PHARM. 785. PRINCIPLES OF MODERN DRUG DESIGN

Course Description: This class is taught through a combination of didacticism, assigned reading, classroom discussion, laboratory activities and student projects. The course covers the basic principles of the modern drug discovery and validation process, with emphasis on molecularly-targeted drugs used in cancer therapy.

Credit Hours: 2 semester hours

Course Prerequisites: It is expected that students will have already completed basic courses in biochemistry, physiology and pharmacology; students without such academic prerequisites must obtain the director's approval before enrolling. Prior approval by either the Graduate Director of the program in which the student is enrolled or the student's faculty advisor is also required.

Course Dates: Spring Semester. (January 4 – May 14, 2010) See the schedule below for an overview of course content and format. Specific dates and times of classes will be arranged.

Date	Room	Lecture #	Topic
	CW214	1	Course overview
	CW214	2	Signal transduction & molecular pathology
	CW214	3	Disease markers in diagnosis & therapy
		NONE	VETERAN'S DAY HOLIDAY
	CW214	4	Human genetics & chromosomal disease loci
	CW214	5	Bioinformatics: theory & statistical design
	CW214	9	INDEPENDENT STUDY: Identify drug for class project
		NONE	THANKSGIVING HOLIDAY
		NONE	THANKSGIVING HOLIDAY
	CW214	6	Genomics theory
	G223	7	DNA hybridization array lab assignment (preparation)
	G223	8	DNA hybridization array lab assignment (analysis)
	CW214	10	Real-time PCR & other genetic query techniques
	CW214	11	Proteomics I: mass spectrometry
	CW214	12	Proteomics II: monoclonal antibodies & MAb arrays
	CW214	13	Proteomics III: protein-protein interaction mappings
	CW214	14	Therapeutic target characterization: biochemical methods
	CW214	15	Therapeutic target characterization: biophysical methods
		NONE	WINTER BREAK
		NONE	WINTER BREAK
		NONE	WINTER BREAK
		NONE	WINTER BREAK
		NONE	WINTER BREAK
		NONE	WINTER BREAK
		NONE	WINTER BREAK
	CW214	16	Therapeutic target characterization: computational methods
	CW214	17	Recently identified prospective therapeutic targets
	CW214	18	High-throughput screen design: general considerations
	CW214	19	Enzyme assays for HTS
	CW214	20	Interaction assays for HTS
	CW214	21	Cell-based assays for HTS

	CW214	22	Combinatorial chemistry & optimization of lead compounds
	CW214	23	Recombinant therapeutic proteins
	CW214	24	Monoclonal antibody therapy & novel vaccine therapies
	CW214	25	Gene therapy
	CW214	26	Cellular modeling of drug metabolism & toxicity
	CW214	27	Countering drug resistance & drug tolerance
	CW214	28	Animal models for pre-clinical trials
	CW214	29	Current GMP standards for pharmaceutical production
	CW214	30	Clinical trial design & evaluation
		NONE	M2 Pharmacology exam conflict
	CW214	32	Current pre-market evaluations of novel cancer drugs
	CW214	33	CLASS PROJECT PRESENTATIONS
	CW214	34	CLASS PROJECT PRESENTATIONS
	CW214	35	CLASS PROJECT PRESENTATIONS (Final grades due)

Course Times: 1:00 to 2:00 p.m. on Mondays, Wednesdays, Fridays. Special arrangements will be made for laboratory activities.

Course Location: Classroom Wing 214. Special arrangements will be made for laboratory activities.

Instructor: Roy J. Duhe, Ph.D.

Required Text and Other Learning Resources:

Course handouts;

Principles of Modern Drug Design, Roy J. Duhe (Springer, in preparation, draft manuscript chapters will be provided as handouts)

Course Overview: This course addresses the basic principles of the modern drug discovery and validation process, with emphasis on applications in cancer therapy. The course begins with the identification and characterization of disease-specific molecular targets using genetic and biochemical techniques. The second section describes the selection of lead drugs through high-throughput screening assays, combinatorial chemistry, and computer-assisted rational drug design. The final section covers preclinical and clinical trials and the potential use of database analyses to ensure that the drugs are safe and effective, and that the chosen therapeutic regimen will yield the best outcome for any given patient. Offered only in winter quarter of odd years.

Course Objectives: Upon completion of this course, students will be able to:

(1) lead (or participate in) a team effort to develop a novel drug.

(2) identify a novel drug target through the use of bioinformatics and other scientific disciplines.

(3) characterize the biochemical and biophyical properties of the drug target.

(4) develop a multi-tiered set of assays to screen novel drug candidates from a library.

(5) develop a series of pre-clinical assays and procedures to optimize the pharmacokinetic, pharmacodynamic, and anti-target properties of a lead drug compound such that it will have an optimal efficacy and therapeutic window.

(6) implement the use of biomarkers in clinical drug trials and in personalized medicine.

(7) insist on ethical behavior in all aspects of drug design and distribution.

Grading Policy and Rubric. The final grade in this course will based on active participation, documented evidence of a successful biomedical research ethics examination, and presentation of a drug development project.

Three components will determine the level of course mastery achieved by the student, which will be reflected by the final grade:

1. Active participation is expected & attendance (≥ 30 lectures) is required.
2. Each student will develop & present a drug development project.
3. Each student will undergo IRB-approved training in the protection of human subjects & obtain a certificate of training.

Course grade will be determined by satisfactory fulfillment of these requirements. The student must complete all 3 requirements with distinction in order to receive a grade of "A" (90% or higher). The student must complete #2 in a scholarly fashion to receive a grade of "B" (80% to 89%) or higher. Substandard performance in any or all of the components may result in a grade of "C" (70% to 79%) or lower.

The general grading scheme will be as follows:

Component of Grade	Percentage of Grade
Participation	
a. contributed to discussion (yes/no)	50
b. apparent depth of knowledge, analysis, critical thinking	10
Project presentation (clarity, knowledge, ability to answer questions)	30
Certified training in the protection of human subjects	10
Total:	100

Course Policies:

Attendance at scheduled classes, active participation in discussion, professional behavior and timely completion of assignments are required. Course materials will be posted via BlackBoard. Class project assignments will be presented as to the class and peer-evaluations will be considered in the grading of each project.

Information related to this course will be relayed verbally, as written documents or electronically through Groupwise.

University Policies:

Students with disabilities (ADA) statement Refer to UMC policy
Academic honesty statement Refer to UMC policy