Current topics in pharmaceuticals and biotechnology focusing on transforming small molecules, proteins, and genes into therapeutic products. This will include new drug therapies, drug design, pharmacogenomics, molecular modeling, high throughput screen, production and stability considerations, and delivery systems of protein and gene therapeutics in relation to pharmacokinetic and therapeutic responses.

Course goals:

- To introduce concepts/tools used in developing biotherapeutic agents.
- To gain a better understanding of toxicity and stability issues associated with biotech products.
- To understand the apparently similar, but unique biotech drugs that are in development or currently used.
- To gain a basic knowledge enabling one to critically evaluate pharmacokinetic and pharmacodynamic study results of these drugs.
- To expose students to the state-of-the-art therapeutics strategies in development/clinical trials.

Class requirements:

Recommended Textbook - Biotechnology and Biopharmaceuticals: Transforming Protein and Genes into Drugs, Rodney J.Y. Ho and Milo Gilbaldi (Available in HSL Reference Section).

There will be some other outside reading assignments. Students are expected to learn to integrate the material and discuss it in class.

_for credit in this course, class attendance is mandatory and recorded. If you are unable to attend two or more class meetings you must notify Dr. Kelly in writing or email._

Grading criteria:

For C/NR 2 credits—Self-assessment (1-2 pages) summarizing what each student learned from the course. The student is expected to provide a broad overview of the subject areas that are covered and choose one aspect that provides not only new learning insights, but also could influence their career development and practice. Due on last day of lectures (May 29th).
For 3 graded credits—Students will perform literature research, analysis and develop a presentation theme based on topics discussed in the class, write a short summary report, and present to the class. The written report is due by the second to last Friday (May 25th) and the 20 min presentation is scheduled for the last day of class (June 1st). Your final grade will be based on the quality of your report and presentation.

Research and Presentation Project
PCEUT 586

I will be available to discuss these issues as you prepare for and present your project.

As a part of the course grade, you have two different options:

1) Research a topic encompassing current developments related to potential biologic products.

   You should focus on one potential product starting from concept to final scale up of the product that will be used in a clinical trial to test its safety and efficacy.

   You will be expected to put together a written report and a 20 min presentation of your research that addresses the following questions:

   (1) Research and development of your product-- why you chose this one and what is the current knowledge in this area and your reasons for this choice.
   (2) How would you make this product in a small scale and characterize it before attempting to make bulk quantities.
   (3) How would you go about testing its biologic activities and toxicities.
   (4) Do you need to consider a special delivery system for your product. If so, why?
   (5) What other laboratory and preclinical information will you need prior to clinical testing?
   (6) What is the basic hypothesis to be tested in your clinical trials? What other issues should your clinical trials address?
   (7) Discuss the pros and cons of your proposal in bringing the idea or concept to product--Are there alternative products or approaches available? What are the key elements that may increase your chances of success?

2) Prepare a Pharmacy and Therapeutics Monograph on a recently-approved biologic, following UWMC guidelines detailed as follows:

   Pharmacy and Therapeutics Committee
   UW Medicine
   Insert Meeting Date

   Generic Name:

   Proprietary Name/Manufacturer:

   Similar Formulary Medications:
Requestor

Executive Summary

Clinical Indication

Dosing Regimen (Dosing and Administration)

Pharmacology/Mechanism of Action

Pharmacokinetics

Storage (if relevant e.g. refrigeration)

Contraindications

Precautions

Use in Pregnancy/Lactation

Drug Interactions

Adverse Effects

Safety Issues (look a like/sound a like etc and text summary of FMEA worksheet)

Clinical Trials
Study design
Results
Conclusions

Critique of the study (this is key!)

Financial Impact
Acquisition Cost
Cost to Patient (only for take home ambulatory medications)
Reimbursement
Anticipated Usage
Overall annual financial impact to UW Medicine

Discussion

Recommendation

Submitted by:

References