

Course Syllabus
MGT 681 WS
Managing Pharmaceutical Research and Development
Web Campus
Dr. Joel Dobbs

| Week | Topic | Assignments |
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| 0 | Orientation Week | <ul style="list-style-type: none"> • See Website |
| 1 | Course Introduction Introduction to Pharmaceutical Research and Development <ul style="list-style-type: none"> • The pharmaceutical value chain • The economics of pharmaceutical R&D and the cost of drug development • The information value chain | <ul style="list-style-type: none"> • Ng-Chapter 1 • <i>The Life Sciences: A Technical Primer</i>-HBS Case 9-602-118 |
| 2 | R&D Organizations <ul style="list-style-type: none"> • The organization and governance of R&D organizations • Collaboration across the value chain • Challenges in the management of R&D | <ul style="list-style-type: none"> • Bamfield-Section B Chapter 1 • <i>Good Governance Gives Good Value: Rising to the Productivity Challenge in Biopharma R&D</i>- BCG Focus July 2004. • <i>GlaxoSmithKline: Reorganizing Drug Discovery</i>- HBS Case 9-605-074 |
| 3 | Drug Discovery <ul style="list-style-type: none"> • The discovery process • Biological targets • Small and large molecules • Drug discovery technologies • Managing creativity and fostering a creative environment | <ul style="list-style-type: none"> • Ng- Chapters 2-4 • Bamfield- Section C Chapter 1 • Thomke,Stefan: <i>Enlightened Experimentation: The New Imperative for Innovation</i>, HBR On-Point 6099 |
| 4 | Case Study I- Drug Development Strategy-Eli Lilly | <ul style="list-style-type: none"> • <i>Eli Lilly and Company: Drug Development Strategy</i>- HBS Case 9-698-010 |

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| | | <ul style="list-style-type: none"> • <i>Student papers</i> |
| 5 | <ul style="list-style-type: none"> • Pre-clinical Studies and early development • Early Decision Points • The Stage-Gate Process | <ul style="list-style-type: none"> • Ng- Chapter 5 • Bamfield- Section D Chapter 2 |
| 6 | Case Study II- Millennium | <ul style="list-style-type: none"> • Champion, David: <i>Mastering the Value Chain: An Interview with Mark Levin of Millennium Pharmaceuticals</i>, HBR June 2001. • <i>Millenium Pharmaceuticals, Inc (A&B)</i>.- HBS Cases 9-600-038 and 9-602-063 • <i>Student papers</i> |
| 7 | <p>Clinical Trials</p> <ul style="list-style-type: none"> • Strategy, design and conduct. • Managing and measuring effectiveness: Clinical trial metrics • <p>The Regulatory Submissions and Approval Process</p> | <ul style="list-style-type: none"> • Ng- Chapter 6 • Ng- Chapters 7-8 |
| 8 | R&D Strategy | <ul style="list-style-type: none"> • Raynor, Michael and Panetta, Jill: <i>A Better Way to R&D?</i> HBR Strategy and Innovation Newsletter, March-April 2005. • <i>Rising to the Productivity Challenge: A Strategic Framework for Biopharma</i>- BCG Focus, July, 2004. • <i>Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products</i>- Food and Drug Administration, March 2004. • <i>Pharma 2010: The Threshold of Innovation</i>, |

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| | | IBM Business Consulting Services 2004. |
| 9 | Case Study III- R&D Strategy-Merck | <ul style="list-style-type: none"> • <i>Discovering the Future: R&D Strategy at Merck</i>- HBS Case 9-601-086 • <i>Student papers</i> |
| 10 | Outsourcing, Partnerships and Strategic Alliances | <ul style="list-style-type: none"> • Bamfield- Section C Chapters 2 and 3 • Quinn, James Brian: <i>Outsourcing Innovation: The New Engine of Growth</i>- Sloan Management Review, Summer 2000. • Chesbrough, Henry W and Teece, David J: <i>Organizing for Innovation: When is Virtual Virtuous?</i> HBR August 2002. • Hagel, John and Brown, John Seely: <i>Productive Friction: How Difficult Business Partnerships Can Accelerate Innovation</i>. HBR February 2005. • Gottfredson, Mark, et.al.: <i>Strategic Sourcing :From Periphery to the Core</i>. HBR February 2005. |
| 11 | Measuring and Managing R&D Performance <ul style="list-style-type: none"> • People • Processes • Performance | <ul style="list-style-type: none"> • Bamfield- Section A Chapters 1-3 • Drucker, Peter F: <i>They're Not Employees, They're People</i>. HBR February 2002. • Lam, Michael: <i>How to Win Friends, Influence People, and Make NMEs</i>, Pharmaceutical Executive, August 2004. • Other Readings TBD |
| 12 | Portfolio Management | <ul style="list-style-type: none"> • Bamfield- Section D Chapter 1 • Sharp, Paul and Keelin, Tom: <i>How SmithKline Beecham Makes Better Resource-Allocation Decisions</i>, HBR March-April 1998. |

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| | | <ul style="list-style-type: none"> • Nichols, Nancy: <i>Scientific Management at Merck: An Interview with CFO Judy Lewent</i>, HBR Jan-Feb 1994. • Other reading TBD |
| 13 | Final Research Papers | <ul style="list-style-type: none"> • Final Papers Due |

Required Texts

Drugs-From Discovery to Approval by Rick Ng.
Wiley-Liss 2003
ISBN 0471601500

Research and Development Management in the Chemical and Pharmaceutical Industry, 2nd Edition by Peter Bamfield
Wiley-VCH 2003
ISBN 3-527-30667-6

Sources for Cases and Articles

Harvard Business Review (HBR) articles and Harvard Business School (HBS) cases may be ordered on-line from
http://harvardbusinessonline.hbsp.harvard.edu/b02/en/hbr/hbr_home.jhtml

Good Governance Gives Good Value: Rising to the Productivity Challenge in Biopharma R&D- BCG Focus July 2004 -
http://www.bcg.com/publications/files/Good_Governance_Gives_Good_Value.pdf

Rising to the Productivity Challenge: A Strategic Framework for Biopharma- BCG Focus, July, 2004.-
http://www.bcg.com/publications/publications_search_results.jsp?PUBID=1205

Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products- Food and Drug Administration, March 2004. - <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf>
or <http://www.mdbio.org/newsite/news/Innovationfinal.pdf>

Pharma 2010: The Threshold of Innovation, IBM Business Consulting Services 2004. -- <http://www-1.ibm.com/services/us/index.wss/ibvstudy/imc/a1001099>

Pharma 2010: Silicon Reality, IBM Business Consulting Services 2004.- http://www-1.ibm.com/businesscenter/smb/us/en/contenttemplate/gcl_xmlid/27876

Lam, Michael: *How to Win Friends, Influence People, and Make NMEs*, Pharmaceutical Executive, August 2004-
<http://pharmexec.com/pharmexec/article/articleDetail.jsp?id=110435>

Grading

1. Case write ups- 20 points each
2. Final Paper- Each student will select either an area or process in drug development or a key or emerging technology used in this process and prepare a 20 page research paper. Guidance for the paper is provided below.- 30 points
3. Participation 10 points

Introduction to the Case Method

- Cases provide the opportunity to evaluate a real-life business problem.
- We use published cases primarily from the Harvard Business School.
- Cases are set at a point in time and describe a real problem or situation faced by the subject company.

When Evaluating a Case

1. Read the case through once quickly to gain a general understanding of the company, industry and situation.
2. Read it a second time, this time noting items such as:

1. The state of the industry and/or subject company at the time of the case.
2. The opportunities and options available to them.
3. Identify the central problem or issue posed by the case.
3. Research the company especially focusing on what has happened since.
4. What did you learn from the case (lessons learned).

Guidelines for case write-ups

- All case analyses should be typewritten, approximately 10-15 pages in length.
- References should be used to support all quotations or data sources

Outline for case write-ups

1. Overview of the company and the business climate.
2. SWOT analysis of the company (see below).
3. Analysis of the opportunities and risks
4. Alternatives
5. Recommended strategy and specific recommendations for action
6. Update-What has happened since?
7. Lessons learned

SWOT Analysis

- Stands for Strengths, Weaknesses, Opportunities and Threats
- SWOT references
 1. <http://www.quickmba.com/strategy/swot/>
 2. http://www.mindtools.com/pages/article/newTMC_05.htm
 3. http://www.valuebasedmanagement.net/methods_swot_analysis.html

Guidelines for final papers

- Select Either
 - A key function or process 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 of your company
- Prepare a brief proposal (1-2 pages) that describes:
 - The area or problem to be studied
 - Why this is important
 - Your approach (how will you research the subject)
 - What you plan to do with what you learn
- This proposal should be e-mailed to me for prior approval no later than the middle of the term.
- I must pre-approve your proposal.
- Final paper must be a minimum of 20 pages in length (12 point type-double spaced) not including the title page and appendices.
- Must contain a minimum of 10 references each linked to their citation.
- You may include supporting materials (analyses such as SWOT analyses, large figures and graphs or other supplementary materials). The appendix DOES NOT count as part of the 20 page minimum.

Final Paper: Minimal Table of Contents

- I. Title page
- II. Abstract
- III. Statement or problem or summary of the area of study
- IV. Background
 - I. History or relevant background
 - II. Review of the literature
- V. Analysis of the problem or situation and opportunities presented including strategic issues and managerial challenges
- VI. Formulation of alternative approaches (list alternatives and discuss pros and cons of each)
- VII. Specific recommendations (recommendations must flow from alternatives)
- VIII. Risk analysis (see below)
- IX. Implementation plan

- X. Lessons learned
- XI. References
- XII. Appendix