Proposed Syllabus
CTSC 5105
Perspectives in Drug Development – Fall Semester 2013
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Overview
This course provides a detailed overview of the drug and biologics development process from discovery through regulatory approval. 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, translational human models 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, individual homework assignments, and a final project. Each student will analyze three cases involving health care, translational medicine, and drug development, and corporate structure and culture of biopharmaceutical companies. The final project will be a written paper touching on some aspect of pharmaceutical research and development.

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

Class Notes
Class lectures will be given except for Week 4, Week 7, and Week 10. 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
There will be three case studies that must be analyzed. 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).

Final Project
The final project will be a paper discussing the role of R&D management in the pharmaceutical value chain. Some topics you might choose to write about could be a key function, process or strategy in drug development; an emerging technology used in the drug discovery and/or development process; or a current problem or challenge in the R&D area. By Week 6 of the course, I will need from you a brief proposal (1 page) that describes the area or problem to be studied, why this is important and your approach (how will you research the subject). Students should be prepared to discuss their specific project by Week 13. The final project will be due Week 15.

Final Paper: Suggested Table of Contents
1. Title page
2. Abstract
3. Statement or problem or summary of the area of study
4. Background
5. History or relevant background
6. Review of the literature
7. Analysis of the problem or situation and opportunities presented including strategic issues and managerial challenges
8. Formulation of alternative approaches (list alternatives and discuss pros and cons of each)
9. Specific recommendations (recommendations must flow from alternatives)
10. Risk analysis
11. Implementation plan
12. Lessons learned
13. References
14. Appendix

Homework 33%
Case Studies 33%
Final Project 34%

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 Case Study: Eli Lilly - Developing Cymbalta
Required Reading: Littman & Krishna - Chapter 2

Week 5 Regulatory Affairs Required Reading:
Ng - 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 6 Clinical Trials
Required Reading: Ng - Chapter 6

Week 7 Case Study: Sirtris Pharmaceuticals - Living Healthier, Longer

PROPOSALS FOR FINAL PAPER DUE
Required Reading: Littman & Krishna - Chapter 4
Week 8 R&D Strategy

Week 9 Biomarkers - Public:Private Partnerships (PPPs)
Required Reading: Littman & Krishna - Chapters 8 and 9

Week 10 Case Study: Pfizer Inc.-Building an Innovation Center
Required Reading: Littman & Krishna - Chapter 6

Week 11 R&D Organizations

Week 12 Modeling and Simulation
Required Reading: Littman & Krishna - Chapter 13

Week 13 Project Discussions: Students discuss their final projects

Week 14 The Pharmaceutical Industry in the 21st Century
Required Reading: Littman & Krishna - Chapter 14

Week 15 FINAL PROJECT DUE