MCS New Course Proposal Form

Course Title: Medicinal Chemistry and Drug Development

Instructor(s): Dr. Danith Ly

Course Number: 09-737      Cross Listing: None

Prerequisites/Corequisites: 09-218, Organic Chemistry II, Or 09-220, Modern Organic Chemistry II

Semesters Offered: Spring

Semester Length: Full semester

Location: Pittsburgh

Course Offering Frequency: Every year

Suggested Days and Times: MWF 1:30-2:20PM

Evaluation Type: Letter grade

Course Unit Justification

Total Units: 12 units

In-class Hours: 3      Recitation Hours: 0      Lab Hours: 0

Out of Class Hours: 9

Target Population: Juniors, seniors and graduate students in chemistry, biological sciences, and biomedical engineering

Anticipated Enrollment: 20-25

Rationale for Course:

This 12-unit course will introduce students to the application of organic and medicinal chemistry and pharmacology in the development of new drugs, highlight the barriers to and opportunities for the development of safe and effective therapies, and examine the financial considerations in the pharmaceutical industry. While the course covers a broad range of topics that provide a comprehensive view of the pharmaceutical industry, a major emphasis will be on the molecular aspects of drug design and development (encompassing ~ 80% of the course content). To engage students in the discovery process, relevant case studies will be presented, and students will analyze the steps taken and propose more effective strategies for moving the lead candidates through the drug development pipeline. With the
goal to assimilate the real-world working environment, lectures will be delivered in an informal, “team-meeting” format that is designed to promote active-learning and independent thinking. In addition to in-class learning, development of original research ideas, and team work/competition, students will have opportunities to hear first-hand from invited industry speakers about the working dynamics in the pharmaceutical industry. Below are the topics and agenda to be covered in the course:

- **Lecture topics**: Drug discovery, preclinical development, clinical investigation, regulatory guidelines, and economic/financial considerations.
- **Development of original research ideas**: Students are required to develop an original research proposal based on the topic of their choice. The work will be reviewed by their peers in a convened panel following the NIH review guidelines.
- **Team work/competition**: Students will work in teams of five to address a contemporary problem in drug development. The topic is a real-world problem, selected upon consultations with local medical experts at Pitt/UPMC and/or research scientist(s) at pharmaceutical companies. The teams will pitch their ideas against one another in a formal 30-minute presentation at the end of the course in front of their peers and medical experts in the field. The winning team will get a chance to hoist the “Drug Discovery Grand Challenge” trophy and bring home other perks (TBA).
- **Industry speakers**: 1-2 industry speakers will be invited to give lectures in class. This will give students the opportunities to hear first-hand from experts working in the field. Another purpose for bringing industry speakers on campus is to build connections between CMU and pharmaceutical companies, providing avenues for job placement for our students and bringing visibility to the department and university as a whole.

**Special Facilities Needed**: None

**Textbook and/or Other Materials**: No textbooks; only assigned readings from published literature.

**Assessment**: In-class midterm exams (3) and final exam, problem sets, original research proposal, and team competition.

**Topics Covered**:

**Course Outline and Learning Objectives**

**Topic 1: Drug Discovery**

Drug discovery is a multi-faceted effort focused on the design and development of lead compounds for clinical testing. Students will be introduced to the various concepts and practices of molecular design and combinatorial synthesis, high-throughput screening, target identification, determination of structure-function relationship (SAR), and lead optimization. **Students should understand the intricacies of chemical and biological research involved in the discovery of lead compounds (the front-end of drug development).**
Topic 2: Preclinical Development
Preclinical development is a stage of research that begins before in-human clinical trials. During this stage, biologic feasibility and drug safety profiles are determined in cell cultures as well as in animal models. Various pharmacological concepts, including pharmacodynamics, pharmacokinetics, ADME (adsorption, distribution, metabolism, and excretion), toxicity and side-effects, will be introduced, and the latest findings on best-used animal practices and regulatory guidelines will be discussed. Students should be able to gain a better understanding of the obstacles and barriers to drug development and an appreciation for the work put forth in developing a drug.

Topic 3: Clinical Investigation
Clinical investigation is the third and final stage of drug development, involving studies or trials that are completed in humans. Students will be introduced to the concepts, requirements, and outcomes of the various stages of clinical trials en route to filing an NDA (New Drug Application) for approval by the FDA. Case studies relevant to clinical trials of small-molecule drugs, oligonucleotide therapeutics, antibody-drug conjugates, and vaccines will be presented, as each therapeutic modality undergoes a different path. Students should understand the scope and limitation of clinical trials and be able to design more rigorous studies to ensure effectiveness and safety of the drug.

Topic 4: Regulatory Guidelines
The mission of the FDA’s Center for Drug Evaluation and Research (CDER) is to ensure that the drugs that are marketed in the U.S. are effective and safe. Such guidelines are constantly evolving to meet the rigorous requirements for manufacturing safe and effective drugs, and the demands of emerging therapies, such as gene editing and regenerative medicine, for which there are no concrete guidelines for their therapeutic development. The lectures/discussions will be presented from the standpoint of policy-making, designed to promote students’ involvement and allowing them the chance to voice their opinions as to what kind of policies or guidelines the FDA should institute to encourage creativity and innovation in drug development and at the same time ensure the safety of the public. Students should be able to understand the pros and cons of the current drug development guidelines and institute more rigorous and effective policies for drug development.

Topic 5: Economic/Financial Considerations/Ethics
The financial paradigm for drug development has undergone a major transformation over the last six decades, from the days of sending scientists out in the field to search for new lead compounds, to building in-house medicinal chemistry infrastructure, to outsourcing chemical and biological R&D to second-parties, to acquisition of startup companies. Likewise, ethics (or lack thereof) have played an important role in the decision-making of drug development. Students will be introduced to the various business models and philosophical guidelines, and in-class discussions will be concentrated on assessing the pros and cons of each based on the specific drug discovery platform and present day financial climate towards improving human health. Students should be able to learn not only the chemistry and biology of drug development, but also the financial considerations and business decisions that have been made—an important component of the drug development business, as some of these students will go on to become leaders in the pharmaceutical industry.
Course Catalog Description: Medicinal chemistry is the art and science of creating molecules that have the potential to improve human health, and drug development is the realization of this ambitious goal, in the translation of lead compounds into safe and effective drugs. Students will learn about the various steps involved in drug development, including lead discovery, preclinical development, clinical investigation, regulatory guidelines, and economical/financial/ethical practices in the pharmaceutical industry. In addition to immersing in active-learning through in-class discussions, developing original research ideas, and participating in team work and competitions, students will have opportunities to hear first-hand from experts in the field about careers in the pharmaceutical industry and potentially establish a professional working relationship with these experts.

Department Approval Date: November 11, 2016

CUA Recommendation: not required

College Council Approval Date:  

Date Sent to Enrollment Services:  

Comments:  