COURSE DESCRIPTION

To develop a successful career in the pharmaceutical industry requires understanding of the market, clients, and the environment. Leaders in the industry must make decisions on a daily basis in order to stay competitive and grow. A company's ultimate survival depends on the successful pipeline of new drugs. Competitive pressure in the market place compels companies to invest continuously in the R & D activities in order to have new drugs lined up to replace the expiring patents. The amount of investment for each new drug developed has been increasing tremendously. Once a drug is marketed, there is no guarantee that it will have its financial success. Other companies might come up with a better drug in its therapeutic class, or the regulatory agency might restrict its marketing due to unexpected health outcome. The point is, it is a very risky business. The course syllabus has been developed with the advice and support from Mr. Irwin Lerner, former President and CEO, Hoffmann-La Roche.

COURSE MATERIALS

Recommended Books


2. Understanding Pharma by John J. Campbell, Pharmaceutical Institute, 2008

CLASS ORGANIZATION & ADMINISTRATION

There is no text for this course but requires a set of readings mentioned as follows. Other readings may be added later during the semester. The students will be evaluated based on the performances in three equally weighted papers. Requirements for the papers are explained below. Students are required to attend the on-line seminar series by the FDA's Center for Drug Evaluation and Research (CDER) (www.fda.gov/training/forhealthprofessionals/default.htm, and take the available on-line quiz following each of the seminar for your own evaluation. The courses (seminars) available are: Risk Assessment and Communication, FDA Medwatch and Patient Safety, Field Investigators: Adverse Drug Effects (ADE) Investigators, The FDA Process for Approving Prescription Drug Labeling.
**Requirements for the papers**

You will need to select three topics of your choice involving the issues of pharmaceutical industry. Examples of topics are: Product Pricing Strategies, Impact of Drug Importation on Price, Quality and Access, Impact of Alliances on Drug Development, Impact of Genomics on Drug Development, Valuing Product Pipeline, Impact of Mergers & Acquisitions on R&D Capacity, Examine the Growth of Outsourcing and its impact on Drug Development, Compare Drug Development Costs at Biotech Firms Versus Large Pharmaceutical Companies or any other topic relevant to this course. The selected topics must not be too broad. Examples of too broad topics are: R&D Process, Mergers & Acquisitions, Product Launching etc. The papers must be analytical. Use of actual data is highly recommended.

The Rutgers Library system has subscribed the on-line version of the FDC reports. Check the site [www.libraries.rutgers.edu/indexes/fdc_reports](http://www.libraries.rutgers.edu/indexes/fdc_reports) for a list of the reports, click on CONNECT, you will get a page by Pharma&MedTech Business Intelligence, use the drop down menu under “Headlines From Your Subscription” to select the publication i.e Pink Sheet, Tan Sheet, Gray Sheet etc. There are other data sets as well such as Parexel’s Pharmaceutical R&D Statistical Sourcebook (available in the Science & Medicine library in the Busch campus). The Lerner Center has several IMS data sets. If you would like to use the IMS data sets, you need to talk to me for the procedure of getting access to the data sets.

**Class Attendance**

You are required to attend every class, and participate in class discussion. You should come prepared to ask questions to the speaker of the day. If you are absent for more than two classes, your grade may be lowered by one notch (from A to B+, B+ to B etc).

**Course Objective**

The objective of this course is to give the students an understanding of the successful development of a new drug. In this context, the students will be exposed to different concepts of drug development phases, the role of the Food and Drug Administration in the development of new drugs, role of patenting & licensing, drug pricing, product life cycle, genomics & biotechnology and other related issues. The course will have many guest speakers from the industry to orient the students on practical point of view. After successful completion of the course, the students should be able to explain the R & D process to their peers, participate and contribute in managerial decision makings with respect to the development of new drugs.
## COURSE SCHEDULE

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### Readings

Overview of the Drug Discovery and Development Process

**Speaker**

Bob Seltzer

Partner

Care Capital, LLC

**Readings**

NDA Pipeline Online, FDC Reports.


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2/5  Competitive Pressure:

Mergers, Acquisitions and Restructuring

Of the Pharmaceutical Industry

**Speaker**

Cliff Cramer

Former Vice President, Corporate Planning & Development, Merck & Co. Inc.

Former Managing Director, J.P. Morgan and Merrill Lynch

2/12  Market Access Strategies: Key to Achieving Commercial Success

**Speaker**

Zeba M. Khan, RPh, Ph.D

Vice President

Strategic Market Access & Policy

Celgene Corporation

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**Readings**

Schweitzer, Stuart and Comanor, William, “Prices of Pharmaceuticals in Poor Countries Are Much Lower Than in Wealthy Countries”, *Health*


Patents and Intellectual Property Rights
Speaker
George Johnston, J.D
Former Vice President and Chief Patent Counsel, Genentech/Roche
Senior Patent Counsel
Gibbons Law, LLC

Readings

Zinner, Darren E. "Medical R & D At The Turn Of The Millennium",
Eisenberg, Rebecca S. "The Shifting Functional Balance Of Patents And Drug Regulation",

Schweitzer, Stuart O. "Pharmaceutical Economics and Policy",

Readings

2/26 Measuring Product Launch and Branding Success

Speaker

Dale Benner
Director, tGas

And

Brian Voellmeck
Director, tGas

Patents and Intellectual Property Rights
3/5 Product Commercialization Framework

**Speaker**

Rohit Sood  
Vice President  
Campbell Alliance

**Readings**

TBA

Paper 1 due

3/12 Impact of Genomics on Pharmaceutical Product Development

**Speaker**

Deborah Ricci, Ph.D  
Director, Oncology Biomarkers  
Janssen Pharmaceuticals

**Readings**


Blair, Edward et al. “Aligning the Economic Value of Companion Diagnostics and


3/19 No Class – Spring Break
3/26 The Role of the FDA
Kenneth Berkowitz, J.D
Former Vice President, Public Affairs, Drug Regulatory Affairs and Drug Safety
Hoffmann-La Roche

Readings


FDA Organization Charts


Miscellaneous Guidances on Risk Management

FDA REMS Q&A 2010

FDA Public Health Advisory: Ketek


Overview of the Medical Device Market

Speaker
K. Mosaddeq Hossain
Director, R&D/Engineering
Nostrum Technologies, LLC

Readings
TBA

4/9
Licensing, Partnering and Contracting for Product Development

Speaker
David Brooks, Ph.D., F. A. H. A.
Senior Director, Business Development
Janssen Global Services, LLC
Johnson & Johnson

Nancy Ondovik, PharmD, M.B.A.
Senior Director, Business Development
Johnson & Johnson

Readings
TBA

Paper 2 due

4/16
Pharmaceutical Outcome Studies

Speaker
Todd Williamson
Vice President
Bayer Pharmaceuticals

4/23
Impact of Healthcare Reforms on the Pharmaceutical Industry

Speaker
Richard Evans
CEO, Sector Sovereign Inc.

Readings


Evans, Richard; Hinds, Scott; and Baum, Ryan; “Co-Pay Cards: A Bottle for the Drug Pricing Genie”, Sector & Sovereign, LLC, August 8, 2012.

Evans, Richard; Hinds, Scott; and Baum, Ryan; “An Index of Value in Large Cap Pharma Cos’ mid-to Early-Stage Pipelines”, Sector & Sovereign, LLC, November 8, 2012.

4/30 Project Valuation and Portfolio Management in Pharmaceutical R&D

Speaker

John Cavallaro, Ph.D

Technical Director, Portfolio and Asset Strategy

Bristol-Myers Squibb

Paper 3 due

Readings
TBA