USC Department of Regulatory and Quality Sciences

MPTX 513: Regulation of Medical Devices

Units: 3
Summer Term, Five full days, 9am-5pm

Instructor: **Susan Bain, DRSc, USC School of Pharmacy**
Frances Richmond, PhD, USC School of Pharmacy

Office: 1540 Alcazar Street CHP 140
Los Angeles, CA 90033

Contact Info: bain@usc.edu
fjr@usc.edu

Recommended Preparation:

Undergraduate degree in pharmacy, medical or independent health sciences, engineering or equivalent mix of post-secondary training and industry experience.

Course Description and Purpose:

The medical device industry is one of the most vibrant and important drivers of the economy of Southern California. Regulations to ensure the safety of devices and in vitro diagnostics are evolving rapidly in both the US and the international arena. In this course, students with a basic knowledge of biomedical science and regulatory structures will explore in depth the policies and practices of regulatory research and management for these product classes. At the completion of the course, students should exhibit a detailed understanding of American and international laws, policies and regulations. They should be able to integrate this knowledge with scientific principles related to the development of experimental protocols and testing paradigms, in order to plan and manage complex research programs.

Learning Objectives

To assure that students acquire a strong understanding of the regulations and guidelines regarding the design, development, and regulation of Medical Devices

Upon successful completion of this course, you should be able to:

- Classify any medical device or diagnostic into its appropriate product class, and understand the regulatory significance of this classification
- Understand the requirements for 510(k) and PMA submissions to market new devices
- Understand the engineering requirements for assuring product safety and quality
- Understand the goals and range of testing needed to evaluate biocompatibility
- Design an animal testing plan for an assigned implantable device
- Create a strategy for developing a combination drug/device product
- Identify time points to meet with regulatory agencies and agenda items to be discussed at those meetings
- Organize a third-party audit of a device manufacturing facility
- Understand the current rules regarding single-use vs reuse devices
- Describe the differences between product approval in the US and Europe/Asia
- Be able to identify the steps to obtain a CE mark
- Describe the requirements for post-marketing surveillance and adverse event reporting

Class Topics/ Discussion Items

Course topics are identified in three-hour blocks. In addition to these classroom blocks students will participate in two one-hour computer labs in which electronic databases will be used for information retrieval and submission.

1. Introduction to US Regulations for new medical devices and diagnostics

- Relevant laws and regulations
- Historical development of medical device regulations
- Organization of FDA and CDRH
- Washington
- Field offices

- Role of FTC and other regulatory bodies
- FDA databases
- Investigational Device Exemptions (IDEs)

2. 510(k) and PMA Pathways to Market

- Key points to consider before beginning the process
- Interacting with the ODE
- Contents of a 510(k) submission
- Abbreviated and Special 510(k)s
- 510(k) case studies
- Contents of a PMA dossier
- Planning and managing the process
- Negotiating and budgeting approaches
- Post-marketing Activities

3. Engineering Management Labeling and Humanitarian Devices:

- Design control and qualification review
- Risk assessment
- Faults and hazards analysis using HACCP, fault-tree and quantitative methods
- Failure mechanisms of metals and polymers
- Electrical and electronic components and functions
- Bench testing for mechanical integrity
- Importance of device class and risk category
- Labeling regulations and requirements
- What information is needed?
- Symbols, language considerations
- Internet Advertising
- Unique Device Identifier (UDI) requirements
- Elements of a Humanitarian Use Device (HUD) Submission
- Obtaining a HUD Designation

4. In Vitro and In Vivo Biocompatibility Testing, Combination Products and Various Audit Platforms

- Accelerated life testing
- Cytotoxicity testing
- cytotoxicity
- irritation and sensitization
- genotoxicity and carcinogenicity
- implantation
- hemocompatibility
- Combination Products and how they’re regulated
- ISO 13485 Audits
- MDSAP Audits
- QSIT Auditing Methods

5. CE Mark and Student Presentations

- Requirements to obtain a CE Mark for your medical device
- Student presentation on 510(k) project

Course Requirements and Grades:

Assignment #	Title	Due Date	% of Grade
I.	Assignment 1: Researching a Medical Device	TBA	15%
II.	Midterm Exam	TBA	20%
III.	510(k)	TBA	25%
IV.	Quizzes (2)	TBA	10%
V.	Final Exam	TBA	30%

Assignment 1: The student will learn to navigate and locate information on FDA's websites as well as websites of other organizations that promulgate standards related to medical devices.
510(k) Project: The students will work in small groups to develop a mock 510(k) for an assigned Class II medical device. The finished document is expected to be of the quality and accuracy required for an industry submission.

Course Readings:

Refer to the electronic binder and Blackboard
Recommended Textbook:
Kahan, Jonathan S, (2000) Medical Device Development: A Regulatory Overview 2000. Parexel Int Corp: Chicago
The textbook will be supplemented by a list of readings that will compliment the text. In some cases in which the reading is necessary to cover topics outside of the scope of the text, materials will be available in hand-outs. Additional relevant materials will also be provided as a reader at a modest charge.

Distance Students:

Please contact Erin Chow at erinchow@usc.edu with any questions and for testing arrangements.

ALL STUDENTS:

All submissions are to be entered in to http://blackboard.usc.edu and emailed to Erin Chow at erinchow@usc.edu to ensure confirmation of receipt. Be sure to see the accompanying Getting Started sheet for directions.

Please format MS Word file titles with your last name, initial, course number and assignment number, for example: Brown_C_516_A1.doc. Be sure to include your name, the course number and title at the beginning of the text itself.
If applicable, provide details of accessing course if not in a traditional classroom setting.

Statement on Academic Conduct and Support Systems

Academic Conduct:

Plagiarism – presenting someone else's ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, "Behavior Violating University Standards" policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on Research and Scholarship Misconduct.

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call
studenthealth.usc.edu/counseling
Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call
suicidepreventionlifeline.org
Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press "0" after hours – 24/7 on call
studenthealth.usc.edu/sexual-assault
Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086
eeotix.usc.edu
Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298
usc-advocate.symplicity.com/care_report
Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - (213) 740-0776
osas.usc.edu

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - (213) 821-4710

campussupport.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - (213) 740-2101

diversity.usc.edu

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

dps.usc.edu, emergency.usc.edu

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

ombuds.usc.edu

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

*Occupational Therapy Faculty Practice - (323) 442-33*40 or otfp@med.usc.edu

chan.usc.edu/otfp

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.