#### PHAR 5023 Drug Discovery and Development Fall 2019

#### CLASS DAYS and TIME: Tuesday 10:00 AM-12:00 PM

CLASSROOM: LIB 2.015, UTHSA, with appropriate video-conferencing support to the bridge network

#### **COURSE DIRECTORS**

Dr. Stanton McHardy, UTSA Dr. Francis Lam, UTHSA

**OFFICE LOCATION and HOURS:** Dr. McHardy SRL 1.438 UTSA; Dr. Lam: MCD 3.4, Greehey Campus. By appointment

EMAIL: Dr. McHardy (Stanton.mchardy@utsa.edu); Dr. Lam (lamf@uthscsa.edu)

TELEPHONE: Dr. McHardy 210-458-8676; Dr. Lam 210-567-8319

#### COURSE FACULTY:

- Dr. Charles France (france@uthscsa.edu)
- Dr. Ken Hargreaves (Hargreaves@uthscsa.edu)
- Dr. Veronica Hargrove (vhargrove@bexas.org)
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- Dr. Roger Shi (shiy4@uthscsa.edu)
- Mr. Miguel Villarreal (mvillarrreal@gunn-lee.com)
- Dr. Guangming Zhong (zhongg@uthscsa.edu)

## READ THIS DOCUMENT CAREFULLY – YOU ARE RESPONSIBLE FOR ITS CONTENTS.

#### **COURSE DESCRIPTION AND OBJECTIVES**

Drug Discovery and Development is a 2.5 credit hour course that provide students with an understanding of the overall process of drug discovery and development. It covers the basic principles of how new drugs are discovered, how drugs interact with their biological targets, and application of medicinal chemistry in lead optimization. Focused lectures on specific therapeutic areas will include drug development for cancer, diabetes, pain, and psychiatric disorders. Patenting, phase 1, 2 and 3 clinical trials, and marketing processes

will be covered, as will contract opportunities for basic science researchers with drug companies. Case studies of both successful and unsuccessful drug candidates will be presented, where students will learn about the entire drug discovery and development process. Upon successful completion of this course, students will have a comprehensive knowledge of the fundamental principles of drug discovery and development, though to successful implementation of the new drug in the clinic.

# Pre-requisites – IBMS 5000 or at the discretion of the course directors

# Semester credit hours – 2.5

By the end of this course, each student should be able to describe and discuss:

- Examples of how new drugs are discovered
- How drugs interact with their biological target
- Fundamentals of medicinal chemistry
- Importance of preclinical studies in drug development
- The purpose of each phase in a clinical trial, and procedures used in each phase
- Steps involved in patenting a new drug
- Ways in which basic science researchers and drug companies interact
- Examples of successful and unsuccessful drug development, including all stages of the process

## **COURSE ORGANIZATION**

## The main teaching modalities used in this course include:

1) Conventional didactic lectures, 2) Case study discussion, and 3) Student participation

Materials – Handouts and assigned readings by faculty, where appropriate

Computer Access – Assigned readings can be access online

Reading Assignments - As assigned by faculty

## ATTENDANCE

In order to achieve the expected level of competency, students must be fully engaged. Therefore, attendance at every class session is expected. Part of the course grade will be based on attendance and participation in class discussion.

## TEXTBOOKS

Required: As assigned by faculty

Recommended: As assigned by faculty

## **GRADING POLICIES AND EXAMINATION PROCEDURES**

There are three written examinations that, together with discussion participation, will be used to determine each student's overall course grade. The format of the examination will be at the discretion of the course faculty members.

## **Missed examination policy**

Make-up examinations <u>may</u> be offered in case of emergencies at the discretion of the course directors. A phone call (Dr. McHardy 210-458-8676; Dr. Lam 210-567-8319) or email to the course directors <u>is required</u>. Failure to comply with the policies as outlined above will result in a score of 0 (zero) for the examination in question. If the student is allowed to take a make-up examination, it must be taken within one week of the original examination date. The format of make-up examination is at the discretion of the course directors. The maximum percentage point obtainable on a make-up examination is 70%.

#### **Grading System**

The final course grade will be assigned according to the grading system within the Graduate School of Biomedical Science as follows:

A = 90-100% B = 80-89.9% C = 70-79.9% F = < 69.9%

#### **REQUESTS FOR ACCOMODATIONS FOR DISABILITIES**

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under the American with Disabilities Act (ADA, form 100) to his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at <u>http://uthscsa.edu/eeo/request.asp</u>.

#### ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at

http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/

## TITLE IX AT THE UNIVERSITY OF TEXAS HEALTH SAN ANTONIO (UTHSA)

#### Title IX Defined:

Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

## University of Texas Health San Antonio's Commitment:

UTHSA is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UTHSA does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at <u>http://students.uthscsa.edu/titleix/</u>

Every student is issued a University e-mail address and account at the time of enrollment. As a matter of University Policy, communications between students and faculty that occur using the student's University e-mail address is considered official business. Therefore, students are expected to check their university email inboxes on a regular basis so that any announcements, instructions, or information regarding this course will be received in a timely way. Missed communications due to inadequate monitoring of incoming emails on the University's email server will never be a valid excuse for unsatisfactory academic progress.

#### USE OF RECORDING DEVICES

Recording of lectures and other learning activities in this course by any means (e.g., video, audio, etc.) is only permitted if approved by the instructor or required for compliance with Americans with Disabilities Act (ADA).

#### **ELECTRONIC DEVICES**

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed only for participating in classroom activities (e.g., viewing slides presented in lecture or conference materials). No texting, tweeting, emailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.

WEEK	DATE	ΤΟΡΙϹ	INSTRUCTOR
Week 1	7/23/19	History of Drug Discovery and Development	Risinger
Week 2	7/30/19	Modern Drug Discovery and Development/Overview of the Drug Discovery Process Time, costs and attrition Basic science to support new drugs ideas Discovery process for drug candidates Basic science to clinical trials	McHardy
Week 3	8/6/19	Investigational New Drug (IND) Enabling Studies	McHardy
Week 4	8/13/19	EXAM 1 (in class)	
Week 5	8/20/19	Organic Chemistry's Role in Drug Discovery, Design and Development	McHardy
Week 6	8/27/19	Drug Discovery and Medicinal Chemistry (Part 1) Molecular properties and interactions Bioisosteres and functional groups	McHardy
Week 7	9/3/19	Drug Discovery and Medicinal Chemistry (Part 2) Structure activity relationships (SAR) and quantitative SAR (QSAR) techniques Improving absorption, distribution, metabolism, and excretion (ADME) profiles in lead compounds	McHardy
Week 8	9/10/19	Drug Discovery and Medicinal Chemistry (Part 3) Balance clearance and permeability	McHardy
Week 9	9/17/29	Drug Discovery and Medicinal Chemistry (Part 4) Toxicology screening	Hargrove
	9/17/19	Drug Discovery and Medicinal Chemistry (Part 4) Evaluating abuse liability	France
Week 10	9/24/19	Drug Discovery and Medicinal Chemistry (Part 5) Patch-clamp technology and ion channel investigation for drug-induced cardio-toxicity	Judge
	9/24/19	Design, Conduct, and Analysis of Clinical Trials for Evaluation of Drug- Induced QT prolongation	Lam
Week 11	10/1/19	EXAM 2 (in class)	
Week 12	10/8/19	Case Study	McHardy
Week 13	10/15/19	Drug Development for Treatment of Pain	Hargreaves
	10/15/19	Development and Regulatory Approval of Medical Devices	Niederauer

Week 14	10/22/19	Drug Development for Treatment of Cancer	Risinger
	10/22/19	Drug Development for Treatment of Psychiatric Disorders	Koek
Week 15	10/29/19	Vaccine Development	Zhong
Week 16	11/5/19	Drug Development for Pediatric Cancer	Houghton and Kurmasheva
Week 17	11/12/19	Clinical Trial and IND Application	Lodge
	11/12/19	The Patent Process for Drug Discovery and Development	Villarreal
Week 18	11/19/19	Drug Development for Treatment of Diabetes	Shi
	11/19/19	Starting a Biotechnology Company as an Entrepreneur	Shi
	11/26/19	Thanksgiving week (no class planned)	
Week 19	12/3/19	Case Study	McHardy
Week 20	12/10/19	EXAM 3 (take home)	