



SAN JOSE STATE UNIVERSITY COLLEGE OF ENGINEERING

Course: BME 272, Medical Devices Design and Principles - 3 units
Dates: January 27 ~ May 18
Day & Times: Mondays, 6pm – 8:45pm
Room: ENG 341
Instructor: C. Travis Rappleye
Office hours: By Arrangement
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COURSE DESCRIPTION: The need for biomedical devices is constantly increasing, with a very wide array of devices being constantly developed to meet the growing demand. Unlike other engineering products, biomedical devices are special because they come into intimate contact with the human body. This contact can range from a very short time span of a few minutes, for surgical devices and instruments, to several years, for implants. Therefore, the reliability with which these devices interact with the human body is of paramount concern. In addition, all biomedical devices have to go through stringent testing so that they can be approved by the Food and Drug Administration (FDA). This course will educate senior-level and graduate-level students on the principles that govern the design and manufacture of biomedical devices. The course will cover a variety of areas including cardiology, otolaryngology, sports medicine, wound healing, sleep apnea and local drug delivery therapies, among others.

OBJECTIVES: The fundamental objective of this course is to educate engineers on the principles of medical device design control process. Of particular importance here is the understanding of the function of the device, how design principles are employed during the conception and development phase, and how these play a key role in the design, manufacture, clinical performance, long-term reliability and quality/regulatory assurance. In addition, it is the objective of this course to expose engineers to key regulations that enable design process and subsequent introduction of the medical device product to market for human use.

TEXT: Marie B. Teixeira, Design Controls for the Medical Device Industry (2nd ed), CRC Press.

Additional reading materials, including instructor handouts, published papers and relevant chapters from other books will also be required.

PREREQUISITES: BME 115 or instructor consent.

EXAMINATIONS: There will be one mid-semester examination, and one final examination. These examinations will cover the entire course material covered until the time of the examination. The dates of the mid-semester and final examinations are indicated in the Lecture Schedule.

ASSIGNMENTS: Homework will be handed out from time to time, and must be submitted on the due date. There may be "surprise quizzes" which will be given only at the beginning of class. No late assignments will be accepted.

All assignments must be submitted electronically, via Canvas

LEARNING OBJECTIVES: The learning objectives for this course are listed separately. Attainment of these objectives will be assessed via homework, in-class quizzes, the mid-term examinations, and the term project.

TERM PROJECT: All students are required to undertake a team term project, and present it in class on the last week of classes. The term project will be completed in teams of 3-4 people. The project goal is to put together a comprehensive plan for design and development of a medical device. The selected device for term project must be FDA class II or III and be approved prior to project initiation. Essential term project components are outlined below. Additional details will be provided throughout the course.

1. Device design
2. Description of anticipated design control process, project plan within DHF (Design History File) outline with reference to appropriate guidelines
3. Regulatory strategy
4. Marketing specifications
5. Verification test list (including biocompatibility)
6. FMEA (Failure Modes and Effects Analysis)
7. IFU (Instructions for Use)

Teams will work to select a device to study, and then create the above documentation during the course of the semester. Students are encouraged to select Class II or III device design of interest to them; however, these must be approved by the instructor. Students who are currently working in industry may select a topic that is of relevance to their work environment.

Please note that all deadlines will be strictly adhered to.

GRADING: Mid-term	20%
Final Examination	35%
Homework, Quizzes and presentations	10%
In class participation	5%
Term Project	30%

No late assignments will be accepted.

Absence during examinations and quizzes, without prior approval, will result in a zero.

Prior approval will be given only under exceptional circumstances.

Seating arrangements may be handed out for mid-term and final examinations.

There will be no make-up examinations.

Office hours: I am not holding regular office hours. I will be happy to arrange a mutually convenient time as needed.

You are responsible for understanding the policies and procedures about add/drops, academic renewal, withdrawal, etc.

For expectations about classroom behavior; see Academic Senate Policy S90-5 on Student

Rights and Responsibilities.

For a definition of plagiarism, please refer to <http://info.sjsu.edu/static/policies/integrity.html>

If you would like to include in your project or any material you have submitted, or plan to submit, for another class, please note that SJSU's Academic Integrity policy F06-1 requires approval by instructors. In general, material that has been, or will be, submitted to another source for credit will not be accepted.

Students are encouraged to collaborate on assignments. However, each individual HW assignments that is submitted must be individually prepared by each student.

Engr 272 – Biomedical Devices Design and Principles Learning Objectives:

- Comprehend the design principles involved in biomedical implants and devices
- Appreciate highly regulated nature of medical device industry and rules associated with developing products in this environment
- Understand issues of biocompatibility with living tissue, and principal mechanisms of material/implant interaction with tissues.
- Analyze and describe the numerous steps that are required in the development of a medical device from the concept phase to full-scale production, including short-term screening, qualification tests designed to characterize materials chemically and biologically, and advanced biocompatibility testing appropriate to the intended end use of the material.
- Demonstrate ability to work collaboratively, in team environment, to develop product development plan
- Demonstrate a working knowledge of biocompatibility and cytotoxicity screening tests and methods currently used in industry.
- Demonstrate competency in searching electronic data bases for literature relevant to a topic of interest.
- Demonstrate competency in searching FDA and other regulatory data bases for information relevant to a topic of interest.
- Demonstrate ability to generate cohesive plan for taking the product through all product development phases, from concept to commercialization
- Demonstrate the ability to deliver a professional presentation, using presentation software, to an audience of peers.