Course Title: **Pre Clinical Drug Development (3 credits)**
Fall Semester 2014
Instructor: William J. Welsh, PhD
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**Overview**
This course provides a detailed overview of the drug and biologics development process from discovery through regulatory approval and beyond to marketing strategy. Special attention is given to the roles, functions and significance of the various disciplines involved in the R&D process, their interactions with each other, and the strategic management of these functions. Attention will also be given to key technologies used throughout the R&D process, specifically: biomarker development, imaging, computer-aided drug design and examples of their application. The economics of pharmaceutical R&D as well as trends in licensing, outsourcing and partnerships will be covered. The student will gain an understanding of R&D strategy and the relationship between R&D and overall organizational success.

**Pedagogy**
The course will employ lectures notes, assigned readings, case analyses and individual homework assignments. Each student will analyze three cases involving health care, translational medicine, and drug development, and corporate structure and culture of biopharmaceutical companies.

**Learning Goals**
After taking this course, the student will be able to:
- Understand the drug development process
- Understand the scientific, financial and managerial challenges involved in drug development
- Understand the importance of translational medicine in drug development
- Understand the interaction of risk and strategy in drug development

**Required Texts**
- *Drugs-From Discovery to Approval*, Second Edition by Rick Ng. Wiley-Blackwell 2009

**Class Notes**
Class lectures will be given except for Week 5, Week 10, and Week 13. On these weeks, you will work on the three assigned Case Studies.

**Required Readings**
Required and supplemental readings are outlined in the course schedule.

**Assignments**
*Homework Questions*
Each week, there will be a series of homework questions, to aid in helping you test your understanding of the material. Students should come prepared to discuss their answers to each week’s questions.

*Case Studies*
The students will analyze three case studies in their 15-week curriculum; Cases are set at a point in time and describe a real problem or situation faced by the subject organization. When evaluating a case read the case through once quickly to gain a general understanding of the situation; read it a second time, this time noting items such as:

- *The central problem or issue posed by the case.*
- *What is known or unknown about the problem?*
- *The opportunities and options available for addressing the problem.*

Discuss the **strategic nature** of the case, the ramifications of different decisions that might have been made and how you would have handled the case. Be sure not to ignore the strategic, business and financial aspects of the case. Research what has happened since the case took place; was the strategy described in the case successful or not; and if not, why not? Describe what you learned from the case (lessons learned). Use standard methods of analysis that you may have learned in other classes or in your work, such as SWOT, decision-tree, etc.

Case analyses should be 3 – 5 pages in length and should **NOT be a recapitulation of the events or the case**, but should be an analysis of the case. These should be in Microsoft Word format (or some compatible format).

**Basis for Grade Assignments**

<table>
<thead>
<tr>
<th>Assignment</th>
<th>MBS: Pre Clinical Pharmacology</th>
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</thead>
<tbody>
<tr>
<td>Homework</td>
<td>33%</td>
</tr>
<tr>
<td>Case Studies</td>
<td>67%</td>
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Grades will be

A, B+, B, C+, C and F

**Course Schedule**

**Week 1** Introduction to Pharmaceutical Research & Development
Required Reading: Ng - Chapter 1; Littman & Krishna - Chapter 1

**Week 2** Drug Discovery
Required Reading: Ng - Chapters 2-4

**Week 3:** Preclinical Development  
Required Reading: Ng - Chapter 5

**Week 4:** Modeling and Simulation in Drug Discovery  
Required Reading: Handout

**Week 5:** **Case Study 1:** *Eli Lilly - Developing Cymbalta*  
Required Reading: Handout

**Week 6:** Regulatory Affairs  
Required Reading: Chapters 7 and 8  
21 CFR 58, subparts 15, 29, 35, 43, 47, 49, 63, 81, 90, 105, 120, 130  
21 CFR Part 50  
21 CFR Part 312, subparts 3, 6, 7, 20, 21, 22, 23, 32, 33, 40

**Week 7:** Clinical Trials and Drug Safety  
Required Reading: Ng - Chapter 6

**Week 8:** R&D Organizations & Strategy  
Required Reading: Ng – Chapter 8-10

**Week 9:** Biopharmaceuticals  
Required Reading: Ng – Chapter 7

**Week 10:** **Case Study 2:** *Pfizer Inc.-Building an Innovation Center*  
Required Reading: Handout

**Week 11:** Pharmaceutical Industry in the 21st Century  
Required Reading: Ng - Chapter 14-15

**Week 12:** Pharmaceutical Formulation & Good Manufacturing Practices (GMP)  
Required Reading: Ng – Chapter 16

**Week 13:** **Case Study 3:** *Sirtris Pharmaceuticals - Living Healthier, Longer*  
Required Reading: Handout