

BME 3012: Clinically-Inspired Engineering Design

Spring 2023

Day	Block	Time	Location
Tuesdays	7 & 8	1:55 pm – 3:50 pm	Communicore
Thursdays	7	1:55 pm – 2:45 pm	C1-15

Instructor

Jennifer A. Nichols, Ph.D.
Assistant Professor
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Office Hours: TBD

Office Location: NEB 355

Supervised Teaching Student (STS)

Stephanie Herrera
Graduate Student, Biomedical Engineering

Grant Maddox
Graduate Student, Biomedical Engineering

STS Office Hours: TBD

STS Office Hours Location: TBD

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 and PCB 3713C – Cellular and Systems Physiology (minimum grade of C in listed courses)

Co-requisites: BME 3101 – Biomedical Materials and EGM 2511 – Engineering Mechanics

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/ufli/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. Note, if you are upgrading from a previous version of SolidWorks you must do a complete uninstall of the old version before beginning the install process for the new version. Select Advanced Options on the uninstall screen and select all items for complete removal.

1. Go to <http://www.solidworks.com/SEK>
2. Complete the access form:
 - a. Select "Yes, I already have a Serial Number that starts with 9020"
 - b. Select Version 22/23
3. Click "Request Download"
4. Read and accept the SolidWorks Student Access Initiative agreement
5. Download and install the software using the on-screen instructions
6. Use Serial Number 90200053751301354PKXH528

Course Schedule

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

	Date		Topic	Project Due Dates
Section 1. The Design Process				
1	Tues.	Jan. 10	Intro to Design	
	Thurs.	Jan. 12	Ask: Needs Finding	
2	Tues.	Jan. 17	Ask: Design Constraints & Stakeholders	
	Thurs.	Jan. 19	Imagine: Brainstorming	
3	Tues.	Jan. 24	Project 1: Guest Speaker & Project 1 Workday	
	Thurs.	Jan. 26	Imagine: Concept Selection	
4	Tues.	Jan. 31	Team Dynamics & Clinical Communication	
	Thurs.	Feb. 2	Create: Prototyping & Simulating	
5	Tues.	Feb. 7	Project Management & Project 2: Guest Speaker	Project 1 Due
	Thurs.	Feb. 9	<i>Project 2 Workday</i>	
6	Tues.	Feb. 14	Iteration & Design Review (<i>special guest Dr. Lee Murfee</i>)	
	Thurs.	Feb. 16	Experiment: Experimental Design & Testing	
7	Tues.	Feb. 21	Improve: Risk, Reliability, and Safety	
	Thurs.	Feb. 23	Technical Writing & Oral Communication	
Section 2. Drafting: A Useful Design Tool				
8	Tues.	Feb. 28	Introduction to CAD & Multiview Drawings	
	Thurs.	Mar. 2	Geometric Dimensioning & Tolerancing	
9	Tues.	Mar. 7	3D Printing & Assemblies	
	Thurs.	Mar. 9	CAD Applications	Project 2 Due
--	Tues.	Mar. 14	No Class. Spring Break.	
--	Thurs.	Mar. 16		
Section 3. Ethics, Law, Regulatory & Economics				
10	Tues.	Mar. 21	Project 3: Guest Speaker Panel	
	Thurs.	Mar. 23	<i>Project 3 Workday</i>	
11	Tues.	Mar. 28	Ethics: Primer & Historical Cases	
	Thurs.	Mar. 30	Ethics: Ethical Analysis & Engineering Applications	
12	Tues.	Apr. 4	Law: U.S. Legal System & Intellectual Property	CAD Project Due
	Thurs.	Apr. 6	Law: Case Studies & Engineering Applications	
13	Tues.	Apr. 11	Regulatory: FDA History & Pathways	
	Thurs.	Apr. 13	Regulatory: Drugs vs. Devices	
14	Tues.	Apr. 18	Economics: Market Analysis	
	Thurs.	Apr. 20	Economics: Commercialization	
Section 4. Conclusion				
15	Tues.	Apr. 25	Summary: The Design Process Revisited	Project 3 Due

Course Policies

Attendance Policy, Class Expectations, and Make-Up Policy

Flipped Classroom Format: This course will use a flipped classroom format. This means students will watch short videos prior to class. Scheduled class sessions will then be an opportunity to participate in active discussion and complete activities designed to practice concepts and engage with the course material.

Participation: Students are expected to attend scheduled class sessions. Attending class is critical for understanding the course material. The highest total grades are regularly earned by students who come to class having reviewed all assigned materials and are prepared to actively participate in 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 are designed to help students be prepared for this course, and also be prepared to excel in senior design. Additional readings pertinent to specific topics may also be assigned.

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 as a take-home assignments and are designed to assess students' understanding of the course videos. The lowest quiz grade will be dropped.

Coursework: In-class assignments provide students with an opportunity to apply concepts and affirm their understanding of the course material. All assignments should be turned in electronically via the course website. 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/or 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 Assignments: The CAD assignments are designed to introduce students to CAD throughout the semester. CAD is a skill that requires practice and training. Thus, students are strongly encouraged to dedicate a little bit of time each week to learning CAD, instead of completing all assignments in the final days before the deadline.

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.

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. All re-grade requests should be sent via Canvas e-mail. 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.

Zoom & Class Recordings: Given that most class periods will focus on classroom discussion and small group activities, most class periods will not be recorded. If a class period or any portion of a class period is being recorded, it will be announced. **All classroom materials, including video recordings, are intended for exclusive use by students enrolled in the course. Other individuals who wish to view the recordings must receive permission from the responsible faculty member.**

Slack Workspace: A Slack workspace has been created for this course. 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. 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 coursework, 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. Some office hours may be held via Zoom. Office hours will not be recorded. But, they should not be considered private. This means that students can come and go from the in-person or virtual office hours at any time, resulting in hearing and listening in on other students' questions. If for any reason, you need a private meeting with the Instructor or STS, please let them know. We are happy to schedule private meetings, as needed.

Evaluation of Grades

Assignment	Percentage of Final Grade
Coursework & Assignments	10%
Quizzes	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
- 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

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 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.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/>.

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 Honor 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. 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: <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/>.

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 Connections 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: <https://distance.ufl.edu/state-authorization-status/#student-complaint>.