COURSE PURPOSE

The purpose of this course is to provide a framework of the drug development process and its regulation as well as its impact on workers and the environment. Graduate students in toxicology, pharmaceutics, comparative medicine, bioengineering, occupational and environmental health as well as professional disciplines such as medicine, pharmacology, and nursing interested in working with the biotechnology industry will find this course particularly useful. In addition to faculty, students will benefit from presentations from guest lecturers working in and with the industry. Students will develop a proposal for a pre-Investigational New Drug (IND) meeting with Food and Drug Administration (FDA) and present a summary of their proposal to a mock FDA Review Committee.

COURSE LEARNING OBJECTIVES
At the end of this course, the student should be able to:

• Explain the regulatory framework for controlling and managing drug development in the United States and Europe.
• Describe risk assessment methods used in the drug development process, including in vitro (human and animal) and in vivo methods.
• Explain the strengths and limitations of at least 2 animal models for testing drug safety and efficacy.
• Explain the therapeutic mode of action, and understand structural considerations of at least four classes of biopharmaceutical agent.
• Outline the drug manufacturing process including the role of quality control and quality assurance in protecting the public, workers, and the environment.
• Describe human health effects and mechanisms of toxicity as presented in case studies of at least 2 biopharma agents.
• Outline the requirements and process of a human clinical trial.
• Organize data and information on a specific biopharmaceutical agent in the form of a pre-IND meeting regulatory submission.
• Give an oral presentation to scientific audience on the biological mechanism of action and proposed evaluation of safety, efficacy and manufacturing controls on a biopharmaceutical agent.

COURSE REQUIREMENTS
Pre-requisites: ENVH 505 or ENVH 514-516 or PCEUT 501-503 or equivalent or instructor permission.

Recommended Text: A significant portion of the course content will draw upon FDA guidelines available online (http://www.fda.gov/RegulatoryInformation/Guidances/)

In addition, each guest speaker may provide additional references and resources related to their individual lectures.
**Attendance**
Since this class is intended to be interactive, participation is important. Class members will be called upon to discuss different aspects of the topics under consideration.

**Writing Assignments**
Students will work in teams to develop a 15-20-page product proposal for a pre IND briefing with the FDA in advance of the testing to support a Phase I clinical trial. The projects will be prepared and turned in by sections during the quarter. Each student in the team will be primarily responsible for at least one functional area of the briefing package. The team will be responsible for identification of the therapeutic target and drug design, and for compiling the individual sections into a coherent pre-IND briefing packet format (template will be provided by faculty). The scope of the briefing packet should include a description of the product and its intended mode of action; a plan to evaluate safety and efficacy using in vitro and in vivo models, a review of product manufacture methods, bio-analytical assays and quality controls; and the design of the Phase I clinical study emphasizing the safety issues to be addressed. Final proposals will be submitted to the mock FDA Review Committee by the due date indicated on the syllabus for review. Student teams also will present an overview of their proposals to the FDA Review Committee.

**Proposal Presentation**
Each team will give a 30-minute oral presentation to a mock FDA Review Committee followed by a 10-15 minute question and answer period. The Review Committee will be comprised of faculty and 1-2 students. The Review Panel will receive the proposal at least 3 days prior to the presentation for review and to prepare questions. This will be a formal presentation (students will be graded on content and professional presentation skills).

**GRADING**
Course grading scale 0-4.0

Grade weighting:

**Class Assignments: 20%**
Each product team will complete 4 class assignments (each worth 5% of the final grade) outlined in the syllabus. It is the teams' discretion whether each of these individual assignments are assigned to one team member or to the entire team; the grade for each section will apply to all team participants. Faculty will provide feedback on each section to assist in the development of the final product proposal.

**Product Proposal for IND: 40%**

The product proposal paper will be evaluated on clarity in addressing the target biology of the proposed product, the manufacturing, bio-analytical, and preclinical safety assessments, and the specificity of the discussion of known or suspected occupational and environmental impacts of testing and producing the product.
Oral presentation of product proposal: 30%

The presentation should be crafted to address a scientific audience but not necessarily one that is familiar with your particular product, biological system, or the occupational and environmental health principles related to possible hazards. Each student will participate in the product proposal presentation. The presentation will be evaluated on clarity of presentation, ability to convey complicated science in a parsimonious but thorough manner, expertise and command of specific content areas, ability to keep to time, and specificity of responses to questions.

Class Participation: 10%

The format of this course is one in which student participation is expected. The faculty are open to your questioning and encourage this. In addition to participation during the quarter, each student will serve on one of the "FDA" panels for evaluation of team IND presentations.

Course Grading criteria:

3.9 - 4.0 Superior performance in all aspects of the course with work exemplifying the highest quality.

3.5 - 3.8 Superior performance in most aspects of the course; high quality work in the remainder.

3.2 - 3.0 High quality performance in all or most aspects of the course.

2.9 – 2.8 Satisfactory performance in the course

<2.8 Substandard performance in most of the course

Disability Notice. If you would like to request academic accommodations due to a disability, please contact Disability Resources for Students 448 Schmitz, (206) 543-8924, 206-543-8925 (TTY). If you have a letter from Disabled Student Services indicating you have a disability that requires academic accommodations, please present the letter to us so we can discuss the accommodations you might need for class.