USC School of Pharmacy

RXRS 416: Medical Products: From Idea to Market

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Spring 2021: **M 2:00-4:50pm** **Location: CPA260**

Course Weight: **4 Units**

Course Hours: **Meets 3 hours per week**

Catalogue description: *Progress of medical product development through intellectual property, animal and clinical trials and commercialization. Emphasis on safety, quality systems and efficacy*

Introduction

Ideas do not turn into products without the help of many different types of experts. Medical devices, drugs and diagnostics are particularly hard to turn into products because they are highly regulated and require disciplined adherence to quality systems. In this course, we follow the progress of products through the identification of intellectual property, the animal and clinical trials to establish safety and efficacy, the gradual refinement of the product composition and quality specifications to the final goal of commercialization. You will be exposed to many types of activities, some of which may help you to define if further study or career development is right for you. You will see how business concepts merge with project management and science in order to make and keep products safe and saleable. A more detailed agenda for the course will be posted on Blackboard before the course starts, to specify the content of the lectures for each day of the class.

Objectives

After completing this course, you should be able to:

- Describe the typical structure and goals of different departments in a biomedical business, and recognize when individuals from these departments should be involved in decisions about medical product development
- Understand intellectual property rules sufficiently to read a patent effectively, write an invention disclosure and review the patent literature without assistance
- Show how to find the classification of a product in the FDA database system, and to connect that classification with appropriate regulations
- Identify the types of safety and efficacy testing that must be applied to implantable devices and drugs prior to use in humans
- Apply design controls to new product development and organize a design history file
- Describe how to design and manage a simple clinical trial under Investigational Exemption rules
- Develop a rudimentary qualification test plan for a new product based on a faults and hazards analysis
- Describe the basic principles and components of a quality assurance program
- Demonstrate how to implement and maintain standard operating procedures, travelers, and inspection reports.
- Be able to differentiate the rules for foods and dietary supplements, and know when either is misbranded
- Understand and avoid potential ethical and legal liability problems

Assignments and Grading

10 quizzes/assignments @ 6 pts each:	60 pts (15%)
1 midterm exam @ 80 pts:	80 pts (20%)
1 written report @ 60 pts:	60 pts (15%)
1 group project	100 pts (25%)
1 final exam	100 pts (25%)
Total:	400 pts.

Attendance at all classes is expected unless prior arrangements have been made. Participation will include asking and answering questions and being actively involved in the discussion. It is expected that the students read the assigned papers prior to the lecture (if instructed to do so) and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture.

There will be 10 quizzes or short assignments over the course of the semester.

The midterm (80 points) will include multiple choice, T/F, and short answer questions (2-4 points each), and 1 short essay (4-6 points). Students will be required to write one written report designed to demonstrate their critical thinking and understanding of the subject. The reports should be 10 pages, Times New Roman 12pt font, 1-inch margins, and double-spaced.

References, tables, and figures will not be included in the page count. In addition, there will be one oral presentation assigned during the semester.

The group project deliverable will include a written report and a presentation on creating a target product profile for a selected therapeutic indication.

There are no make-up exams. If exceptional circumstances prevent you from attending an exam, your reason for missing it must be accompanied by a written statement from a third party (e.g., a note from a medical doctor).

Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

Students will be asked to complete an anonymous critical evaluation of the course at its completion.

Readings and Useful Textbooks

Readings for each week will be posted on blackboard. The reference textbook for the course is:

An Overview of Regulated Products: from Drugs and Cosmetics to Food and Tobacco, Pacifici, E and Bain, S., eds., London: Academic Press. This book is available online through the USC Libraries.

Course Plan and Outline *(DRAFT)*

The course plan is built around three-hour sessions designed to introduce you to different aspects of product development and regulation. We will use case studies, group projects and sometimes bring experts to the classroom so that you can see how different experts work together. We will emphasize projects that cut across different areas of development and help you to develop your teamwork capabilities.

Session	Date	Primary Lecturer	Reading	Topic	Activity
1	Aug. 23	Pacifici	1-24, 49-50	Intro. to Regulated Products; Product Lifecycle	Ice breaker
2	Aug 30	Pacifici, Bain	105-116, 137-155	Medical product regulation: Drugs, Biologics, Device and Combination Product	Quiz/Assign #1
3	Sept. 6		-	Labor Day	
4	Sept. 13	Loeb	blackboard	Intellectual Property	Quiz/Assign #2
5	Sept. 20	Stan Jhee	blackboard	Case Study #1 (Drug)	Quiz/Assign #3
6	Sept. 27	Stan Jhee	blackboard	Case Study #1 cont'd	Quiz/Assign #4
7	Oct. 4	Bain	251-262	GMPS and Quality Systems	Midterm Exam
8	Oct. 11	Kaufman	blackboard	Case Study #2 (Combo)	Quiz/Assign #5
9	Oct. 18	Mary Ellen Cosenza	121-125, 130-136 blackboard	Case Study #3 (Biologic)	Quiz/Assign #6
10	Oct. 25	Mohamed Abou-el-Enein?	blackboard	Case Study #4 (CAR-T)	
11	Nov. 1	Myles	blackboard	Project Management	Quiz/Assign #7
12	Nov. 8	Loeb	blackboard	Case Study #4 (Device)	Quiz/Assign #8
13	Nov. 15	Kaplan	blackboard	Case Study #5 (Regenerative Therapy)	Quiz/Assign #9
14	Nov. 22	Pacifici	blackboard	Case Study #6 (Gene Tx)	Quiz/Assign #10
15	Nov 29	All		Project Presentations	Reports due
	Dec. 10	2:00 to 4:00 pm		Cumulative – all lectures	Final Exam

Final Exam: Friday, December 10, 2021, 2:00-4:00 PM, CPA 260

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 scientific misconduct, policy.usc.edu/scientific-misconduct.

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 of Equity and Diversity (OED) - (213) 740-5086 | Title IX – (213) 821-8298
equity.usc.edu, titleix.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 of Equity and Diversity |Title IX for appropriate investigation, supportive measures, and response.

The Office of Disability Services and Programs - (213) 740-0776
dsp.usc.edu
Support and accommodations for students with disabilities. Services include assistance in providing readers/notetakers/interpreters, special accommodations for test taking needs, assistance with architectural barriers, assistive technology, and support for individual needs.

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 at USC - (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.