

USC School of Pharmacy

RXRS 302: Pharmacology and Drug Development

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Course Weight: 4 units

Days/Time/Location: Tuesday; 2:00-4:50pm at VPD 106

Office Hours: TBD

Catalogue description: Introductory course in pharmacology/drug development- Drug/Receptor interactions, pharmacodynamics, pharmacokinetics, toxicology, therapeutic interventions, biotransformation, pharmacogenomics, FDA, regulatory requirements and challenges, intellectual property, global challenges of drug development.

Recommended Preparation: Students should have at completed at least one year of undergraduate biology and/or chemistry.

Introduction

Pharmacology is the study of substances that interact with living systems through chemical processes, especially by binding to regulatory molecules and activating or inhibiting normal body processes. These substances may be chemicals administered to achieve a beneficial therapeutic effect on some process within the patient or for their toxic effects on regulatory processes in parasites infecting the patient. "Introduction to Pharmacology and Drug Development," will provide students with an introduction to the nature of drugs and drug

development including: principles of drug receptors; how drugs interact with the body (PD); and potentially damage the body (toxicology); how the body alters the effects of the drug (PK); drug biotransformation; important drug interactions and their mechanisms of action and pharmacogenomics. The student will also learn about the regulatory challenges associated with the discovery and development of a new drug. The student will be introduced to the use of different types of pharmaceutical interventions, from the use of patented to generic to over-the-counter drugs, the current approaches to dietary supplement and alternative medicines. Selected cases studies and emerging “hot” topics will be discussed. This course should have broad appeal to many science and non-science undergraduates including students interested in drug discovery research, chemistry, biology, pharmacology, biochemistry, toxicology, formulations, pharmaceutical industry, FDA, business analysts, entrepreneurs and venture capitalist interested in understanding the pharmaceuticals industry.

Chapters from the core textbook will be supplemented with a variety of source materials including online resources and articles from scientific journals.

Upon successful completion of this course, the student should be able to demonstrate a working knowledge regarding:

- The nature of drugs and drug development
- The role and importance of different pharmacokinetic parameters (absorption, distribution, metabolism and elimination; ADME) that affect drug dosing in a patient.
- The basic terminology used in characterizing a drug (e.g. potency, EC50, IC50, MTD, efficacy, selectivity, etc....).
- Different drug-receptor interactions and the basic principles of pharmacodynamics (PD)
- The basic principles in the use of drugs to prevent and treat diseases (Pharmacotherapy).
- The importance of pharmacogenomics.
- Why particular drugs are prescribed and how their effects are monitored (clinical pharmacology)
- The importance of good laboratory practices (GLP), good manufacturing practices (GMP) and good clinical practices (GCP).
- The processes involved in the discovery and development of new therapeutic agents.

Evaluation and Grading:

Evaluation will be based on two midterm examinations, a final examination and course quizzes.

Class/Group participation:	20 pts (10%)
1 group presentation	20 pts (10%)
4 quizzes @ 10 pts each:	40 pts (20%)
2 midterm exams @ 35 pts each:	70 pts (35%)
1 final exam (partially cumulative):	<u>50 pts</u> (25%)
Total:	200 pts (100%)

Attendance at all classes is expected. Participation will include asking and answering questions and being actively involved in the discussion as well as group assignments. It is expected that the students read the assigned papers prior to the lecture, prepare for group presentations and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture.

There will be 1 group presentation, approximately 10 minutes and a 5 minutes Q&A at the beginning of selected class sessions. Students will be presenting in groups to discuss a content of peer-review paper or current news events relating to pharmacology, pharmaceutical sciences, or regulatory aspects. This will be 20 points contributed to the overall grade.

There will be 4 quizzes over the course of the semester that will be primarily based on questions pulled from the text book and lecture notes. The midterms (35 points each) will include multiple choice questions T/F questions fill-in the blank questions and possibly short answers.

The final exam (50 points) 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 2nd midterm.

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.

Course Readings

Required Readings

The text is mandatory for this course as it will greatly improve your grasp on the course content. There is a supplemental online student companion website for this course that can be accessed once the textbook is purchased. The chapters identified for your assigned reading in the in the text will support your learning process throughout the semester.

Pharmacology by Karen Whalen, Pharm.D., BCPS

Edition: 7th ISBN 978-1-4963-8413-3

Format: Paperback w/ Access Code

Pub. Date: 2019

Publisher(s): Wolters Kluwer

Other topical materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on <http://blackboard.usc.edu/>. Students will also be encouraged to use the online discussions sessions (via Blackboard) as an additional learning tool.

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. Because this is an area of rapid change in policies, the readings may vary from one term to the next. Additional readings for each section that may be of added use are listed in the table below. Course schedule is as follows:

Date	Subject	Lecturer
1/14/2020	Introductions& Expectations Principles of Pharmacodynamics <ul style="list-style-type: none"> • Basic Principles of Pharmacology (Definitions) • Drug, Dosage forms and Routes of Drug Administration • General PD terminologies, Receptor types, Drug- Receptor Interactions 	Isaac Asante, PhD
1/21/2020	Pharmacokinetics <ol style="list-style-type: none"> 1. Absorption, Distribution, Metabolism and Elimination of Drugs 2. PK Calculations Factors impacting on Drug Levels <ol style="list-style-type: none"> 1. Genetics 2. Age effect 3. Sex 4. Drug-drug interaction 5. Diet and environment Assigned and Supplemental Reading Basics on Pharmacokinetics/pharmacodynamics: https://www.youtube.com/watch?v=NKV5iaUVBUI Very brief overview of PD and PK: Youtube: https://www.youtube.com/watch?v=tobx537kFaI	Isaac Asante, PhD
1/28/2020	Quiz 1: Jan 28, 2020 Principles of Pharmacodynamics (part 2) <ol style="list-style-type: none"> 1. PD Interactions and Calculations 2. Drugs for Special Populations 3. Adverse Drug Effects 4. Intracellular receptors 	Isaac Asante, PhD
	Introduction to Pharmacogenomics	Negin Sazegar, PharmD
2/4/2020	Drug Discovery and Development <ol style="list-style-type: none"> 1. Drug discovery process 2. Screening 	Isaac Asante, PhD

	3. ADME evaluation 4. Drug synthesis and formulation 5. Toxicology Evaluation	
2/11/2020	<u>Exam 1</u>	
2/18/2020	CNS Stimulants Pharmacology 1. Overview of Psychomotor Stimulants 2. Methylxanthines 3. Nicotine 4. Varenicline 5. Cocaine 6. Amphetamine 7. Methylphenidate 8. Hallucinogens <i>Assigned and Supplemental Reading</i> Chapter 15: CNS Stimulants	Lizeth Rivera, PharmD
	Antidepressants Pharmacology 1. Mechanism of Antidepressant Drugs 2. Selective Serotonin Reuptake Inhibitors 3. Serotonin-Norepinephrine Reuptake Inhibitors 4. Atypical Antidepressants 5. Tricyclic Antidepressants 6. Monoamine Oxidase Inhibitors 7. Serotonin-Dopamine Antagonists Assigned and Supplemental Reading Chapter 10	Tam Phan, PharmD
2/25/2020	Quiz 2: Feb 25, 2020 Clinical Management of Generalized Anxiety Disorder	Jessica Che, PharmD
	Clinical Management of Major Depressive Disorders	Tam Phan, PharmD
3/3/2020	Anemia, Iron, EPO pharmacology 1. Iron 2. Folic Acid 3. Cyanocobalamin and hydroxycobalamin 4. Erythropoietin and darbepoetin 5. Agents used to treat Neutropenia 6. Agents Used to treat Sickle Cell Disease	Tam Phan, PharmD
	Clinical Management of Anemia (oral agents)	Tam Phan, PharmD
3/10/2020	Quiz 3: Mar 10, 2020 Estrogen, Progesterone, and Hormonal Contraceptives 1. Estrogens	Yuen Ng, PharmD

	<ol style="list-style-type: none"> 2. Selective Estrogen Receptor Modulators 3. Progestogens 4. Contraceptives 5. Androgens <p>Assigned and Supplemental Reading Chapter 25: Estrogens and Androgens</p>	
	Pharmacists initiation of hormonal contraceptives and emergency contraceptives	Tam Phan, PharmD
3/17/2020	<u>SPRING RECESS</u>	
3/24/2020	<u>Exam 2</u>	
3/31/2020	Pharmacology of GI agents <ol style="list-style-type: none"> 1. Histamine H2 Receptor Blockers 2. Inhibitors of the H/K ATPase Proton Pump 3. Antacids 4. Mucosal Protective Agents 5. Antiemetic Drugs 6. Laxatives <p>Assigned and Supplemental Reading Chapter 37 and Chapter 40: Gastrointestinal and Antiemetic Drugs</p>	Tam Phan, PharmD
	Clinical Management of GERD + PUD	Stefanie Koch LeGrand, PharmD
4/7/2020	Principals of Antimicrobials <ol style="list-style-type: none"> 1. Cell Wall Inhibitors 2. Protein Synthesis Inhibitors 3. Quinolones 4. Folic Acid Antagonists 5. Urinary Tract Antiseptics <p>Assigned and Supplemental Reading Chapter 28: Principles of Antimicrobial Therapy Chapter 29: Cell Wall Inhibitors Chapter 30: Protein Synthesis Inhibitors Chapter 31: Quinolones, folic acid Antagonists, and Urinary Tract Antiseptics</p>	Nina Wang, PharmD
	Applications of Antimicrobials Introduction to Antimicrobial Stewardship	Tam Phan, PharmD

4/14/2020	Quiz 4: Apr 14, 2020 Introduction to Oncology Oncology Pharmacology <ol style="list-style-type: none"> 1. Overview 2. Principles of Cancer Chemotherapy 3. Antimetabolites 4. Antibiotics 5. Alkylating Agents 6. Microtubule Inhibitors 7. Steroid Hormones and their Antagonists 8. Platinum Coordination Complexes 9. Topoisomerase Inhibitors 10. Antibodies and Immunotherapy Assigned and Supplemental Reading Chapter 35: Anticancer Drugs	Isaac Asante, PhD
4/21/2020	Clinical Management of Patients with Cancer <ol style="list-style-type: none"> 1. Case studies 2. Interactive discussion Adjunct and Supportive Therapies for Chemotherapeutics	Alanah Bell, PharmD
4/28/2020	Current Events in Pharmacy and Pharmaceutical Sciences <ol style="list-style-type: none"> 1. PharmD scope of practice and current legislation 2. PharmD role in Transition of Care 3. Ranitidine Recall and Regulatory Aspects Final Exam Review	Tam Phan, PharmD
5/7/2020	<p style="text-align: center;"><u>FINAL EXAM</u> <u>Thursday, May 7, 2020, from 2-4pm</u></p>	

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, policy.usc.edu/scientific-misconduct.

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 and 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 of Equity and Diversity (OED)- (213) 740-5086 / *Title IX* – (213) 821-8298
equity.usc.edu, titleix.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. The university prohibits discrimination or harassment based on the following *protected characteristics*: race, color, national origin, ancestry, religion, sex, gender, gender identity, gender expression, sexual orientation, age, physical disability, medical condition, mental disability, marital status, pregnancy, veteran status, genetic information, and any other characteristic which may be specified in applicable laws and governmental regulations. The university also prohibits sexual assault, non-consensual sexual contact, sexual misconduct, intimate partner violence, stalking, malicious dissuasion, retaliation, and violation of interim measures.

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 of Equity and Diversity | Title IX for appropriate investigation, supportive measures, and response.

The Office of Disability Services and Programs - (213) 740-0776

dsp.usc.edu

Support and accommodations for students with disabilities. Services include assistance in providing readers/notetakers/interpreters, special accommodations for test taking needs, assistance with architectural barriers, assistive technology, and support for individual needs.

USC Support and Advocacy - (213) 821-4710

uscsa.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity at USC - (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.