Slack workspace for questions.

Private Communication & Questions: If you have a question that needs to be handled privately (e.g., documentation of an excused absence, requesting accommodations, etc.), please send a message to the Instructor through Canvas. The use of the Canvas message system will enable the most efficient response.

Office Hours: Both the Instructor and STS will hold office hours on a weekly basis. Please refer to the first page of the syllabus for times and locations. The students who find office hours most effective are the ones who come to office hours prepared with specific questions. Questions can be based on the homework, projects, quizzes, and/or course material. If office hours are scheduled during a time that you are not available, you can request an individual meeting with either the Instructor or STS by contacting them through Canvas. Individual meetings are best scheduled at least one week in advance.

Evaluation of Grades

Assignment	Percentage of Final Grade
Homework (10 total)	10%
Quizzes (5 total)	15%
Design Project 1	10%
Design Project 2	20%
Design Project 3	30%
CAD Project	15%
	100%

Grading Policy

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

More information on UF grading policy may be found at:

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

Relevant University Policies

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@ufl.edu

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

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center (DRC) by visiting 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.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/>.

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.

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: <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>.