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

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.

Suggested Books

LEARNING GOALS AND OBJECTIVES

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.

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 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.

ACADEMIC INTEGRITY

I do NOT tolerate cheating. Students are responsible for understanding the RU Academic Integrity Policy (http://academicintegrity.rutgers.edu/).

I will strongly enforce this Policy and pursue all violations. On all examinations and assignments, students must sign the RU Honor Pledge, which states, “On my honor, I have neither received nor given any unauthorized assistance on this examination or assignment.” I will screen all written assignments through SafeAssign or Turnitin, plagiarism detection services that compare the work against a large database of past work. Don’t let cheating destroy your hard-earned opportunity to learn. See business.rutgers.edu/ai for more details.

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 SCHEDULE

Class Schedule

<table>
<thead>
<tr>
<th>Day</th>
<th>Topic, speaker, Readings, and Due Dates of Assignments</th>
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Course Information

Readings


Reinhardt, Uwe E. "Perspectives On The Pharmaceutical Industry",


Mullins, Daniel ; Wang, Junling ; Palumbo, Francis; and Stuart, Bruce


Overview of the Drug Discovery and Development Process

Speaker

Readings

NDA Pipeline Online, FDC Reports.


Schweitzer, Stuart O. "Pharmaceutical Economics and Policy", 
*Oxford University Press, New York, 2007, Chs. 1, 2 and 9.*

Competitive Pressure:
Mergers, Acquisitions and Restructuring
Of the Pharmaceutical Industry

**Speaker**

Licensing, Partnering and Contracting for Product Development

**Speaker**

**Readings**
TBA

Patents and Intellectual Property Rights

**Speaker**
Readings


https://www.uspto.gov/sites/default/files/about/offices/ous/Cooper_Union_20130604.pdf

*Frequently Asked Questions on Patents and Exclusivity, U.S. Food & Drug Administration* (last visited December 14, 2016)


Zinner, Darren E. "Medical R & D At The Turn Of The Millennium",


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

Readings

Commercializing Targeted Therapies : How Things Need to Change
Speaker

Product Commercialization Framework

Speaker

Readings

TBA

Paper 1 due

Impact of Genomics on Pharmaceutical Product Development

Speaker

Readings

“Use of Standards in FDA Regulatory 2 Oversight of Next Generation 3 Sequencing (NGS)-Based In Vitro 4 Diagnostics (IVDs) Used for 5 Diagnosing Germline Diseases”, “U.S. Department of Health and Human Services, July 8, 2016.”

“Use of Public Human Genetic Variant 2 Databases to Support Clinical Validity 3 for Next Generation Sequencing 4 (NGS)-Based In Vitro Diagnostics”, “U.S. Department of Health and Human Services, July 8, 2016.”

David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

Fontes, Denis et al, “Impact of a Biomarker-Based Strategy on Oncology Drug Development: A Meta-Analysis of Clinical Trials Leading to FDA Approval”, 


Paving the Way for Personalized Medicine, “U.S. Department of Health and Human
Services, October 2013.


No Class – Spring Break

Pricing and Market Access: Case of Oncology

**Speaker**

**Readings**

TBA

Pharmaceutical Market Trends and Dynamics

**Speaker**

**Readings**

TBA
Overview of the Medical Device Market

**Speaker**

**Readings**
TBA

Paper 2 due

The Vaccine Market: A Global Perspective

**Speaker**

**Readings**
TBA

Project Valuation and Portfolio Management in Pharmaceutical R&D

**Speaker**
Readings

TBA

Concepts and Applications of Pharmaco Economics

Speaker

Readings

TBA

Paper 3 due

SUPPORT SERVICES


[Rutgers University-New Brunswick ODS phone (848)445-6800 or email dsoffice@echo.rutgers.edu]

[Rutgers University-Newark ODS phone (973)353-5375 or email ods@newark.rutgers.edu]

If you are pregnant, the Office of Title IX and ADA Compliance is available to assist with any concerns or potential accommodations related to pregnancy.
If you seek religious accommodations, the Office of the Dean of Students is available to verify absences for religious observance, as needed.

If you have experienced any form of gender or sex-based discrimination or harassment, including sexual assault, sexual harassment, relationship violence, or stalking, the Office for Violence Prevention and Victim Assistance provides help and support. More information can be found at http://vpva.rutgers.edu/.

If students who have experienced a temporary condition or injury that is adversely affecting their ability to fully participate, you should submit a request via https://temporaryconditions.rutgers.edu.

If you are a military veteran or are on active military duty, you can obtain support through the Office of Veteran and Military Programs and Services. http://veterans.rutgers.edu/

If you are in need of mental health services, please use our readily available services. [Rutgers University-Newark Counseling Center: http://counseling.newark.rutgers.edu/]
If you are in need of **physical health** services, please use our readily available services.

[Rutgers Health Services – Newark: http://health.newark.rutgers.edu/]
[Rutgers Health Services – New Brunswick: http://health.rutgers.edu/]

If you are in need of **legal** services, please use our readily available services: http://rusls.rutgers.edu/

Students experiencing difficulty in courses due to *English as a second language (ESL)* should contact the Program in American Language Studies for supports.

[Rutgers–Newark: PALS@newark.rutgers.edu]
[Rutgers–New Brunswick: espals@english.rutgers.edu]

If you are in need of additional **academic assistance**, please use our readily available services.

[Rutgers University-Newark Learning Center: http://www.ncas.rutgers.edu/rlc]
[Rutgers University-Newark Writing Center: http://www.ncas.rutgers.edu/writingcenter]
[Rutgers University-New Brunswick Learning Center: https://rlc.rutgers.edu/]

[Optional items that many faculty include:]

- Students must sign, date, and return a statement declaring that they understand the RU Academic Integrity Policy.
- Students must sign, date, and return a statement declaring that they understand this syllabus.]