BME4800C: Design of Biomedical Systems & Devices
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Course Description and Purpose

Introduction to Biomedical engineering design, materials selection, product and process development, and manufacturing of medical devices. Application of modern software tools in device design and simulation.

Course Objectives

Upon completing this course, students will be able to:

- Apply the principles of engineering design from recognition of need to a fully-tested product.
- Interview users to identify a need/opportunity, process and evaluate that data set.
- Collaborate with a team of peers to analyze the data and propose various alternatives (minimum 3) for meeting the need, select and formulate a path to an optimized solution to the user's needs.
- Presentation to peers to explain and defend their optimized solution
- Engaging with peer presentations and providing feedback and critical analysis.
- Incorporate biocompatibility, global regulatory requirements, and other considerations and constraints pertinent to medical devices, into the design process.
- Apply knowledge of natural physiological systems to the design of their replacements and devise means to overcome constraints in doing so.
- Design and conduct tests to verify design inputs and validate the final product to meet user needs while considering global constraints related to logistics, socio-economic and environmental conditions
- Write and present a project proposal that communicates a need, its corresponding design solution(s), and a path from the need to the solution to the Senior Design Proposal Review Committee. The proposal should include data, plans, charts, and calculations as needed.

Course Outcome:

No.	Course Learning Outcomes By the end of this course, students should:	Corresponding Program Learning Outcomes
1	Ability to apply the principles of engineering design from recognition of need to a fully-tested product.	A, B, F, G
2	Ability to identify a need/opportunity, analyze alternatives for meeting the need and formulate a path to an optimized solution	A, B, [illegible]
3	Ability to incorporate biocompatibility, global regulatory requirements, and other considerations and constraints pertinent to medical devices, into design process.	[illegible]D
4	Ability to apply knowledge of natural physiological systems to the design of their replacements and to devise means to overcome constraints in doing so.	A, F
5	Ability to design and conduct tests to verify design input and validate the final product to meet user needs considering global constraints related to logistics, socio-economic and environmental conditions	A, B, F
6	Ability to Communicate items 1 through 5 in written, [illegible] and graphical form.	C, E
7	Ability to form/join a team and effectively work toward completion of an engineering design project.	C, E
8	Ability to write a project proposal that communicates a need, its corresponding design solution(s), and a path from the need to the solution presenting data, plans, charts, and calculations as needed	C, F

Global Learning Student Learning Outcomes

This is a discipline-specific course that counts toward your Global Learning Graduation requirement.

1. Global Awareness: Students will be able to identify, analyze and integrate ethics, similarities and differences in multiple markets, cultures, and regulatory requirements.
2. Global Perspective: Students will be able to develop plans to conduct an analysis of an engineering problem and its global impact by identifying different factors such as technology, economics and society, and their contributions to the problem and/or solutions well as regional regulatory requirements.
3. Global Engagement: Students will be willing to work in teams to develop solutions and action plans to address local, global and international engineering

Examples of the reading assignments:

- "Does culture matter for product design" by Don Norman
- "Factors that have influenced the direction of design and production"
- "Influence of trends in society on design and production"
- Chapters 3-8 of the text book

These learning outcomes will be assessed by the instructor as well as the Senior Design Project Proposal Review Committee as part of the final oral presentation and the written proposal.

Textbook(s):

Reliable Design of Biomedical Devices, Second or Third Edition (Richard Fries) by Taylor & Francis Group (ISBN 0-824[illegible]2375-9 or (978082472370)

Important Information

Before starting this course, please review the following pages:

Things you need to do every week

1. Look at your "Homework due next class" module on Canvas. Do this at the same time every week – maybe Saturday or Sunday afternoons in order to plan your study and homework times for the week ahead. If you know what is due, you can schedule for it!
2. Log into Canvas multiple times per week to complete the work that is due before every class session.
3. Complete class assignments (worksheets) and submit them prior to the due date listed on Canvas.
4. Read sections of the textbook assigned, watch the videos posted and take notes in a well-organized fashion (for example a notebook).
5. Complete the Pre-Class assignments/worksheets and submit them by the due date listed on Canvas.
6. Be actively engaged and actively participate in every class discussion

7. Taking notes during class helps with focus and engagement. The instructor will not post answers to the worksheet, **so you need to ensure you are doing your own work and writing things down in class**.
8. Learn to work with others and be a good team member.
9. Ask for help when needed. Reach out to your instructor.
10. Check your FIU emails and Canvas emails often and respond to emails within 24 hours.

*The professor reserves the right to change or modify the syllabus at any time during the semester.

Grading Scheme

Points Distribution: The course will consist of homework assignments, in class exercises and discussions, quizzes, two exams (mid-term exam and final), written and team presentation of the Senior Design project proposal. Lectures are from the textbook and custom presentations. Following is the grading methodology and the point distribution based on the topics above.

Participation	5%
Peer Review	5%
Attendance	10%
Interim Assignments & Quizzes	25%
Mid-Term Exam	15%
Design Project Proposal and presentation	20%
Final Exam	20%

Letter Grading scale:

Letter	Range%	Letter	Range%	Letter	Range%
A	95 or above	B	83 - 86	C	70 - 76
A-	90 - 94	B-	80 - 82	D	60 - 69
B+	87 - 89	C+	77 - 79	F	59 or less

Policy regarding student misconduct: Students at Florida International University are expected to adhere to the highest standards of integrity in every aspect of their lives. Honesty in academic matters is part of this obligation. Academic integrity is the adherence to those special values regarding life and work in an academic community. Any act or omission by a student which violates this concept of academic integrity shall be defined as academic misconduct and shall be subject to the procedures and penalties established by the university. **Students violating academic integrity will receive a failing grade for the course and the incident will be forwarded to Student Academic Affairs.** Academic misconduct includes, but is not limited to copying homework, copying work, copying of projects, or plagiarism. Plagiarism is using others' ideas and words without clearly acknowledging the source of that information. This includes, but is not limited to, the internet, textbooks, journals, or any other material that is not your own work. It is the responsibility of students to report misconduct, which may include another student copying from your, or another student's exam, homework, projects or any other assignment. Therefore, if a student copies from you, it's your responsibility to report it, otherwise you are also responsible.

As part of this course, students are grouped in teams by the instructor. The teams will remain intact through the following semester to complete their senior design course. **Member exchange or substitution across the teams is not permitted**. In extreme cases, exceptions may be granted by the instructor with a valid reason and proper documentation of the reason.

Any student who must miss an exam needs to notify the instructor and make arrangements (if possible) prior to exam time and have documentation for the reason.

General thoughts and rules regarding remote learning

Welcome to BME 4800C at Florida International University. **This class will be taught in hybrid (in-class, remote synchronous and asynchronous format) mode. Per mandate by FIU**

Both in and out of class, let's all try our best to create the best learning experience we can. However, this will require all of us to do our parts and work together. You are expected to speak in class and participate You must participate to receive participation points.

You will find this course to be interesting and rewarding if you do all the assigned work, attend class regularly and keep up with the material. This course builds on itself. We all have a lot of demands on our time, especially now, but we can all make an effort to put this on our schedules and come to class regularly. ***There is a direct correlation between class attendance and class performance.***

- If you consistently miss class, catching up with be hard and it will eventually affect your performance and your chances for success in the course. So please make an effort to attend class and do the work outside of class too.

- **If there are extenuating circumstances** causing you to miss class(es), please reach out to me at the earliest so that we can talk and figure out how best to address your unique situation. **Timely communication is essential.**

Canvas: Canvas is FIU's preferred learning management system. **In addition to the scheduled class meetings, the course also includes readings, other assignments (worksheets) to be completed outside of class which can be accessed on Canvas. Details about due dates of assignments are also placed in the same folder.** Within Canvas, you will find all the details within our Canvas course, under "Homework due before next class" which contains details and due dates for assignments due before each class meeting.

- If you are registered for classes as a FIU student, you can access canvas by going to online.fiu.edu
- The login and password are the same as for your "myFIU" page.
- ***Students get access to Canvas on the first day of the semester.***
- If this class is not showing on your Canvas page, please visit the website: https://canvas.fiu.edu/support/ (Link to an external site.)

Always check the ""Homework due before next class" module in Canvas to see what homework is due before the next class meeting.

Textbook: An electronic earlier edition of the textbook ***will be provided to you at no cost*** (available for download on the course canvas site). In addition, you will be given links to on-line textbooks and resources that will be useful.

BME Program Outcomes

A. An ability to identify, formulate, and solve complex engineering problems (including those associated with the interaction between living and nonliving systems) by applying principles of engineering, physical (calculus-based physics, chemistry) and life sciences (biology, human physiology), and mathematics (through differential equations and statistics).

B. An ability to apply engineering design to realize/produce solutions that meet specified biomedical engineering problems and needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors.

C. An ability to communicate effectively with a range of audiences.

D. 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, health, safety, and societal contexts.

E. 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.

F. An ability to develop and conduct appropriate experimentation to measure, analyze and interpret data from living and non-living systems, and use engineering judgment to draw conclusions.

G. An ability to acquire new knowledge as needed, using appropriate learning strategies in acquiring techniques and skills necessary for biomedical engineering practice; including the ability to model and perform engineering analyses of biomedical devices, systems, components and processes.