

USC School of Pharmacy

Pharmacy Undergraduate Programs

Spring 2022: RXRS 407: The Discovery, Development and Marketing of Modern Medicines

Instructors:

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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, WPH 103

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:

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

Short Reflections and Attendance (10 pts): On a scale of 10, 0-indicating no participation, 10-indicating best participation. You can therefore increase the probability of getting a higher mark by being proactive in terms of asking (relevant) questions in class and/or contributing to discussions.

Attendance at all classes is expected. Participation will be evaluated by accepting “short reflections” throughout the semester (2 pts per submission) 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.

There will be 5 quizzes over the course of the semester that will primarily be based on questions pulled from the textbook and lectures.

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

Discussion Board Assignments	Due Date	Points
Blackboard Assignment 1	TBD	10
Blackboard Assignment 2	TBD	10

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.

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

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://blackboard.usc.edu/>. The students will also be encouraged to use the online discussions among students via Blackboard.

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-heroine-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>
- 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>

Online learning Etiquette

- If it is not possible to have you webcam on during the entire class, do you best to have it on when speaking
- Turn off your microphone when not speaking
- If you need to step away from your computer during class (e.g. get a drink of water, use the bathroom, attend to a family member/pet) please do so quietly and without disturbing your classmates. Return to the class when you can.
- Be aware the contents of conversations typed into the chat box, even private conversations, are visible by the instructors

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 Jan 11, 13	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 Blackboard. Hill/Rang, Chapter 22.
Week 2 Jan.18, 20	Development of Pharmaceutical Industry- History of the Discovery and Development of Modern Medicines Quiz 1 Jan 20th	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=rAblbUmyQgk	Hill/Rang , Chapter 1 Chapter 2 Hill/Rang , Chapter 3
Week 3 Jan.25, 27	Nature of Disease Hovik Gukasyan	Etiology, pathology, research highlights, current drug treatments and future drug development. Therapeutic Interventions; Therapeutic modalities Novel use of Ketamine: https://youtu.be/GnL4p-35Grg	Hill/Rang , Chapter 4
Drug Discovery			
Week 4 Feb. 1, 3	An Overview of Modern-Day Drug Discovery Hovik Gukasyan	General Principles; Case Histories,	Hill/Rang , Chapter 4
Week 5 Feb 8, 10	DD Defining a Market DD Project Management of Drug Quiz 2 Feb 10th	Defining the Market. Where and how does it start. The role of Project Management in Drug Discovery	Hill/Rang , Chapters 5-6
Week 6. Feb.15, 17	Dr. Robert Pacifici, CHDI	Drug Discovery, where does it all start? Identifying the Project; Identifying the Target Role of CROs in new drug development	Hill/Rang , Chapter 12
Week 7 Feb. 22, 24	Dr. Ashutosh Kulkarni	Understand the role of drug metabolism and pharmacokinetics (DMPK) and early stage toxicology studies as major hurdles in the drug discovery process; 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
Midterm March 1			
Week 8 March 3	Hovik Gukasyan	Confidence In Chemical Matter: Drug Discovery Implications	Hill/Rang Chapter 16
Drug Development			
Week 9 March 8, 10	Pharmaceutical Development Hovik Gukasyan	Drugabl Property Space: Desired properties and qualities of an ideal candidate? Safety, Efficacy, Delivery Development products for clinical testing and comparability	Hill/Rang , Chapter 16
MARCH 13, 2022 – MARCH 20, 2022: SPRING RECESS, no class 3/15 or 3/17			
Week 10 March	The Components of Drug Discovery	Biopharmaceuticals; Assessing Drug Safety;	Hill/Rang , Chapters 10-12;13-14

22, 24	Mary Ellen Cosenza Quiz 3 March 22th		
Week 11 March 29, 31	Larisa Yedigarova	"Clinical development of novel therapeutics"	Hill/Rang , Chapter 17
Week 12 April 5, 7	Hovik Gukasyan Quiz 4 April 7th	Development Strategies and Considerations for Combination Products-- Drug+Drug combinations, Drug:Device combinations; drug eluting stents. Future research directions. Channeling gene-therapy and Crispr cas9	Hill/Rang, Chapter-20
Week 13 April 12, 14	Michael R. Hamrell, PhD	Regulation of Advertising and Promotion for Prescription Drugs	
Week 14 April 19, 21	Repurposing DD: Patents: Importance of IP in Academia Quiz 5 April 21st	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
Week 15 April 26, 28	Hovik Gukasyan	Comprehend different drug delivery systems Scale-up /formulation challenges	
<i>Final Exam: Tuesday May 10, 2022 from 8-10 a.m.</i>			

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.