Proposed Syllabus

CTSC 5105

Perspectives in Drug Development

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 translational medicine and its impact on drug development. The final project will be a written paper touching on some aspect of managing 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

Drugs-From Discovery to Approval, Second Edition by Rick Ng. Wiley-Blackwell 2009 ISBN 978-0-470-19510-9.

Translational Medicine and Drug Discovery, Bruce H. Littman and Rajesh Krishna, Editors. Cambridge University Press 2011 ISBN 978-0-521-88645-1.

Code of Federal Regulations, at www.gpoaccess.gov.

Class Notes

Class notes will be provided except for Week 4, Week 7, and Week 10. On these weeks, you will work on the assigned cases.

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.

Cases

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

Grading	Grade Percent
Homework	33%
Case Studies	33%
Final Project	34%

Course Schedule

Date	Topics	Readings
Week 1	Introduction to Pharmaceutical Research & Development	Required Reading: • Ng – Chapter 1 • Littman & Krishna – Chapter 1 Supplemental Reading: • The Life Sciences: A Technical Primer (HBS Case 9-602-118) • The Pharmaceutical Industry: Challenges in the New Century (HBS Case 9-703-489) • Pursuit of High Performance Through Research and Development (Accenture) • Changing Patterns of Pharmaceutical Innovation (NIHCM Report) • Big Pharma Faces Grim Prognosis (WSJ) • Tufts Center for the Study of Drug Development Impact Report, Nov/Dec, 2006 • The Price of Innovation (Journal of Health Economics)
Week 2	Drug Discovery	Required Reading: • Ng – Chapters 2 – 4 Supplemental Reading: • Drug Discovery: Selecting the Optimal Approach (Drug Discovery Today) • The Druggable Genome: An Update (Drug Discovery Today) • Enlightened Experimentation: The New Imperative for Innovation (HBR On-Point 6099) • ISOA/ARF Drug Development Tutorial – Institute for the Study of Aging • Drug Discovery (Chemical and Engineering News, July 26, 2004) • Improving the Hit-To-Lead Process (Drug Discovery Today)
Week 3	Preclinical Development	Required Reading: • Ng – Chapter 5 Supplemental Reading: • Optimizing the Stage Gate Process (Research Technology Management, Vol 45, 2002) • Technology Stage-Gate (Ajamian and Koen) • Why Optimize Cancer Drugs for ADMET? (Drug Discovery) • Guidance for Industry: Estimating The Safe Starting Dose (FDA)

Date	Topics	Readings
Week 4	Case Study: Translational Medicine and Its Impact on Diabetes Drug Development	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 Supplemental Reading: • The eClinical Equation (IBM Institute for Business Value) • Adaptive Methods for Faster, Cheaper and Safer Clinical Trials (Jour Clinical Research Best Practices) • Clinical Trials' EDC Endgame • The Two Headed Beast (Signals Magazine) • FDA Guidance for Industry: E6 Good Clinical Practice Consolidated Guidance • Using It to Speed Up Clinical Trials (McKinsey)
Week 7	Case Study: Obesity **PROPOSALS FOR FINAL PAPER DUE**	Required Reading: • Littman & Krishna – Chapter 4
Week 8	R&D Strategy	Supplemental Reading: • Rising to the Productivity Challenge (BCG, July, 2004) • New Drug Development (GAO Report) • A Better Way to R&D? (HBS Reprint S0503E) • The Future of the Life Sciences Industries (Deloitte) • The Changing Face of R&D in the Pharmaceutical Landscape (Deloitte) • Big Pharma Blurring the Lines with Big Biotech (CNN News) • Drug Firms Dreaming of Deals (Wall St Jour)
Week 9	Biomarkers – Public and Private Partnerships	Required Reading: • Littman & Krishna – Chapters 8 and 9
Week 10	Case Study: Neuroscience	Required Reading: • Littman & Krishna – Chapter 6

Date	Topics	Readings
Week 11	R&D Organizations	Supplemental Reading: • Good Governance Gives Good Value (BCG Focus, July, 2004) • GlaxoSmithKline: Reorganizing Drug Discovery A (HBS Case 9-605-074) • GlaxoSmithKline: Reorganizing Drug Discovery B (HBS Case 0-605-075) • Scientists as CEOs • Anatomy of a Founder • Investors call for surgical strike on GSK • The J&J Credo • Reinvent Your Company (Fortune, June, 2000) • The Cult of Three Cultures (strategy + business) • The Hidden Traps in Decision Making (HBR Reprint R0601K) • Glaxo CEO and R&D Overhaul • Sanofi New R&D Model
Week 12	Modeling and Simulation	Required Reading: Littman & Krishna – Chapter 13 Supplemental Reading: • Competing on Analytics (Davenport) • Pharma 2020: Virtual R&D
Week 13	Project Discussions	Students discuss their final projects
Week 14	The Pharmaceutical Industry in the 21st Century	Required Reading: • Littman & Krishna – Chapter 14 Supplemental Reading: • Pharma 2020: The Vision
Week 15	**FINAL PROJECT DUE**	