

Engr 296Y

Regulatory, Clinical &  
Manufacturing Aspects of  
Medical Devices

Guna Selvaduray

Summer 2006



# Course & Instructor Information

- Regulatory, Clinical & Manufacturing Aspects of Medical Devices
- 3 semester units
- Tuesdays/Thursdays 6 ~ 8:10 p.m.
- Room: E 301
- Guna Selvaduray
- Office: E 179
- Phone: (408) 924-3874
- Email: [gunas@email.sjsu.edu](mailto:gunas@email.sjsu.edu)
- Office Hours: Tues/Thurs 4:00 ~ 5:30 p.m.
- Homepage: [www.sjsu.edu/faculty/selvaduray](http://www.sjsu.edu/faculty/selvaduray)



# OBJECTIVES

The objectives of this course are to educate engineers on the importance of understanding the following:

Regulations that relate to biomedical devices including the different classes of devices and the different regulations that pertain to each class;

Regulations that pertain to the development and approval process and those that pertain to the manufacturing process and be able to distinguish between these;

The manner in which clinical trials are designed and conducted, including the different requirements for different classes of biomedical devices;

What constitutes good quality practice;

Methods used for manufacturing medical devices;

Sterilization techniques used in manufacturing;

Appropriate means of safeguarding intellectual property and proprietary information;

Ethical issues related to the development, testing, deployment and reliability of biomedical devices;

Industry trends and current developments and areas of focus.



A **Secondary Objective** of this course is to enhance the written communications and oral presentation skills of the students.

**LEARNING OBJECTIVES:** Listed separately  
Attainment of Learning Objectives will be assessed via assignments, in-class quizzes, examinations, and the term project.



# Tentative Schedule

Please refer to handout



# Text & Reading Materials

- Instructor handouts will be posted on course website
  - [www.sjsu.edu/faculty/selvaduray](http://www.sjsu.edu/faculty/selvaduray)
    - Click on Biomedical Devices
    - Click on Engr 296Y
  
- Reading of published papers and relevant chapters from other books will also be required



# Assignments & Examinations

- One page summary of each lecture, covering the most important points
- Assignments will be due in one week
- Assignments must be word processed in grammatically correct English
- Final Examination: August 10, 2006



# Term Paper - 1

- Must be Medical Device related
- Focus either on a particular medical device, or a case history of a medical device failure
- If the term paper focuses on a medical device, then it should include the following:
  - A general description,
  - The related physiology,
  - The market it serves and the potential size of the market,
  - The regulatory aspects related to the device,
  - The clinical trials required for the device, and
  - How the device is manufactured.



# Term Paper - 2

- Must include search of current peer-reviewed literature, using electronic data bases
- References must include a minimum of five peer-reviewed journal papers
- Approximately 15 ~ 20 pages
- Format: Must follow CME Thesis Guidelines



# Term Paper - 3

- June 20: Abstract & Proposed Table of Contents
- July 6: Results of Literature Search - Abstract and complete Citation
- August 3 & 8: PowerPoint Presentation
- August 8: Submit final paper
- Two hard copies with evaluation sheet attached
- One electronic copy in MS Word format



# PRESENTATION

- All students are required to do a presentation of their term paper
- PowerPoint or other equivalent presentation software
- Must include color graphics and animation
- Each presentation will be 15 minutes long
- 10 minutes for questions and answers
- Active participation by the rest of the class during Q&A is required



# Grading

- Assignments 25%
- Field Trip Flow Charts 10%
- Final Examination 15%
- Attendance & Class Participation 10%
- Term Paper 30%
- Term Paper Presentation 10%



# Notes - 1

- No late assignments will be accepted
- Absence during class periods, without prior approval, will affect grades
- 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



# Notes - 2

- Please be punctual for class and field trips
- Please turn off your cell phones and pagers when you enter the classroom



# Self Introductions

- Name
- Major
- Graduate student/Undergraduate?
- Work experience?
  - Where?
  - How long?
- Interest in this class?



Please fill out the  
Student Background Information  
Survey Sheet

Thank You