

Syllabus

MIS 672 – New Drug Development in the Pharmaceutical Industry

Overview

This course addresses the organizational, management, and technology issues surrounding the discovery, development, and commercialization of new drugs within the pharmaceutical industry. Central to this course is a detailed description of the pharmaceutical research and development process, the importance of information technology in enabling the discovery and development of new medicines, the conduct of clinical research, the management of pharmaceutical drug portfolios, electronic submissions and reporting, and the meeting of global regulatory compliance obligations.

This course will also examine the regulatory and ethical considerations surrounding the conduct of clinical research and will examine current issues related to informed consent, institutional review and approval of clinical protocols, patient privacy and electronic medical records, transparency of reporting clinical research results, and regulatory reporting compliance.

Topics include: Molecules to Medicines, Drug Discovery and Screening, Early Testing and Safety, Clinical Research, Global Drug Review and Approval, Trends and Issues in Pharmaceutical Drug Development.

Introduction to Course

This course provides a comprehensive overview of the drug discovery and development process and the importance of information technology in the identification, screening, development, and commercialization of new medicines. Students will learn how promising new drugs are discovered, screened, and evaluated from the standpoint of their safety and efficacy. How drug commercialization decisions are made at each major phase in the drug development process. How information technology is used to increase drug development productivity as well as enhance the commercial potential of drug portfolio candidates.

Students are expected to participate in class discussions surrounding relevant case studies. Individually present the results of a research project involving the effective application of information technology to enhance drug discovery and development productivity or enhance the commercial potential of drug candidates. Research reports and presentations should address the following questions:

What stage(s) of the drug development process is the technology used within?
To what benefit?

What specific business need(s) does the technology address?

In what ways does the technology address those needs? To what benefit? At what cost?

Who are the major business stakeholders involved in the process?

In what way(s) are these stakeholders effected by the technology?

What technical/organizational obstacles must be overcome in implementing a technology solution?

How would you propose overcoming these obstacles?

A case study exemplifying these issues is acceptable. It should include appropriate citations.

Technology topics for consideration include:

Data Gathering

- Automatic Data Collection – Electronic Data Capture, Data Analysis
- Data Capture and Analysis Tools
- Data Entry and Verifications Software
- Web Based Electronic Data Capture
- Data generation, collection and Analysis Tools
- Statistical Analysis
- Robotics

Paperwork Management

- Document Management Tools
- Validation Electronic Records and Signatures
- Electronic submissions
- NDA - New Drug Application for small molecules
- BLA - Biologics License Application for protein/antibody drugs.
- Case Report Form Design
- CFR Part 11 Validation

Process Management

- Clinical Trial Management
- Computer Assisted Trial Design – Simulation Software
- LIMS – Laboratory Information Management Software
- Toxicology Management
- Trials Management Software
- Patient Management Tools (Pharmacogenomics, Molecular Profiling)

Experimental Facilitation

- DNA and Proteomic Analysis Tools
- Drug Target Validation tools

- Experimental Design Tools
- Expression Profiling Tools
- Imaging/Image Analysis Tools

Knowledge Facilitation/Exchange

- KM/ BioInformatics
- KM/Informatics
- Knowledge Management tools
- Decision Support Systems

Data Management

- Adverse Reaction Data Base
- Centralized Databases
- Centralized Databases, Electronic Libraries

Integrity Management

- Security
- Validation and Change Management
- Change Management

Communications Management

- Networking
- Web Based Technology

Other

- Design/Graphics
- Autoencoders
- BioInformatics

Relationship of Course to Rest of Curriculum

The role of the course in the total curriculum is to build on knowledge gained in prior core courses. It provides the student with an overview of drug discovery, development, and commercialization and the role of technology in increasing research and development productivity and enhancing the commercial potential of new drug compounds. The course integrates what the student has learned about how technology is currently being used in drug development with specific focus on the effective application of technology to address emerging needs around increased drug development productivity, reporting and disclosure, and global registration.

Learning Goals

This course provides a comprehensive overview of the drug discovery and development

process and the importance of information technology in the identification, screening, development, and commercialization of new medicines. Students will learn how promising new drugs are discovered, screened, and evaluated from the standpoint of their safety and efficacy. How drug commercialization decisions are made at each major phase in the drug development process. How information technology is used to increase drug development productivity as well as enhance the commercial potential of drug candidates. Class discussions will focus on ethical issues surrounding the conduct of clinical research, disclosure of clinical research results, and issues of regulatory compliance and reporting.

After taking this course, the student will be able to :

1. Outline the process of drug development from discovery through commercialization.
2. Describe the principal business drivers impacting drug development productivity.
3. Describe the role of information technology in the discovery, development, and commercialization of new drugs.
4. Identify key stakeholders for each major component of the drug development process.
5. Derive stakeholder requirements for applying new technologies to either enhance drug development productivity or increase the commercial value of new drug candidates.
6. Identify ways in which technology is used to address stakeholder requirements.
7. Identify organizational/technical roadblocks and impediments to implementing solutions.
8. Recommend how organizational/technical roadblocks and impediments can be overcome.

Pedagogy

This course typically combines lecture and cases. There are individual written assignments and formal presentations. Students are expected to use business terminology to credibly present their work to a knowledgeable business audience. Students are encouraged to understand both business and technology issues from the perspective of senior business technology managers.

Required Text(s)

Guarino, Richard A. (2004). *New Drug Approval Process: Fourth Edition Accelerating Global Registration*. Marcel Dekker, Inc., NY. ISBN: 0-8247-5041-1

Chapter	Topic
1	Drug Development Teams
2	Non-Clinical Drug Development: Pharmacology, Drug Metabolism, and Toxicology

3	The Investigational New Drug (IND) Application and the Investigator's Brochure
4	General Considerations of the New Drug Application (NDA)
5	The New Drug Application, Content and Format
10	Clinical Research Protocols
12	Biostatistics in Pharmaceutical Product Development
15	Data Presentation for FDA Submissions
19-22	The Management of Clinical Studies

Required Readings

Champion, D. 2001. Mastering the Value Chain: An Interview with Mark Levin of Millennium Pharmaceuticals. HBR Reprint R0106G.

Allyn, M. 2001. Diagnostic Genomics. HBR Reprint 9302004.

Enriquez, J, Pisano, G., and Bok, G. 2002. In Vivo to In Vitro to In Silico: Coping with Tidal Waves of Data at Biogen. HBR Reprint 9602122.

Arnold, R. et. al. 2006. Pharma 2020: The Vision. Price Waterhouse Coopers. Available at: <http://www.pwc.com/extweb/pwcpublishings.nsf/docid/91BF330647FFA402852572F2005ECC22>

Goldberg, R. and Pitts, P. 2006. Prescription for Progress: The Critical Path to Drug Development. Center for Medical Progress. Available at: http://www.manhattan-institute.org/html/fda_task_1.htm

Assignments

Exercises and Case Study Critiques

The course will use five case studies/industry reports to help students gain a more in-depth appreciation for relevant topics, and students are expected to read and provide a one page written critique of each case study including the following:

- Critique the Author(s) Conclusions or Propositions (Agree or Disagree)
- Highlight the Key Lessons Learned
- Suggestions on How to Improve the Author(s) Point
- If possible, suggest alternative rationale in the case study
- If possible, broaden or expand their key points with other examples, personal or work related.

Students are also expected to discuss the case study in class regarding their insights gained from the case study. The critiques will be due as per the class schedule.

Research Paper and Presentation

Each student is expected to do a report consisting of a written paper (10-15 pages) and an oral presentation (15 – 20 minutes). Presentations should include copies of the slides for other class members.

The context of the report should discuss how a specific technology can be used to impact the discovery, development, or commercialization of a new drug. The report should outline the specific business need or needs the technology is targeted to address, along with highlighting stakeholder issues and benefits, technical/organizational obstacles to be overcome, and recommended steps to be taken in addressing those obstacles.

Format Guidelines: The research paper should be typed in a **12 point** font, one inch margins, and a minimum of **1 ½ line spacing**. There are no formal requirements regarding the length of the paper, but typical reports (that include the necessary information) range from **10-15 pages (plus exhibits)** when spaced at 1 ½ lines. The oral report should consist of a Powerpoint presentation of your work (providing enough detail about your work to make it coherent) in class.

Assignment	Grade Percent
Class Discussions and Exercises	10%
Case Study Critiques	25%
Presentation	25%
Research Paper	40%
Total Grade	100%

Ethical Conduct

The following statement is printed in the Stevens Graduate Catalog and applies to all students taking Stevens courses, on and off campus.

“Cheating during in-class tests or take-home examinations or homework is, of course, illegal and immoral. A Graduate Academic Evaluation Board exists to investigate academic improprieties, conduct hearings, and determine any necessary actions. The term ‘academic impropriety’ is meant to include, but is not limited to, cheating on homework, during in-class or take home examinations and plagiarism.”

Consequences of academic impropriety are severe, ranging from receiving an “F” in a course, to a warning from the Dean of the Graduate School, which becomes a part of the permanent student record, to expulsion.

Reference: The Graduate Student Handbook, Academic Year 2003-2004 Stevens Institute of Technology, page 10.

Consistent with the above statements, all homework exercises, tests and exams that are designated as individual assignments MUST contain the following signed statement before they can be accepted for grading.

I pledge on my honor that I have not given or received any unauthorized assistance on this assignment/examination. I further pledge that I have not copied any material from a book, article, the Internet or any other source except where I have expressly cited the source.

Signature _____

Date: _____

Please note that assignments in this class may be submitted to www.turnitin.com, a web-based anti-plagiarism system, for an evaluation of their originality.

Course Schedule

Week	Topic	Material Discussed
1	Introduction and Overview	<p>Molecules to Medicines</p> <p>Overview of the drug discovery, development, and commercialization process and how technology is being used to carry out that process. Discussion of the critical business issues and drivers facing the industry along with the ways technology is being used to address those issues.</p> <p>Readings:</p> <ul style="list-style-type: none"> • <i>Guarino (2004) – Chapter 1</i> <p>Case Study Critiques:</p> <ul style="list-style-type: none"> • <i>Champion (2001) – Mastering the Value Chain: An Interview with Mark Levin of Mellennium Pharmaceuticals</i>
2 - 3	Drug Discovery and Screening	<p>Drug Candidate Screening, Identification, and Development</p> <p>Overview of the drug discovery process, from idea generation through the filing of an Investigational New Drug Application (IND). Discussion of the key enabling technologies, such as: molecular modeling, high throughput screening, combinatorial chemistry, robotics, modeling and simulation.</p> <p>Readings:</p> <ul style="list-style-type: none"> • <i>Guarino (2004) – Chapter 2 and 3</i> <p>Case Study Critiques:</p> <ul style="list-style-type: none"> • <i>Enriquez, J, Pisano, G., and Bok, G. (2002) – In Vivo to In Vitro to In Silico: Coping with Tidal Waves of Data at Biogen</i>
4 - 6	Early and Full Development	<p>Ensuring Drug Candidates are Safe and Effective</p>

		<p>Overview of early and full drug development with in-depth discussions of the conduct of pre-clinical and clinical research, patient privacy and informed consent, research protocols, ethics surrounding the conduct of clinical trials and the reporting of results, pharmacoeconomic modeling, drug portfolio management, clinical data analysis and reporting, study drug supply.</p> <p>Discussion of the key technologies used in the early and full development of new drug compounds.</p> <p>Readings:</p> <ul style="list-style-type: none"> • <i>Guarino (2004) – Chapter 10, 12, and 19 through 22</i> <p>Case Study Critiques:</p> <ul style="list-style-type: none"> • <i>Allyn (2001) – Diagnostic Genomics</i>
7	Registration	<p>The Road to Registration: the NDA Submission, Review, and Approval Process</p> <p>Discussion of the process of submitting a NDA for Regulatory review and approval. In-depth look at how the evidence compiled throughout the development of a new drug is submitted for review by an organization like the FDA. Discussion of the contents of a pharmaceutical product label, the specific requirements, content, and format for a computer-assisted NDA (CANDA). Reporting compliance obligations. Drug safety reporting and pharmacovigilance.</p> <p>Readings:</p> <ul style="list-style-type: none"> • <i>Guarino (2004) – Chapter 4, 5, and 15</i> <p>Case Study Critiques:</p> <ul style="list-style-type: none"> • <i>Arnold (2007) Pharma 2020: The Vision</i> • <i>Goldberg (2006) Prescription for Progress:</i>

		The Critical Path to Drug Development
8-10	Student Presentations	All case study critiques are due.
11-13	Special Topics	<p>Special Topics in New Drug Development</p> <p>Discussion of important topics related to the way technology is changing the model of drug discovery, development, and commercialization. Topics include:</p> <ul style="list-style-type: none"> • Pharmacogenomics • Patient Surveillance Databases and Outcomes Modeling • Safety Data Mining and Signal Detection • Electronic Clinical Trials • Electronic Health Records • Knowledge Integration <p>Particular topics for discussion are based on student interest.</p>