ME 683 Design of Medical Devices

Spring 2016  TTh 2:00-3:15 pm  Room PSFA-113  3 units

Prerequisites: ME 314 Engineering Design: Mechanical Components and ME 580 Biomechanics or equivalent.

Textbooks (Required)

-Biodesign: the process of innovating medical technologies, Zenios, Makower, Yock, Brinton, Kumar, Denend, Krummel, 2009.

Instructors: Dr. Karen D. May-Newman, Professor of Mechanical Engineering
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Course Description

The successful design of medical devices requires integration of knowledge from biology, engineering, business and regulatory compliance. This course is designed for engineering students or medical device professionals that desire an in-depth study of relevant topics including design control, regulatory affairs, and manufacturing with examples from the cardiovascular and spinal implant fields. In addition, issues such as biomaterials, preclinical and clinical testing, and quality will be discussed. Whenever possible, professionals from local biomedical companies will be invited to give lectures, in order to provide relevance and “real world” applications for the lectures. The final design project will require maintaining a design folder over the course of the semester to assemble the documentation required to gain initial regulatory approval.

Evaluation Policy

Individual Design Project  (75 points max)  30%
- Design Input
- Design Report (Input and Output)
- Presentation

Group Design Project  (100 points max)  40%
- Prototype
- Presentation
- Final Group Design Report

Assignments  (75 points max)  30%
- Regulatory (CDRH website) – 30 points max
- Needs finding and ideation (Textbook) – 50 points max
- Materials Selection (in-class activities, some preparation required) – 40 points max

Attendance: Attendance to class will be taken randomly and a deduction of 5 points taken for each absence.