Bioengineering 207 Medical Device Design II

Version 1.0

Syllabus: Important information

Lectures: MW 2pm–3:20pm
Location : Design and Innovation Building, Room 254

Book for the course: There is no mandated text for the course. All materials will be provided via CANVAS. A *recommended* text for students is Yock, *et al.* (2015). Biodesign: The Process of Innovating Medical Technologies. United Kingdom: Cambridge University Press.

Discussion board: We will use Piazza via Canvas.

Instructor: Dr. Alyssa Taylor, Associate Teaching Professor of Bioengineering
atayloramos@ucsd.edu

Software:

- Fusion360 (Autodesk, free!): Should have access from last quarter
- Other software: many packages available to you as a UC San Diego student – your team may have different needs.

Course Summary and Objectives:

This series of courses aims to provide basic skills and training needed by all students seeking the opportunity to work in burgeoning biomedical research and industry activity. It provides an introduction to medical device development from identification of idea, through development, implementation into a clinical setting including regulatory pathways and business development. We will continue team-based design work this quarter, as you work to prototype, test, iterate and present your final design solutions.

In this course, students will:

- Integrate skills and knowledge learned throughout two-quarter experience by completing an open-ended design project with recognizable implications for healthcare.
- Utilize hands-on skills to develop design prototypes, use testing results to make informed design decisions, and iterate on designs to ultimately produce a solution that meets an unmet clinical need.
- Develop effective presentation skills, including visual, oral, and written.
- Develop interpersonal and communication skills that promote effective team work, team leadership, and professionalism.

What to expect:

The class will be a mixture of lectures, industry guest presentations, peer feedback sessions, communication skills practice, and independent, self-driven project work. As we learned from the pandemic, we also need to maintain flexibility.

Last quarter, you worked in a team to devise and present a plan for the design and engineering of a medical device or specific technology to address an unmet clinical need, Given the short timing, we will relax certain possible requirements on IP novelty, but encourage you to devise ideas that are truly innovative to practice this skill in years to come. We expect you to deliver a functioning prototype by the end of this course.

The assignments and deliverables are designed to allow student teams to develop their skills in discovery of unmet medical needs, ranking the unmet needs with respect to engineering feasibility, transforming the feasible idea into a practical medical device or technology under always-present time and resource constraints, and presenting the solution for potential funding and broader interest before prototyping it in the follow-on class. The class will provide an opportunity for you to practice presentation and reporting techniques essential both for dissemination and funding your ideas. This quarter, we will focus on communicating your work in poster presentations and demos at the Bioengineering Day event, as well as via a team website and final write-up.

As last quarter, you'll be expected to actively participate in the classroom discussions, presentations, and group assignments. We have numerous guest speakers from industry lined up this quarter, and we need to make them feel welcomed and valued – ask questions and participate! They are here for you and your learning.

We'll expect you to speak up, ask questions, and to contribute ideas and constructive input to your peers. Don't be shy! We also expect your help to make the class an inclusive, productive, and fun learning environment. Disruptions or disrespectful behavior will simply not be tolerated.

A note on inclusion: It is my intention that students from all backgrounds and perspectives will be well-served by this course, and that the diversity that students bring to this class will be viewed as an asset. I welcome individuals of all ages, backgrounds, beliefs, ethnicities, genders, gender identities, gender expressions, national origins, religious affiliations, sexual orientations, socioeconomic background, family education level, ability – and other visible and nonvisible differences. All members of this class are expected to contribute to a respectful, welcoming and inclusive environment for every other member of the class. Your suggestions are encouraged and appreciated.

Remember: We only have 34 hours together - Becoming an expert will take a few more years. You all can appreciate how quickly last quarter went by – strive for a sense of urgency and impart that to your team mates!

Keep up with the reading, assignments, and project work. Contribute proactively to your team. This hands-on, open-ended course allows you to really self-motivate and get great things done. *See how much you can achieve! You're building your experiences here!*

Grade Evaluation*

Assignments: 30%
Project presentation at BE Day, other materials: 30%
Participation (e.g., peer review, guest speaker interactions): 10%
Final write-up (final exam), including documentation of functional prototype: 30%

*anticipated, but subject to change

No (unexcused*) **late submissions will be accepted. *Communicate with me early about any issues with getting work in on time. Many of us face unexpected crises, including myself, so I will be understanding and flexible as possible.** As a student citizen and developing professional, it is important that you take responsibility for the work and deadlines in this course. Completion of work in a timely fashion provides you with the training you will need to be successful in future endeavors and is vital to your team's success. Thus, the general policy is no late work will be accepted. In fairness to other students, you must make *prior* arrangements with me if *unavoidable* circumstances mean that you will need to turn in an assignment late. I definitely understand that unforeseeable emergencies can occur, especially as you're wrapping up your academic year, and if this happens please contact me as soon as possible.

Suggested reading is from Yock, *et al.*, the text for this class. It is a recommended text only. The book is written for a two-year experience, and we've two quarters. *If you want to become an expert medical device engineer, get the book and read it carefully and completely.* The book is an outstanding resource for the course and your career. Fortunately, much of the material is now transferred to a web-based source, at https://biodesignguide.stanford.edu/

The assignments are closely coordinated with the subject matter covered in class and will be submitted via Canvas. Unless otherwise specified, individually-drafted work is required, although you may consult with each other.

The course's project is mainly tied to a final group poster presentation and the production of report documenting your project work and a prototype, whether software, concept, or actual physical device with supporting evidence. Your team will also generate a website for your project.

Evaluation of Poster Presentation (will include, but not limited to):

- o The content of the presentation: does it address the key points necessary to evaluate the technology, including the background, feedback from

stakeholders, the process to generate a feasible solution to an unmet need, and an embodiment of the design solution? Does it address market, novelty, and regulatory issues and the team's solutions to these issues? Does it convince others of design merits (e.g. evidence of testing?)

- o The presentation is conducted by each team member in a professional and informed manner. Use of effective visual aides, including prototype demonstration.
- o The poster is clear, easy to understand and compelling.

The final exam is a team's written project report on their product. Format will be discussed in class, with examples provided. It will cover the key steps in medical device design, from finding an unmet need, ideation, selection, validation, and proposed implementation. One report will be turned in per group by the end of instruction. We anticipate that much of the work you've completed for the proposal will be utilized in your final report.

Evaluation will include, but not be limited to, (details will be on Canvas):

- o Medical merits and significance: does the selected focus area represent an unmet need? Was down selection based on a rational process?
- o Methods: Has the team brainstormed different ways to solve the selected problem and applied a matrix to down select? Was stakeholder feedback used to guide the problem-solving process? Is there evidence of appropriate testing and iteration? Does it solve the end-user's problem? Has it already been done, patented, or being actively (clinically) researched?
- o Feasibility: Can the selected idea be translated into real life and the clinical setting? Adaption into clinical use: is there an implementation plan including validation, regulatory pathway and ideas for a business development to support the entire process.
- o Communication: are ideas, results, information effectively conveyed?

Academic Integrity:
You are all graduate students and professional, so I don't anticipate any problems but…The Shu Chien-Gene Lay Department of Bioengineering adheres to the UCSD Policy on Integrity of Scholarship and we expect all students to honor this policy. An excerpt of this Policy states that "*Students are expected to complete the course in compliance with the instructor's standards. No student shall engage in any activity that involves attempting to receive a grade by means other than honest effort....*" Any suspected incident of academic integrity violation will be dealt with in accordance with UCSD policy. More information on UCSD's academic integrity policy can be found at: https://academicintegrity.ucsd.edu/process/policy.html. Please be sure that you understand what plagiarism is and how to avoid it. Intentional or not, plagiarism is a violation of the UCSD Policy on Integrity of Scholarship and there are many possible sanctions and disciplinary actions. Talk to the

teaching if you have any questions and refer to UC San Diego library guide UCSD Library Guides on finding and citing information: https://ucsd.libguides.com/CAT2/home

Accommodations for Students Due to a Disability:

I am committed to ensuring access to classes, course material, and learning opportunities for students with disabilities. Students requesting accommodations for this course due to a disability must provide a current Authorization for Accommodation (AFA) letter issued by the Office for Students with Disabilities (OSD) which is located in University Center 202 behind Center Hall. Students are required to present their AFA letters to Faculty (please make arrangements to contact me privately, I am very happy to discuss!) and to the OSD Liaison in the department in advance so that accommodations may be arranged. Contact the OSD for further information: 858.534.4382 (phone), osd@ucsd.edu (email), or http://disabilities.ucsd.edu (website).