USC School of Pharmacy

Spring 2021: RXRS 407: The Discovery, Development and Marketing of Modern Medicines

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

Day/Time/Location: TTH 9:30-10:50 am, THH 202 & ONLINE

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, EC_{50}, IC_{50}, 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 biopharmaceuticals 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:

Class participation:	10 pts	(5 %)
5 quizzes @ 10 pts each	50 pts	(25%)
2 midterm exams @ 45 pts each:	90 pts	(45 %)
1 final exam (Essay Assignment):	50 pts	(25 %)
Total:	200 pts.	

Class Participation 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 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 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 text book and lectures. The midterms (45 points each) will include multiple choice questions T/F questions fill-in the blank questions, and short answers.

Instead of a final exam, a 5-page double-spaced essay (deliverable) will be due by email to ddavies@usc.edu by **5pm PST on the day of the final (Tuesday, May 11, 2020).** The deliverable this year will focus on the Essay Assignment this year will focus on the novel COVID vaccines that have recently been flooding the news blogs.

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>

- 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. 19, 21	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. 26, 28	Development of Pharmaceutical Industry- Nature of Disease	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
Week 3 Feb 2, 4	**Quiz 1** Introduction to Drug Discovery	Etiology, pathology, research highlights, current drug treatments and future drug development. Therapeutic Interventions; Therapeutic modalities	Hill/Rang , Chapter 3 Hill/Rang , Chapter 4
		Drug Discovery	
Week 4 Feb. 9, 11	Choosing the Project Choosing the Target	General Principles; Case Histories,	Hill/Rang , Chapters 5-6
		Midterm 1 Feb. 18 evening	
Week 5 Feb 16, 18	Defining a Market DD Dr. Robert Pacifici, CHDI	Where does it all start? Identifying the Project; Identifying the Target	Hill/Rang , Chapters 5-6
Week 6. Feb. 23, 25	DD Project Management of Drug Dr. Robert Pacifici, CHDI	Documentation Requirements During Pre-Clinical (Non-Clinical) Drug Development Role of CROs in new drug development	Hill/Rang , Chapter 12
Week 7 March 2, 4	Dr. Ashutosh Kulkarni, Allergan **Quiz 2 March 4 in evening**	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
Week 8 March 9, 11	The Components of Drug Discovery Mary Ellen Cosenza	Biopharmaceuticals; Assessing Drug Safety;	Hill/Rang , Chapters 10-12;13-14
Weeks 9 March 16, 18	Amanda Burkhardt **Thursday: Quiz 3 will be presentations by students**	Lecture on Covid.	
		Drug Development	
March 23rd NO CLASS Wellness Day			
Week 10 March 25	Pharmaceutical Development Hovik Gukasyan PhD	Development products for clinical testing and comparability	Hill/Rang , Chapter 16
Week 11 March 30	Anna Papinska, PhD Allergan	"Clinical development of novel therapeutics"	Hill/Rang , Chapter 17

April 1	**Quiz 4 April 1**		
Week 12 April 6 April 8	DD Dr. Church	Future research opportunities Regulatory Affairs	 Hill/Rang, Chapter-20
Week 13 April 13, 15	Michael R. Hamrell, PhD	Regulation of Advertising and Promotion for Prescription Drugs	
Midterm 2 April 15 Evening			
Week 14 April 22 NO Class Wellness day.			
Week 14 April 20	Repurposing DD: Patents: Importance of IP in Academia	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 27, 29	Michael R. Hamrell, PhD Hovik on April 29th GRP **Quiz 5 April 29 evening**	Development Strategies and Considerations for Combination Products. Comprehend different drug delivery systems Scale-up /formulation challenges	
Final Exam: Exam Paper is due by 5:00 pm PST on May 11th			

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, http://policy.usc.edu/scientific-misconduct.

Support Systems:

Student Counseling Services (SCS) – (213) 740-7711 – 24/7 on call
Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.
engemannshc.usc.edu/counseling

National Suicide Prevention Lifeline – 1 (800) 273-8255
Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. www.suicidepreventionlifeline.org

Relationship and Sexual Violence Prevention Services (RSVP) – (213) 740-4900 – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender-based harm. engemannshc.usc.edu/rsvp

Sexual Assault Resource Center
For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: sarc.usc.edu
Office of Equity and Diversity (OED)/Title IX Compliance – (213) 740-5086
Works with faculty, staff, visitors, applicants, and students around issues of protected class. equity.usc.edu

Bias Assessment Response and Support
Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. studentaffairs.usc.edu/bias-assessment-response-support
The Office of Disability Services and Programs
Provides certification for students with disabilities and helps arrange relevant accommodations. dsp.usc.edu

Student Support and Advocacy – (213) 821-4710
Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. studentaffairs.usc.edu/ssa

Diversity at USC
Information on events, programs and training, the Diversity Task Force (including representatives for each school), chronology, participation, and various resources for students. diversity.usc.edu

USC Emergency Information
Provides safety and other updates, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible. emergency.usc.edu
USC Department of Public Safety – UPC: (213) 740-4321 – HSC: (323) 442-1000 – 24-hour