



SAN JOSE STATE UNIVERSITY COLLEGE OF ENGINEERING

Course: Engr 296Y, Regulatory, Clinical & Manufacturing Aspects of Medical Devices
- 3 units

Dates: June 6 ~ June 10, 2006; Tues & Thurs

Times: 6:00 ~ 8:10 p.m.

Room: Engr 301

Instructor: Professor Guna Selvaduray

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Email: gunas@email.sjsu.edu

Hours: TBD

COURSE DESCRIPTION: There are a number of development and manufacturing issues that are unique to, and critical for, biomedical devices. Many of these issues are directly related to the strict regulatory environment that governs the development, approval and manufacturing of devices that are critical for the human health and welfare. The industry is also highly competitive, not only making the development process extremely time-sensitive but one where proper safeguarding of intellectual property and proprietary information is essential. The biomedical device industry is also extremely fast-paced, with new devices for a variety of uses being developed constantly. Engineers working in biomedical device companies need to be aware not only of the regulatory environment that surrounds practically all aspects of their work-environment, but also need to keep up with trends in the industry including latest technologies and developments and the ethical issues involved. This course is designed to provide the engineer with good familiarity with the Food and Drug Administration's (FDA) regulations that relate to biomedical devices including the manner in which clinical trials are conducted, good laboratory practices (GLP), good manufacturing practices (GMP), and current developments. Invited guest lecturers, each an expert in a particular area, will present these diverse array of lectures. The students who complete this class successfully, while being highly competent engineers, will have gained a clear insight of the environment in which biomedical devices are conceived, developed and manufactured, and should be able to interact competently with the specialists in each of these areas.

OBJECTIVES: The objectives of this course are to educate engineers on the importance of understanding the following: (a) Regulations that relate to biomedical devices including the different classes of devices and the different regulations that pertain to each class; (b) Regulations that pertain to the development and approval process and those that pertain to the manufacturing process and be able to distinguish between these; (c) The manner in which clinical trials are designed and conducted, including the different requirements for different classes of biomedical devices; (d) What constitutes good laboratory practice (GLP); (e) What constitutes good manufacturing practice; (f) Appropriate means of safeguarding intellectual property and proprietary information; (g) Ethical issues related to the development, testing, deployment and reliability of biomedical devices; (h) How engineers can successfully collect users' (physicians') feedback for incorporation into design, and (i) 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.

REQUIRED TEXT: Reading materials, including instructor handouts, published papers and relevant chapters from other books will be required.

PREREQUISITES: Graduate standing and instructor consent.

ASSIGNMENTS: A two-page report summarizing the essentials of each of the guest lectures must be turned in at the beginning of the following class period. A term paper addressing a technology that is currently under development, with potential for future deployment, is required. Details of the term paper requirement are explained in the "Term Paper" section. No late assignments will be accepted.

EXAMINATIONS: There will be one mid-term examination and one final examination. The tentative date for the mid-term examination is indicated in the lecture schedule attached. The final examination will be held on the date published in the Schedule of Classes.

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

TERM PAPER: All students are required to write a term paper or undertake a term project, and present it in class on the last week of classes. The term paper should 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) A general description, (b) The related physiology, (c) The market it serves and the potential size of the market, (d) The regulatory aspects related to the device, (e) The clinical trials required for the device, and (f) How the device is manufactured. Students interested in writing their term paper on a case history of a medical device failure are required to discuss this with the course instructor first.

An abstract (300 to 400 words) and a Table of Contents for the term paper must be submitted no later than Tuesday June 20, 2006. All students are required to conduct a literature search using electronic data bases. The completed literature search, including complete citations and abstracts, are to be submitted no later than Thursday July 6, 2006. **The term paper carries 25% of the total credit for this class.** Out of this 25%, 2% will be assigned for submission of the Abstract and Table of Contents on time. Another 3% will be assigned for completing and turning in the literature search on time. Items turned in late will not receive the credit assigned to them. However, in order for the subsequent item to be graded and credited, the preceding item must be turned in. In other words, if the Abstract and the Table of Contents are not turned in, the Literature Search will not be graded and credited, even if the latter is submitted on time. Likewise, if the Literature Search is not submitted, the Term Paper will not be graded and credited. The deadline for turning in the final term paper is the fourteenth week of classes. Two copies of the term paper, with two copies of the attached evaluation sheet, must be turned in. One copy of the term paper, with the evaluation sheet will be returned to the student, and the other will be retained by the instructor. In addition, one electronic copy of the term paper, in MS Word format, must also be turned in. Students will also be required to submit the paper to turnitin.com. The term paper must be word processed on white paper, and be in accordance with the Chemical & Materials Engineering Department's Thesis Guidelines. The formatting must be in accordance with the thesis guidelines published by SJSU's Office of Graduate

Studies and Research. Evaluation criteria for the term paper are attached. Term papers must be original work. Reports written for other classes, including reports written by other individuals, cannot be resubmitted, with or without revisions.

Students are encouraged to select topics 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.

PRESENTATIONS: All students are required to do a presentation of their term paper, using PowerPoint or other equivalent presentation software. The presentation must include color graphics and animation. Each presentation will be 15 minutes long, with 10 minutes for questions and answers.

Please note that **all deadlines will be strictly adhered to.**

GRADING:	Attendance and class participation	10 %
	Mid-term I	10 %
	Final Examination	20%
	Assignments	25%
	Term Paper	25%
	Presentation	10%

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.

**Engr 296 Y – Regulatory, Clinical & Manufacturing Aspects of Medical Device
Tentative Lecture Schedule**

Date	Topic
June 6	Class Organization, Introduction
June 8	No Class
June 13	FDA Regulations Related to Biomedical Devices
June 15	FDA Regulations Related to Biomedical Devices
June 20	Field Trip to Boston Scientific
June 22	Intellectual property and proprietary information
June 27	Design and implementation of clinical trials
June 29	Design and implementation of clinical trials
July 4	Independence Day - Holiday
July 6	Case Studies of Medical Device Development – I
July 11	Field Trip to Neuropace
July 13	Case Studies of Medical Device Development - II
July 18	Sterilization principles and techniques
July 20	Sterilization principles and techniques
July 25	Failure Mode Analysis
July 27	Quality Control for Medical Devices
Aug 1	Applications of Nanotechnology for Medical Devices
Aug 3	Term Project Presentations
Aug 8	Term Project Presentations
Aug 10	Final Examination

Engr 296 Y – Regulatory, Clinical & Manufacturing Aspects of Medical Device

Learning Objectives:

- Identify the different categories of biomedical devices, as defined by the Food and Drug Administration.
- Describe the regulations that define the requirements to be met for FDA approval of biomedical devices.
- Describe the process of setting up clinical trials for implantable medical devices.
- Describe good laboratory practices with examples of acceptable and unacceptable laboratory practices.
- Describe good manufacturing practices with examples of acceptable and unacceptable manufacturing practices.
- Explain significant current problems in medicine that require development of versatile and sophisticated biomedical devices.
- 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 knowledge of standard specifications for different materials used in surgical implant applications, including chemical, mechanical, and metallurgical requirements.
- Evaluate drug delivery systems by mechanism for different applications in-vivo and in-vitro.
- Summarize progress in the design factors for implantable pneumatic artificial hearts, and other devices.
- Demonstrate competency in searching electronic data bases for literature relevant to a topic of interest.
- Demonstrate the ability to write a cohesive and informative paper on a subject related to biomedical devices, including explaining the principles, biocompatibility considerations, design considerations, regulatory requirements, clinical trial requirements, and other pertinent factors.
- Demonstrate the ability to deliver a professional presentation, using presentation software, to an audience of peers.
- Describe the packaging and marking requirements for biomedical devices.

- Demonstrate the ability to discuss ethical issues related to the development, testing and use of biomedical devices.
- Describe the steps that need to be taken to protect intellectual property.
- Demonstrate the ability to understand future trends and road maps and the ability to use these in identifying future technological needs.

ENGINEERING 296 Y: TERM PAPER EVALUATION

NAME: _____

	MAXIMUM	YOUR SCORE
1. Significance of Problem	15	
2. Technical Content	30	
3. Figures, Tables	5	
4. Referencing and References	10	
5. Conclusions	10	
6. Grammar	10	
7. Typewritten	5	
8. Overall Impression (subjective)	15	

	100	

Engr 296Y: Regulatory, Clinical & Manufacturing Aspects of Medical Device

Student Background Information

Name:

Address:.....
.....

Company:.....

Tel:..... FAX:.....

Email:.....

Current (graduate) major:.....

Undergraduate? Yes No Graduate Student? Yes No

Are you taking this class through Open University? Yes No

Highest degree obtained?

If you are a graduate student, or are taking this class through Open University, what was your undergraduate major?.....

How did you find out about this class?

What motivated you to take this class? Your reason for taking this class?

If you are working, what is your current job title and responsibilities?

Experience in Biomaterials, including number of years and area of expertise:

Topics of Interest:.....

Would you be interested in enrolling in the College of Engineering's Master of Science in Engineering Specialization area in Biomedical Devices? Yes No

Comments:.....