USC School of Pharmacy

RXRS 416: Medical Products: From Idea to Market
Fall 2020

Instructors

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Course Weight 4 units

Days/Time/Location: Monday: 2:00pm to 4:50pm, ONLINE

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. A field trip is also planned so that some of the concepts discussed in class can be seen in practice.

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

Assignments

Project: New Product Development: You will work as a team to determine the feasibility of a new product. The team should have subgroups to deal with specific aspects of product development, for example:

- Market Requirements and Reimbursement Strategy
- Design, Technology and Safety Issues
- Regulatory and Clinical Trials Strategy

Each team will be evaluated on its oral presentation and written report of no more than about 30 pages. The report from each subgroup can include any supporting documentation deemed important. There should also be a brief statement from the team listing the individual contributions of each member. One or more members from each team may present as long as the total time does not exceed the time allotted for the team.

Grading

Marks will be based on quizzes, a project, one midterm examination and a final examination. The breakdown of marks is as follows:

Class Quizzes (best 6/9)	20%
Class project	
Report	10%
Presentation	20%
Midterm examination	20%
Final examination	30%

	100%

Delays in submitting the report will be tolerated only if special circumstances exist and permission is given before the deadline. Otherwise marks will be subtracted at a rate of 5% per day.

There will be a brief quiz during each class covering the content in the previous class and any assigned readings. Only the best 6 of 9 such quizzes will be counted. The **midterm exam** will deal with material presented in the prior lectures so that students can calibrate their performance and study methods early in the course. The **final exam** will test on all aspects of the course.

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 on Amazon.

Course Plan and Outline

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 team work capabilities.

Session	Date	Primary Lecturer	Reading	Topic	Activity
1	Aug. 17	Richmond	1-24, 49-50	Intro. to Regulated Products; Product Lifecycle	
2	Aug. 24	Richmond	105-116, 137-155	Device and Combination Product Regulation	Quiz 1
3	Aug. 31	Loeb	blackboard	Intellectual Property	Quiz 2
4	Sept. 7			Labor Day	
5	Sept. 14	Loeb	116-121, blackboard	Design Controls, Documents, Risk	Quiz 3
6	Sept. 21	Richmond	51-82	Drug Classification and Regulation	Quiz 4
7	Sept. 28	Richmond	121-125, 130-136	Clinical Trials	Quiz 5
8	Oct. 5	Bain	251-262	GMPS and Quality Systems	Quiz 6
9	Oct. 12	Bain	blackboard	Ethics & Careers & Presentations	Midterm Exam
10	Oct. 19	Richmond	blackboard	Marketing and reimbursement	Quiz 7
11	Oct. 26	Richmond	blackboard	Project Management	Quiz 8
12	Nov. 2	Richmond	76-83, 217-229	Over-the-counter and generic products; cosmetics	Quiz 9
13	Nov. 9	Richmond	52-58	Animal Testing Project Presentations	Reports Due
	Friday, Nov 20			cumulative – all lectures	Final Exam

FINAL EXAM: Friday, November 20, 2020 from 2-4 p.m.

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.