MPTX 511: Introduction to Medical Product Regulation

Units: 3

Summer 5 full days, 9am-5pm

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Course Description

This introductory course is designed as a first course for students enrolled in the MS (Regulatory Science). It is also an optional course that serves as an overview for students from other disciplines, such as graduate programs in biomedical, pharmaceutical and engineering fields and the Pharm. D program in the School of Pharmacy. The course is designed to introduce the laws, regulations and institutions governing medical products in North America. Students will be introduced to the purposes of regulations and their relationships with the law. Particular attention will be paid to regulations that shape the developmental path of medical products. The students should be able to map the history of regulatory policies in the US. They should be able to differentiate the spheres of authority, organization and operation of FDA, FTC, OSHA, EPA and state regulatory authorities. Students will also become familiar with the regulations shaping the structure and conduct of preclinical and clinical trials.

The course will be taught through case studies and lectures. An emphasis will be placed on relatively informal lecture formats in which students are encouraged to ask and answer questions throughout the didactic session. As part of a novel strategy to meet the needs of part-time as well as full-time students, the course will be taught in a condensed period of full days in the fall, spring, and summer term; lecture-discussions will occupy a total of approximately 40 face-to- face hours.

Learning Objectives

Below are listed some of the capabilities and knowledge expected of students who graduate from this course. Students should be able to:

1. Explain the evolution of drug and device regulations as a result of key medical tragedies or policy-making events
2. Draw an organizational chart for the FDA showing the roles played by different centers
3. Identify the relative roles of field offices of the FDA compared to central offices in Washington
4. Explain the relative roles played by FDA and FTC with regard to medical product advertising
5. Draw a flow chart to explain the drug development process
6. Be able to identify if a drug or device would qualify for orphan product status and why that would be advantageous
7. Describe the differences in the application process for the approval to market a generic vs an innovative drug product
8. Sketch a drug product insert
9. Differentiate between a drug and dietary supplement, and identify which claims are and are not justifiable for a dietary supplement from a provided list
10. Classify devices according to risk and identify the testing that a product in each class might be expected to undergo
11. Explain what is meant by good laboratory practices and good manufacturing practices
12. Suggest the membership for an IRB and explain to a new member what the IRB is expected to do
13. Describe why audits are done and what should be expected during an audit
14. Differentiate between strict liability, negligence and breach of contract
15. Explain why the EPA and OSHA might have regulatory oversight in a manufacturing workplace

Course Notes

Class Topics/ Discussion Items:

1. History of regulation in US biomedical sector; current organization of regulatory bodies
    a. Federal Food Drug and Cosmetic Act; Kefauver-Harris Amendments
    b. Medical Device Amendments, Safe Medical Device Act
    c. Orphan Drug Act
    d. Food and Drug Administration Modernization Act
    e. Administrative Procedures Act and proposed rulemaking

    f. Roles of legislative and judicial bodies
    g. FDA Organization

2. Regulation of new drugs
    a. The drug development path
    b. FDA drug submission procedures; INDs and NDAs
    c. Drug compliance
    d. Generic vs patented drugs
    e. OTC vs prescription drugs

3. Regulation of new devices and diagnostics
    a. The device development path
    b. Device classification
    c. 510Ks and PMAs
    d. Investigational Device Exemptions
    e. Registration and listing of manufacturers

4. Rules governing preclinical testing and trials in animals
    a. Good Laboratory Practices
    b. Protocol development
    c. Proving safety and biocompatibility in models, dishes and animal systems
    d. Animal husbandry and ethics

5. Clinical trials for drugs and devices
    a. Good clinical Practices
    b. Identifying subjects, informed consent
    c. Investigational Review Boards
    d. The sponsor, investigator and patient triangle

6. Claims and advertising in biomedical industries
    a. Product labeling
    b. Rules governing product advertising
    c. Internet advertising
    d. Promotion vs education
    e. Anti-kickback statutes
    f. Role of the FDA and FTC

7. Regulation of foods, dietary supplements and cosmetics
    a. Defining boundaries between products
    b. DSHEA
    c. Rules governing labelling and claims

8. Organization and operation of regulated industries to ensure regulatory compliance
    a. FDA inspection and enforcement options
    b. Adulteration and misbranding
    c. Prohibited acts
    d. Audits
    e. Recalls
    f. Horror stories

9. Legal Liability
    a. Breach of contract, negligence, strict liability
    b. Risk assessment

10. Regulatory activities of OSHA, Drug Enforcement Agency
    a. Defining safe working conditions
    b. Rules for travelling workers and home offices
    c. Controlled substances as marketed products
    d. Use of controlled products in the home and workplace

11. Rules and activities of the EPA
    a. Title 40, CFR
    b. Pollution problems in medical product industries
    c. Anticipating pollution by end users

Course Readings:

"An Overview of FDA Regulated Products: From Drugs and Cosmetics to Food and Tobacco" (Pacifici and Bain, eds.)

Course Requirements and Grades:

Refer to the Blackboard for the most current information

Assignment #	Title	Due Date	% of Grade
I.	Slideshow Submission	TBA	5%
II.	Scavenger Hunt Assignment	TBA	15%
III.	Take Home Exam	TBA	25%
IV.	Midterm Examination	TBA	25%
V.	Group Research Project Presentation	TBA	15%
VI.	Group Research Project Report	TBA	15%

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.