Clinically-Inspired Engineering Design

BME 3012 Section 1

Class Periods: Tuesday, Period 7, 1:55 – 2:45 pm and Thursday, Period 7&8, 1:55-3:50 pm

Location: Communicore-024

Academic Term: Fall 2025

Instructor:
Jennifer A. Nichols, Ph.D
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352-294-8803
Office Hours: See Canvas for details

Supervised Teaching Student:
Please contact through the Canvas website

- See Canvas for details

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.

Materials and Supply Fees
Not applicable

Relation to Program Outcomes (ABET):

Outcome	Coverage*
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 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

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

Required Textbooks and Software

- 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=3007259

Required Computer

Recommended Computer Specifications: https://it.ufl.edu/get-help/student-computer-recommendations/
HWCOE Computer Requirements: https://www.eng.ufl.edu/students/advising/fall-semester-checklist/computer-requirements/

Course Schedule

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

Week	Date		Topic	Important Dates
Section 1. The Design Process				
1	Thurs.	Aug. 21	Intro to Design	
2	Tues.	Aug. 26	Ask: Needs Finding	
	Thurs.	Aug. 28	Ask: Design Constraints & Stakeholders	
3	Tues.	Sept. 2	**Project 1: Guest Speaker**	*Project #1 Assigned*
	Thurs.	Sept. 4	Imagine: Brainstorming *& Project 1 Workday*	
4	Tues.	Sept. 9	Imagine: Concept Selection	
	Thurs.	Sept. 11	Team Dynamics & Communication	**Due: Assessment #1 – Design 1**
5	Tues.	Sept. 16	CAD Sneak Peak & *Project 1 Workday*	*CAD Project Assigned*
	Thurs.	Sept. 18	Create: Prototyping & Simulating	
6	Tues.	Sept. 23	Experiment: Experimental Design & Testing	
	Thurs.	Sept. 25	Improve: Risk, Reliability, and Safety	**Due: Assessment #2 – Design 2**
7	Tues.	Sept. 30	Project Management & Use of AI Tools	
Section 2. Drafting: A Useful Design Tool				
	Thurs.	Oct. 2	Introduction to CAD & Multiview Drawings	**Project 1 Due**
8	Tues.	Oct. 7	Parts & Assemblies	
	Thurs.	Oct. 9	***Project 2: Guest Speaker & Project 2 Workday***	*Project #2 Assigned*
9	Tues.	Oct. 14	Geometric Dimensioning & Tolerancing	
	Thurs.	Oct. 16	3D Printing & CAD Applications	**Due: Assessment #3 - CAD**
Section 3. Ethics, Law, Regulatory & Economics				
10	Tues.	Oct. 21	Ethics: Primer & Historical Cases	

	Thurs.	Oct. 23	Ethics: Ethical Analysis & Engineering Applications	
11	Tues.	Oct. 28	Law: U.S. Legal System & Intellectual Property	
	Thurs.	Oct. 30	Law: Case Studies & Engineering Applications	**CAD Project Due**
12	Tues.	Nov. 4	Regulatory: FDA History & Pathways	
	Thurs.	Nov. 6	Regulatory: Contemporary Engineering Applications	**Due: Assessment #4 – Ethics & Law**
13	Tues.	Nov. 11	*No Class – Veterans Day*	
	Thurs.	Nov. 13	Economics: Market Analysis & Commercialization	
14	Tues.	Nov. 18	Gatorade Case Study	
	Thurs.	Nov. 20	*Project 2 Workday*	**Due: Assessment #5 – Reg. & Econ.**
	Tues.	Nov. 25	*No Class – Thanksgiving Break*	
	Thurs.	Nov. 27		
Section 4. Conclusion				
15	Tues.	Dec. 2	Summary: The Design Process Revisited	**Project 2 Due**

Important Dates

Thurs. Oct. 2, 2025 *Project 1 Deadline*
Thurs. Oct. 30, 2025 *CAD Project Deadline*
Tues. Dec. 2, 2025 *Project 2 Deadline*

Evaluation of Grades

Assignment	Percentage of Final Grade
Skills Assessments (5)	25%
CAD Project	25%
Design Project 1	20%
Design Project 2	30%
	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

Academic Policies & Resources

To support consistent and accessible communication of university-wide student resources, instructors must include this link to academic policies and campus resources: https://go.ufl.edu/syllabuspolicies. Instructor-specific guidelines for courses must accommodate these policies.

Commitment to a Positive Learning Environment

The Herbert Wertheim College of Engineering values varied perspectives and lived experiences within our community and is committed to supporting the University's core values.

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

- Your academic advisor or Undergraduate Coordinator
- HWCOE Human Resources, 352-392-0904, student-support-hr@eng.ufl.edu
- Pam Dickrell, Associate Dean of Student Affairs, 352-392-2177, pld@ufl.edu