

CHEM/BUS/ECON 341 Drug Discovery and Development

Spring 2008

Instructors

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Catalog Description

CHEM/ BUS/ ECON 341. Drug Discovery and Development (3 units)

Three hours of lecture a week. Prerequisite: None

The class will focus on how drugs are discovered, developed and marketed in the context of the pharmaceutical and biotechnology industry. Topics to be covered may include the isolation of compounds from natural sources, the screening of compounds for biological activity, structure-activity relationships of drugs, computer-assisted drug design, combinatorial chemistry, bioinformatics, the FDA approval process for new drugs, and the economic and business aspects of pharmaceutical development.

GenEd-ID: B1, D

Additional Description

The class will follow the progression of drug development from discovery through clinical development to market launch. An overview of scientific methods of discovery and development will be provided. This course will integrate scientific, economic, and business content related to the process by which drugs are discovered and developed into pharmaceutical products.

It is expected that all students will become familiar with the three interdisciplinary aspects of the course: chemistry, business and economics. An understanding of the drug discovery process is important for future scientists, legislators, health care providers and consumers, potential investors, and the media. The course will cover the various ways that drugs are discovered, how drugs are screened and tested, how start-up companies raise capital for developing drugs, the government approval process for new drugs, patents, marketing and pricing of drugs, and generic drugs. Credit in this course could either be applied as an elective in the B.S. in Business (as BUS 341) or as an elective outside of the Business program (as ECON 341 or CHEM 341). Students pursuing a B.S. in Biology should consider taking this course as a general education elective outside of the Biology major. This course provides credit toward the Chemistry minor.

Course Outcomes

Through this course, students will be able to:

- Identify the stages involved in the discovery, development, and approval of a pharmaceutical by the FDA.
- Understand basic chemical properties that make a molecule a good drug.
- Evaluate the scientific and business challenges faced by a pharmaceutical company.
- Understand ethical issues involved in the development of pharmaceuticals.
- Understand business concepts as related to a start-up pharmaceutical company.

Class Schedule

Date	Exam	Location
February 27, 2008	Midterm 1	Science Auditorium
March 26, 2008	Midterm 2	Science Auditorium
April 23, 2008	Midterm 3	Science Auditorium
TBD	Final Exam	

Course Materials

Rick Ng, *Drugs-From Discovery to Approval*, Wiley, 2004

Supplemental articles and lecture notes will be posted on the blackboard website.

Grades

Your grade in the course will be determined as indicated below.

Scores will be weighted as follows:

Class Participation:	10%
2 Exams*:	45%
Written Assignment:	20%
Final Examination:	25%
Total	100%

***The lowest grade among midterm #1, midterm #2, and midterm #3 will be dropped.**

Failure to take the exams, or to complete a problem set, will result in a score of zero and will be factored into your final grade.

Extra credit quizzes may be given during lecture without being announced.

Grades will be distributed in the following manner, with +/- as appropriate in each range.

Percentage	Grade
90-100	A
80-90	B
70-80	C
60-70	D
<60	F

Academic Dishonesty

All students are expected to complete assignments in this course as their own work. Plagiarism is defined as to pass off the ideas or words of another as one's own without crediting the source. If the instructors suspect a student has violated the academic honesty guidelines, they will discuss the apparent violation with the student to provide them with an opportunity to explain the situation. If the instructors feel that Academic Dishonesty has occurred, they will report the matter to the Vice President for Academic Affairs. Depending on the severity of the offense, the instructors may assign the responsible student a failing grade on the assignment/quiz/exam or an overall course grade of an "F."

Students with Special Needs

Students with physical or learning disabilities are encouraged to contact the Student Services office (437-8510) for personal assistance. Handouts are available in alternative accessible formats on request.

Tentative Course Outline for Drug Discovery and Development

- Introduction to the Course and the Syllabus
- Overview of the Drug Discovery and Development Process - the Compound, the FDA, the Patent and the Market
- How Science Works.
- Proteins, Targets, Receptors and Disease
- Pharmacology & Toxicology - reading a Label
- Science and Medical Practice - Prescriptions
- The Heart, cholesterol and Statins
- Pre-clinical Studies - Design, Identification of the Compound, Pharmacodynamics, Pharmacokinetics
- FDA - History and Paradigms of Regulation (or not)

- Basics of FDA Regulations - the IND and NDA
- Intellectual Property - the Compound, Patent Review, Patent Application, Trade Secrets and Trademarks
- The economics of Patents - monopoly, oligopoly, and competition
- Strategic Planning for Pharma
- Market Assessment
- The Inventive Entrepreneurial Process
- Investment Securities and the Firm
- Specification of the Drug - Reliability and Manufacturing
- Clinical trials - Design, Protocol, and the FDA
- Project Management
- Research and Experimentation tax Credits; Accounting for R&E
- Reimbursement and Coding
- Regulatory Systems for Drug Approval and Payment Systems- Foreign
- Pharmacoeconomics
- Social Entrepreneurship
- Orphan Drugs
- Biotechnology, Biologics vs. Traditional Pharmaceuticals
- Branding
- Vaccines and Immunology
- Gene therapy and Stem cells