

USC School of Pharmacy
RXRS 416: Medical Products: From Idea to Market

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Fall 2022: **M 2:00-4:50pm** **Location: LVL 13**

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 beginning with the idea 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 to help ensure products are 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 function and goals of different departments in a biomedical business, recognizing when individuals from each department should be involved in decisions about a product's 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 connect that classification with appropriate regulations.
- Identify the types of safety and efficacy testing required for implantable devices and drugs prior to use in humans.
- Apply design controls to new product development and organize a design history file.
- Describe the basics of designing and managing clinical trials under Investigational Exemption Rules.
- Develop a rudimentary qualification test plan for a new product considering 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, and inspection reports.
- Differentiate between the rules for foods and dietary supplements and describe 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 @ 60 pts:	60 pts (15%)
1 written report @ 60 pts:	60 pts (15%)
1 oral presentation @ 60 pts:	60 pts (15%)
1 group project	60 pts (15%)
<u>1 final exam</u>	<u>100 pts (25%)</u>
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 class 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 (60 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 12-pt font, 1-inch margins, and double-spaced. References, tables, and figures will not be included in the page count.

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

The course plan is built around three-hour sessions designed to introduce the students to multiple aspects of product development and regulation in the biomedical space. Throughout the course case studies, group projects, and discussions with experts will be used to emphasize how an idea works its way through development to commercialization with interactions across multiple different departments throughout the product's development. The course is designed to help students to develop teamwork capabilities.

Session	Date	Primary Lecturer	Reading	Topic	Activity
1	Aug. 22	Pacifici/ Graham	1-24, 49-50	Intro. to Regulated Products; Product Lifecycle	Ice breaker
2	Aug 29	Pacifici/ Graham/	105-116, 137-155	Medical product regulation: Drugs, Biologics, Device and Combination Product	Quiz/Assign #1
3	Sept. 5		-	Labor Day	
4	Sept. 12	Stan Jhee	blackboard	Case Study #1 (Drug)	Quiz/Assign #2
5	Sept. 19	Stan Jhee	blackboard	Case Study #1 cont'd	Quiz/Assign #3
6	Sept. 26	Jay Nayar	blackboard	Digital Technologies	
7	Oct. 3	Loeb	blackboard	Intellectual Property	Quiz/Assign #4
8	Oct. 10	Kaufman	blackboard	Case Study #2 (Combo Drug/Device)	Midterm Exam
9	Oct. 17	Mary Ellen Cosenza	121-125, 130-136 blackboard	Case Study #3 (Biologic)	Quiz/Assign #5
10	Oct. 24	Mohamed Abou-el-Enein	blackboard	Case Study #4 (CAR-T)	Quiz/Assign #6
11	Oct. 31	Susan Bain	blackboard	Medical product quality and medical device regulation	Quiz/Assign #7
12	Nov. 7	Nancy Pire-Smerkanich	blackboard	Medical product commercialization and reimbursement	Quiz/Assign #8
13	Nov. 14	Hovhannes Gukasyan	blackboard	Case Study #5 (Eye product)	Quiz/Assign #9
14	Nov. 21	Loeb	blackboard	Case Study #7 (Device)	Quiz/Assign #10
15	Nov 28	All		Project Presentations	Reports due
	Dec. 9	2:00 to 4:00 pm		Cumulative – all lectures	Final Exam

Final Exam: Friday, December 19, 2022, 2:00-4:00 PM, LVL 13

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) 442-3340 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.