Principles of Drug Development
PHAR 7290.005
Spring Semester 2020

Course Description
This course provides basic understanding of the fundamental principles and process of drug discovery, design, and development.

Additional Course Description
The topics covered include choosing a disease, identifying a molecular drug target, establishing *in vivo* and *in vitro* pharmacological testing, hit identification, rational drug design, structure-activity relationships, optimization of lead compounds to improve pharmacodynamic and pharmacokinetic properties as well as performing transitional, preclinical, and clinical drug testing.

Course Credit
2 credit hours

Pre-Requisites
PHAR 7301 and PHAR7203

Co-Requisites
None

Class Meeting Days, Time & Location
Wednesday, 2:00 PM – 4:00 pm; W.T. Brookshire Hall room #236

Course Coordinator
Ayman K Hamouda, BPharm, PhD
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Office hours: by appointment or walk-in, as available
Preferred method of contact: Email

Fisch College of Pharmacy (FCOP) and UT Tyler Policies
This is part 1 of the syllabus. Part 2 contains UT Tyler and the FCOP course policies and procedures. These are available as a PDF at https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-policies.pdf. For experiential courses (i.e., IPPE and/or APPE), the Experiential Manual contains additional policies and instructions that supplement the Syllabus Part 1 and 2. Please note, the experiential manual may contain policies with different deadlines and/or instructions. The manual should be followed in these cases.

Required Materials
Required materials will be posted on the classes' Canvas site. The site address is: uttyler.edu/canvas. Most course required materials are available through the Robert R. Muntz Library. These materials are available either online* (http://library.uttyler.edu/) or on reserve.

Course Format

The course may include, but is not limited to, the following activities:

1. iRATs
2. Independent study of selected readings
3. Summary team report of papers discussed
4. Team-based learning, team presentation, and class discussions

Course Learning Outcomes (CLOs)

CLOs	Related PLO(s)	EPAs	Assessment Methods	Grading Method	PPCP Skill(s) Assessed	ACPE Std. 11/ 12
1. Discuss basic principles, concepts, and stages of drug design and development.	1	1.1	1-3	Rubric	N/A	N/A
2. Describe the basic principles of pharmacodynamics, including drug receptors interactions.	1	1.1	1-3	Rubric	N/A	N/A
3. Delineate the process of choosing a drug target, establishing in vitro and in vivo pharmacological testing.	1	1.1	1-3	Rubric	N/A	N/A
4. Assess structure-activity relationships and the process of rational drug design, lead identification, and lead optimization.	1	1.1	1-3	Rubric	N/A	N/A
5. Rationalize the optimization process of pharmacokinetic properties.	1	1.1	1-3	Rubric	N/A	N/A
6. Outline efficacy and toxicity evaluation via pre-clinical and clinical trials.	1, 2	1.1, 1.2	1-3	Rubric	N/A	N/A

Course Assessment Methods

	Assessment Method	Description
1	Written report	Summarize assigned weekly readings
2	Team presentation	Presentation of weekly assigned readings
3	Class discussion	Participation and critique of presented papers

Grading Policy & Grade Calculation

Grades will be determined based on evaluation of individual and team assessments, peer evaluation, participation in class discussions, and submission of written reports.

During the time the course is in progress, students whose cumulative course percentage falls below 70.0% may receive an academic alert and be subject to periodic course content review in special sessions with the course instructor(s). The student's faculty advisor may receive an academic alert to act upon on the student's behalf.

All examinations, tests, and assignments, including the final examination, may be **cumulative.** Students are responsible for material presented during the prior courses. The grading scale for all graded material is below. The final course grade will be assigned according to the calculated percentage and the percentages will not be rounded upward or downward. For additional information, see examination/assessment policy below.

Standard Grade Calculation*

Individual Component	50%
iRAT	
Class participation	
Peer evaluation	
Team Component	50%
Team presentation	
Written reports	
Total	**100%**

The final course letter grade will be determined according to the following grading scheme:

A	90 - 100 %
B	80 - 89.999̄ %
C	70 - 79.999̄ %
D	65.0 - 69.999̄ %
F	< 65.0 %

PHAR 7290.005 (Principles of Drug Development) Course Schedule

WEEK	DAY	TOPIC	Instructor	CLO	Disease
1	01/15/2020	Overview of stages in drug discovery, design and development process.*	Hamouda	1	Insomnia
2	01/22/2020	Identifying a molecular target* *(Hoyer and Jacobson Orexin.pdf)*	Hamouda	3	Insomnia
3	01/29/2020	Finding lead compounds* *(Brisbare-Roch et al 2007 Targeting Orexin)*	Hamouda	2-3	Insomnia
4	02/05/2020	Lead optimization: *in silico* and *in vitro** *(Beuckmann et al. 2017 Lemborexant)*	Abdelaziz	2-4	Insomnia
5	02/12/2020	Establishing pharmacological testing: *Winrow et al 2011 Suvorexant.pdf* Team #1 presentation and discussion	Hamouda/ Abdelaziz	3,6	Insomnia
6	02/19/2020	Preclinical pharmacodynamic testing *(Beukmann et al. 2019 Lemborexant)* Team #2 presentation and discussion	Hamouda/ Abdelaziz	3,6	Insomnia
7	02/26/2020	Preclinical pharmacokinetic properties *(Ueno et al. 2019 [^{14}C]Lemborexant)* Team #3 presentation and discussion	Hamouda/ Abdelaziz	5	Insomnia
8	03/04/2020	Clinical Trials *(Rosenberg et. al. 2019 Lemborexant)* Team #4 presentation and discussion	Hamouda/ Abdelaziz	6	Insomnia
9	03/11/2020	Spring Break (NO Class)	---	---	---
10	03/18/2020	P2 TOSCE (NO Class)	---	---	---
11	03/25/2020	Team #1 case presentation, written report, and peer evaluation.	Hamouda	1-6	Insomnia
12	04/01/2020	Team #2 case presentation, written report, and peer evaluation.	Hamouda	1-6	TBD
13	04/08/2020	Team #3 case presentation, written report, and peer evaluation.	Hamouda	1-6	TBD
14	04/15/2020	Team #4 case presentation, written report, and peer evaluation.	Hamouda	1-6	TBD
15	04/22/2020	Placebo effect* *(Kam-Hansen et al. 2014)*	Hamouda	6	Migraine

*Possible iRAT/tRAT