

USC Mann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

Spring 2025: RXRS 407: The Discovery, Development and Marketing of Modern Medicines

1.08.2025

Instructor: **Daryl Davies, PhD**
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HSC Office: PSC 528
UPC Office: Stonier Hall 312
Office Hours by appointment

Course Weight: 4 Units (two 1.5-hour sessions; plus 1 hour outside activities)

Day/Time/Location: TTH 9:30-10:50 am, Vivian Hall (VHE) 217

Introduction

This course introduces the student to the biomedical community as it relates to current strategies undertaken to move research discoveries from the laboratory (bench) into clinical practice (bedside) to diagnose and treat patients. This concept is commonly referred to as Translational Science or Translational Medicine. The tenets of this course will be defined and explained in terms of promoting focused multidisciplinary interactions between science and medicine to enhance disease research and drug development. In addition, the wider inter-relationships with regulatory, ethical and societal sectors will be presented.

Objectives

This course is designed for undergraduates of both scientific and non-scientific majors with an interest in learning about principles and concepts underlying drug discovery and development of medicines. Chapters from the required textbook will be supplemented with a variety of source materials including articles from scientific journals and public websites. Selected cases studies will be critically reviewed, and emerging “hot” topics discussed.

Upon successful completion of this course, the student should be able to:

- Describe the importance of a team effort in the drug discovery/drug development process as seen through the eyes of the pharmaceutical industry.
- Describe the many challenges faced by a start-up pharmaceutical company.
- Explain the importance of intellectual property (IP); critical IP issues and timing.

- Summarize the preclinical drug development process from therapeutic target to marketable drug.
- Become fluent with the basic terminology used in characterizing a new drug (e.g. potency, EC₅₀, IC₅₀, MTD, efficacy, selectivity, ADME, etc....).
- Explain the importance of a properly designing a scientific experiment (Scientific Method).
- Describe critical components of drug discovery as it relates to genotoxicity, carcinogenicity and reproductive/developmental toxicology issues during the course of a drug discovery campaign and how to test for them.
- Summarize the difference between a small molecule drug and a biopharmaceutical and describe the advantages and disadvantages of each therapy.
- Explain the importance of good laboratory practices (GLP), good manufacturing practices (GMP) and good clinical practices (GCP).
- Discuss the various facets and the role of clinical trials in drug development.
- Deduce why so many experimental compounds fail to ever reach the market.

Assignments and Grading:

4 Short Reflections @ 5 pts each	20 pts (10 %)
4 quizzes @ 10 pts each	40 pts (20%)
Discussion Board Participation:	20 pts (10%)
1 midterm exam	50 pts (25 %)
1 final exam:	70 pts (35 %)
Total:	200 pts.

Short Reflections and Attendance (20 pts):

Attendance at all classes is expected. Participation will be evaluated by accepting “short reflections” throughout the semester (5 pts per submission/ total of 4 maximum) and will include evaluating the class material and the method of delivery for any given week. That is, I want you to tell me what is working and what is not working during the semester so I can continue to improve the class in real time. It is expected that the students read the assigned papers prior to the lecture and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture.

Quizzes (40 pts):

There will be 4 quizzes over the course of the semester that will primarily be based on questions pulled from the textbook and lectures.

Discussion Board (20 pts):

Each student will also participate in Discussion Board posts during the semester or other deliverable assignments on Brightspace. Further information regarding the Discussion Board assignments will be provided during the first week of class.

Participation Assignment	Due Date	Points
Brightspace Assignment 1	February 6, 2025 11:59 PM	10
Brightspace Assignment 2	April 29, 2025 11:59 PM	10

Exams:

The midterm (50 points) will include multiple choice questions T/F questions fill-in the blank questions, and short answers.

Final Exam (70 points): The final exam will include multiple choice and T/F questions as well as a series of questions involving short answers. The final exam will be cumulative but will emphasize material covered after the midterm.

Additional details will be presented during week one of the class and included in the Week 1 PPT slides.

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

Important Note on Exams: The midterm exam and final exam dates and times cannot be changed due to travel, nor can the final exam be administered remotely. Please plan accordingly.

Respondus Lockdown Browser for Exams

The midterm and final exam will be administered through Respondus Lockdown Browser. You will not be able to open the exam without downloading the browser. Students ***MUST*** download the Respondus Lockdown Browser on the computer they will be using to take the test. Respondus does not automatically update, so students are encouraged to check their version on the download page below to ensure they have the most up-to-date version. Instructions will be provided on how to download.

Please download the browser ahead of time, it will save time during your exam.

Course Readings

Required Readings

Drug Discovery and Development: Technology in Transition, 2nd Edition

Raymond G. Hill & Humphrey P. Rang; ISBN-13: 978-0702042997

Although not mandatory, it is strongly suggested that the students purchase the textbook for this course as it will greatly improve the students grasp on the Drug Discovery/Development process. The students will be able to use identified chapters in the text to support their learning process throughout the semester.

Other course materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on <http://Brightspace.usc.edu/>. The students will also be encouraged to use the online discussions among students via Brightspace.

Recommended

- Adman Bernstein and Patricia Sullivan. “Frances Oldham Kelsey, FDA scientist who kept

thalidomide off U.S. market, dies at 101.” *Washington Post*. August 7, 2015
https://www.washingtonpost.com/national/health-science/frances-oldham-kelsey-heroin-of-thalidomide-tragedy-dies-at-101/2015/08/07/ae57335e-c5da-11df-94e1-c5afa35a9e59_story.html

- Christine M. Clovis, PhD and Christopher P. Austin, MD. The NIH-Industry New Therapeutic Uses Pilot Program: Demonstrating the Power of Crowdsourcing. *Drug Repurposing, Rescue and Repositioning*. VOL. 1 NO. 1 (March, 2015)
- Cynthia Fox, Reading Leaves a Dramatic Imprint on the Brain:
<http://www.biosciencetechnology.com/articles/2014/12/reading-leaves-dramatic-imprint-brain?location=top>
- [Hepatitis C cure eludes patients as states struggle with costs](https://www.nbcnews.com/health/health-news/hepatitis-c-cure-eludes-patients-states-struggle-costs-n870846)
<https://www.nbcnews.com/health/health-news/hepatitis-c-cure-eludes-patients-states-struggle-costs-n870846>
- Dr. Timothy Scott discusses some of the history of the FDA and how it shaped the industry today. <https://youtu.be/TXAVCaOSi-s>
- Free magazine “Translational Science” <https://www.youtube.com/watch?v=9Cw9v-LnrRU&feature=youtu.be>
 - [Newsletters such as: Drug Discovery Online Newsletter <info@DrugDiscoveryOnline.com>](mailto:info@DrugDiscoveryOnline.com)
 - [Pharmaceutical Processing: https://www.rdmag.com/topics/pharmaceutical-processing](https://www.rdmag.com/topics/pharmaceutical-processing)

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Course Evaluations

Course evaluation occurs at the end of the semester university-wide. It is an important review of students' experience in the class.

Use of Artificial Intelligence

There is an expectation about AI (e.g., ChatGPT and image generation tools) use for this class. Learning to use AI is an emerging skill, and discussions about appropriate use are welcome. It is recommended that you take the opportunity to meet with your professor to get guidance with the use of these tools during office hours or after class. Keep in mind the following:

- AI tools are allowed to help you brainstorm topics or revise work you have already written.
- If you supply minimum-effort prompts, you will get low-quality results. You will need to refine your prompts to get good outcomes. This will take work.
- Proceed with caution when using AI tools and do not assume the information provided is accurate or trustworthy. If it gives you a number or fact, assume it is incorrect unless you either know the correct answer or can verify its accuracy with another source. You will be responsible for any errors or omissions provided by the tool. It works best for topics you understand.
- AI is a tool, but one that you need to acknowledge using. Please include a paragraph at the end of any assignment that uses AI explaining how (and why) you used AI and indicate / specify the prompts you used to obtain the results what prompts you used to get the results. Failure to do so is a violation of academic integrity policies.
- Be thoughtful about when AI is useful. Consider its appropriateness for each assignment or circumstance. The use of AI tools requires attribution. You are expected to clearly attribute any material generated by the tool used.

Course Outline

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session the instructor will engage the students with questions and draw comments or interpretations primarily based on the assigned reading. Students are expected to ask questions and participate in an interactive fashion.

Week & Date	Topic	Subtopics to be Included	Assigned and Supplemental Reading
Introduction and Background			
Week 1 Tues. Jan. 14 Thur. Jan. 16	Daryl Davies Introduction: expectations and goals of this class. General overview of drug development process from therapeutic target to marketable drug.	Pharmacological principles and definitions: Efficacy (EC ₅₀), potency, MTD, ADME, etc. Drug discovery and development: facts and figures	Additional readings to enrich subject matter will be posted on Brightspace. Hill/Rang, Chapter 22.
Week 2 Tues. Jan. 21 Thur. Jan. 23	DD Development of Pharmaceutical Industry- History of the Discovery and Development of Modern Medicines Quiz 1: Jan. 23	History of drug development (where and how it all got started). Case studies illustrating why we have the FDA. What is Translational Science? https://www.youtube.com/watch?v=rAbIbUmyQgk	Hill/Rang, Chapter , Chapter 2 Hill/Rang, Chapter 3
Week 3 Tues. Jan. 28 Thur. Jan. 30	Nature of Disease Daryl Davies Reflection Paper 1 Jan. 30	Etiology, pathology, research highlights, current drug treatments and future drug development. Therapeutic Interventions; Therapeutic modalities	Hill/Rang, Chapter 4
Drug Discovery			
Week 4 Tues. Feb. 4 Thur. Feb. 6	How and why drugs work (or don't) DD Brightspace Assignment 1 Due Feb. 6	General Principles; Case Histories, <u>Novel use of Ketamine:</u> https://youtu.be/GnL4p-35Grg	Hill/Rang, Chapter 4
Week 5 Tues. Feb. 11 Thur. Feb. 13	Dr. Ashutosh Kulkarni Dr. Robert Pacifici, CHDI Quiz 2 Feb. 13	Understand the role of drug metabolism and pharmacokinetics (DMPK) and early stage toxicology studies as major hurdles in the drug discovery process Drug Discovery, where does it all start? Identifying the Project	Hill/Rang, Chapters 5-6
Week 6 Tues. Feb 18	DD	Defining the Market. Where and how does it start. Identifying the Target Role of CROs in new drug development	Hill/Rang, Chapter 12

Thur. Feb 20	Dr. Robert Pacifici, CHDI		
Week 7 Tues. Feb. 25 Thurs. Feb. 27	DD Project Management of Drug Reflection Paper 2 Feb. 27 Dr. Ashutosh Kulkarni	The role of Project Management in Drug Discovery Role of pharmacology (specifically confirmation in vitro assays, target selectivity testing and in vivo pharmacological profiling) in the drug discovery process	Hill/Rang, Chapters 10-11;13-14
Week 8 Tues. Mar. 4 Thurs. Mar. 6	Hovik Gukasyan Midterm Exam: Thursday March 6, 2025	Confidence In Chemical Matter: Drug Discovery Implications	Hill/Rang, Chapter 16
Week 9 Tues. Mar. 11 Thurs. Mar. 13	Hovik Gukasyan	Comprehend different drug delivery systems Scale-up /formulation challenges Future research directions. Channeling gene-therapy and Crispr cas9	
Spring Recess Sunday, March 16, 2025 to Sunday March 23, 2025			
Drug Development			
Week 10 Tues. Mar. 25 Thurs. Mar. 27	Pharmaceutical Development Hovik Gukasyan Tony Succar PhD Reflection Paper 3 Due Mar. 27	“Drugable” Property Space: Desired properties and qualities of an ideal candidate? Safety, Efficacy, Delivery “Bridging the Gap: Regulations Governing Translational Research and Clinical Trials”	Hill/Rang, Chapter 16
Week 11 Tues. Apr. 1 Thurs. Apr. 3	Larisa Yedigarova, PhD	"Clinical development of novel therapeutics" For Assignment #2 Phases of Clinical Trials explained https://www.youtube.com/watch?v=RuzoAjNyJr0	Hill/Rang, Chapter 17
Week 12 Tues. Apr. 8 Thurs.	Michael R. Hamrell, PhD Quiz 3 Apr 8	Regulation of Advertising and Promotion for Prescription Drugs	

Apr. 10			
Week 13 Tues. Apr. 15 Thurs. Apr. 17	Hovik Gukasyan Reflection Paper 4 Due Apr. 15 Cho-Nan Tsai CEO and President, Hyperionsoft	Development Strategies and Considerations for Combination Products—Drug+Drug combinations, Drug:Device combinations; drug eluting stents. AI in the Pharmaceutical Industry. An Introduction into how AI is being used to revolutionize drug discovery, development and implementation.	Hill/Rang, Chapter-20
Week 14 Tues. Apr. 22 Thurs. Apr. 24	The Components of Drug Discovery Mary Ellen Cosenza, PhD Quiz 4 Apr. 24	Biopharmaceuticals. Assessing Drug Safety.	Hill/Rang, Chapters 10-12;13-14
Week 15 Tues. Apr. 29 Thurs. May 1	Daryl Davies Repurposing Patents: Importance of IP in Academia Brightspace Assignment 2 due April 29	The use of a drug repurposing strategy to accelerate new opportunities for currently approved drugs in the pharmaceutical industry	Examples from DD laboratory Hill/Rang, Chapter 19
Final Exam: Tuesday, May 13, 2025 from 8 am to 10 am – NOTE: FINAL EXAM is at 8 AM. Final exam must be taken in class on the date and time noted in the schedule of classes.			

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.

Academic dishonesty has a far-reaching impact and is considered a serious offense against the university. Violations will result in a grade penalty, such as a failing grade on the assignment or in the course, and disciplinary action from the university itself, such as suspension or even expulsion.

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.

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Statement on University Academic and Support Systems

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.

Student Financial Aid and Satisfactory Academic Progress:

To be eligible for certain kinds of financial aid, students are required to maintain Satisfactory Academic Progress (SAP) toward their degree objectives. Visit the [Financial Aid Office webpage](#) for [undergraduate](#)- and [graduate-level](#) SAP eligibility requirements and the appeals process.

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 consists 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) 740-2500

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.

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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, compromises 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.

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