University of Texas at El Paso

Course Title: BME 5304, BME 6304: Biomedical Device Design and Regulation

Class Time: Spring Semester 2021 Room: online
TR: 1:30 PM-2:45 PM

Textbook: Handouts may be available

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Office hours: TWR 10.30-11.30 AM

Goals: Since medical devices are applied for the diagnosis, mitigation, treatment, or prevention of diseases, it becomes essential to regulate the use of such products. In the USA, the Food and Drug Administration (FDA) is responsible for the regulation of medical devices with the purpose of protecting the safety and needs of the people. This course aims to provide an overview of device development and the FDA, and to offer students an opportunity to gain the foundations necessary to build a strong understanding of regulatory affairs.

Course Outcomes: By the end of this course, students should be able to:

1. Apply the principles of engineering design from recognition of need to a fully-tested product.
2. Organize and manage a design project and work effectively in a team to complete the project.
3. Understand the need for regulatory constraints in medical device development, and the ability to design, build, and test a medical device within those constraints.
4. Communicate items 1 through 3 in written, oral, and graphical form.
5. Gain and appreciate the need for standards in the design of biomedical devices
6. Understand and communicate the data requirements addressing quality, safety and usefulness/efficiency, and the conditions to successfully fulfill these requirements

POINTS DISTRIBUTION:

Class Participation (Design Review)	15%
Design Project Exercises	25%
Midterm Report and Presentation	25%
Final Report and Presentation	35%

Week/Week of	Topic
01/22 01/24	The Engineering Design Process Recognition of Need-Case Study
01/29 01/31	Recognition of Need Due/Group Selection Requirements Elicitation
02/05 02/07	Problem Formulation Verification/House of Quality
02/12 02/14	Problem Formulation Due Design Review 1
02/19 02/21	Solution Formulation Design Review 2
02/26 02/28	Feasibility
03/05 03/07	Organization/ Work Breakdown Design Review 3
03/12 03/14	Proposal Prep
03/19 03/22	Spring Break
03/27 03/29	Proposal Prep Formal Proposal Due Failure Mode Analysis
04/02 04/04	Verification and Validation Design Review 4
04/09 04/11	Benefits and Risks Design Review 5

04/16 04/18	FDA Regulatory Process-QSR Design Review 6
04/23 04/25	Medical Device Safety Design Review 7
04/30 05/02	Guidance for Industry and FDA Staff Final Presentation

Disability:

If you have or suspect a disability and need accommodations, you should contact the Disabled Student Services Office (DSSO) at 747-5148. You can also email the office at dss@utep.edu or go by the Union Building East, Room 106. For additional information, visit the DSSO website at www.utep.edu/dsso/

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Academic Integrity

The instructors expect a commitment to truthfulness, honor and responsibility, without which you cannot earn the trust and respect of others. Therefore, we will not tolerate plagiarism, lying, cheating, or stealing in any form.

Honor Code: "I, _____ , hereby pledge that I have read and understood the entire syllabus for the course, *Biomedical Device Design and Regulation*, and I will abide by the policies described above.