

USC Mann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

Fall 2023: RXRS 416: Medical Products: From Idea to Market

Course Weight: 4 Units

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Office Hours: MWF, 12noon-1pm (by appointment)

Onsite Class Day/Time/Location: M/ 2:00-4:50pm/ THH 214

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

5 quizzes/assignments @ 8 pts each:	40 pts (10%)
1 written report @ 60 pts:	60 pts (15%)
1 midterm exam @ 80 pts:	80 pts (20%)
1 oral report @ 60 pts:	60 pts (15%)
1 group project	60 pts (15%)
1 final exam	100 pts (25%)
<hr/> 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 5 quizzes or short assignments over the course of the semester.

The midterm 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 the blackboard. The reference textbook for the course is:

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

<https://www-sciencedirect-com.libproxy1.usc.edu/book/9780128111550/an-overview-of-fda-regulated-products?via=ihub=>

Other assigned readings may include:

Cordes, Eugene H.. Hallelujah Moments : Tales of Drug Discovery, Oxford University Press, Incorporated, 2014. ProQuest Ebook Central,
<https://ebookcentral.proquest.com/lib/socal/detail.action?docID=1602520>.

Ogrodnik P. Medical Device Design - Innovation from Concept to Market. 1st ed. Elsevier; 2013. doi:10.1016/C2016-0-05027-1
<https://www-sciencedirect-com.libproxy1.usc.edu/book/9780128149621/medical-device-design?via=ihub=>

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. 21	Pacifici	1-24, 49-50	Intro. to Regulated Products; Product Lifecycle	Ice breaker
2	Aug 28	Pacifici	105-116, 137-155	Medical product regulation: Drugs, Biologics,	Quiz/Assign #1
3	Sept. 4		-	Labor Day	
4	Sept. 11	Bain	blackboard	Medical Product Quality; Medical Device and Combination Products	Quiz/Assign #2
5	Sept. 18	Hovhannes Gukasyan	blackboard	Case Study #1 (Eye Products)	Quiz/Assign #3
6	Sept. 25	Loeb	blackboard	Intellectual Property	
7	Oct. 2	Pacifici	251-262	Availability vs. Access	Midterm Exam
8	Oct. 9	Pacifici	blackboard	Case Study #2 (Regenerative Therapy)	Quiz/Assign #4
9	Oct. 16	Pacifici	blackboard	Workshop/ presentation	
10	Oct. 23	Mary Ellen Cosenza	121-125, 130-136 blackboard	Case Study #3 (Biologic)	
11	Oct. 30	Loeb	blackboard	Case Study #4 (Device)	
12	Nov. 6	Stan Jhee	blackboard	Neurogenerative Diseases (from symptomatic to disease modifying approaches)	Quiz/Assign #5
13	Nov. 13	Stan Jhee	blackboard	Alzheimer's Case Study	
14	Nov. 20	Pacifici	blackboard	Case Study #6 (Gene Tx)	
15	Nov 27	All		Project Presentations	Reports due
	Dec. 8	2:00 to 4:00 pm		Cumulative – all lectures	Final Exam

Final Exam: Friday, December 8, 2023, 2:00-4:00 PM, THH 214

Course Content Distribution and Synchronous Session Recordings Policies

USC has policies that prohibit recording and distribution of any synchronous and asynchronous course content outside of the learning environment. Recording a university class without the express permission of the instructor and announcement to the class, or unless conducted pursuant to an Office of Student Accessibility Services (OSAS) accommodation. Recording can inhibit free discussion in the future, and thus infringe on the academic freedom of other students as well as the instructor. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

Distribution or use of notes, recordings, exams, or other intellectual property, based on university classes or lectures without the express permission of the instructor for purposes other than individual or group study. This includes but is not limited to providing materials for distribution by services publishing course materials. This restriction on unauthorized use also applies to all information, which had been distributed to students or in any way had been displayed for use in relationship to the class, whether obtained in class, via email, on the internet, or via any other media. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

Academic Integrity:

The University of Southern California is foremost a learning community committed to fostering successful scholars and researchers dedicated to the pursuit of knowledge and the transmission of ideas. Academic misconduct is in contrast to the university's mission to educate students through a broad array of first-rank academic, professional, and extracurricular programs and includes any act of dishonesty in the submission of academic work (either in draft or final form).

This course will follow the expectations for academic integrity as stated in the [USC Student Handbook](#). All students are expected to submit assignments that are original work and prepared specifically for the course/section in this academic term. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s). Students suspected of engaging in academic misconduct will be reported to the Office of Academic Integrity.

Other violations of academic misconduct include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the [student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Statement on Academic Conduct and Support Systems

Academic Integrity:

The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see [the student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

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

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

[988 Suicide and Crisis Lifeline](#) - 988 for both calls and text messages – 24/7 on call

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

[Relationship and Sexual Violence Prevention Services \(RSVP\)](#) - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

[Office for Equity, Equal Opportunity, and Title IX \(EEO-TIX\)](#) - (213) 740-5086

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

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 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) 740-0411

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

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

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) 442-1200 – 24/7 on call
Non-emergency assistance or information.

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

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) 442-2850 or otfp@med.usc.edu

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