NEW COURSE PROPOSAL

PROGRAM: BIOLOGICAL AND PHYSICAL SCIENCES, BUSINESS

1. Catalog Description of the Course. [Include the course prefix, number, full title, and units. Provide a course narrative including prerequisites and corequisites. If any of the following apply, include in the description: Repeatability (May be repeated to a maximum of ___ units); time distribution (Lecture ___ hours, laboratory ___ hours); non-traditional grading system (Graded CR/NC, ABC/NC). Follow accepted catalog format.]

BUS 341. DRUG DISCOVERY AND DEVELOPMENT (3)
Three hours lecture per week.
How are drugs discovered? What determines the price for a drug? What is the difference between a generic and non-generic drug? These questions will be examined with an interdisciplinary approach. Topics 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 investment and development.
Same as CHEM 341, ECON 341. GenEd: B1, D and Interdisciplinary

CHEM 341. Drug Discovery and Development (3)
Three hours lecture per week.
How are drugs discovered? What determines the price for a drug? What is the difference between a generic and non-generic drug? These questions will be examined with an interdisciplinary approach. Topics 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 investment and development.
Same as BUS 341, ECON 341. GenEd: B1, D and Interdisciplinary

ECON 341. Drug Discovery and Development (3)
Three hours lecture per week.
How are drugs discovered? What determines the price for a drug? What is the difference between a generic and non-generic drug? These questions will be examined with an interdisciplinary approach. Topics 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 investment and development.
Same as BUS 341, CHEM 341. GenEd: B1, D and Interdisciplinary

2. Mode of Instruction.

<table>
<thead>
<tr>
<th>Units</th>
<th>Hours per Unit</th>
<th>Benchmark Enrollment</th>
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<tbody>
<tr>
<td>Lecture</td>
<td>3</td>
<td>1</td>
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<td>Seminar</td>
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<td>Activity</td>
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3. Justification and Learning Objectives for the Course. (Indicate whether required or elective, and whether it meets University Writing, and/or Language requirements) [Use as much space as necessary]

Genearl Education Course: B1, D and Upper-division Interdisciplinary

Students who successfully complete this course will be able to:
- Describe the scientific method and how it is used to approach scientific problems
Explain basic chemistry concepts including simple bonding theory, functional groups, molecular structure and geometry, hydrophilicity/hydrophobicity, and acid-base properties.

Explain basic biological and biochemical concepts including the structures of proteins, DNA, and RNA, gene regulation, cell growth and development, interactions between biomolecules, and cancer and other disease states.

Identify the stages involved in the discovery, development, and approval of a pharmaceutical by the FDA.

Evaluate the scientific and business challenges faced by a pharmaceutical company.

Evaluate ethical issues involved in the development of pharmaceuticals.

Explain business concepts as related to a start-up pharmaceutical company.

4. Is this a General Education Course  YES  NO

If Yes, indicate GE category:

| A (English Language, Communication, Critical Thinking) | X |
| B (Mathematics & Sciences) | X |
| C (Fine Arts, Literature, Languages & Cultures) | X |
| D (Social Perspectives) | X |
| E (Human Psychological and Physiological Perspectives) | |

5. Course Content in Outline Form. [Be as brief as possible, but use as much space as necessary]

*Introduction to the Course*
  Sources of Drugs
  Overview of Discovery and Development

*The Amgen Story*

*Basic Chemistry*
  Bonding and Atom Geometries
  Hydrogen-bonding
  Molecular Conformation and Molecular Modeling
  Polarity and Acid-Base Chemistry
  Functional Groups
  Chirality
  Lipophilicity and Solubility

*Basic Biology and Biochemistry*
  Cell Structure
  DNA and RNA Structure and Function
  Amino Acids and Protein Structure
  Ligand-Receptor Interactions
  Molecular Biology

*Basic Pharmaceutical Biology and Chemistry*
  Toxicology
  Drug Metabolism
  Pharmacokinetics

*Challenges and Opportunities in Drug Discovery and Development*
  Identification of Biological Targets
  Biological Informatics and the Human Genome
  Expression and Purification of Targets
  Assay Development
  Organization of the Research Project Team

*Financing the Drug Development Process*
  Venture Capital
  Investment Decision Making
  Capital Allocation

*Advanced Drug Discovery*
  Medicinal Chemistry
  High Throughput Screening (HTS) and Combinatorial Chemistry
  QSAR

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Structural and Rational Drug Design
X-ray Crystallography and Computer-Aided Drug Design

Pre-Clinical Development
Toxicology
Drug Metabolism Studies
Drug Delivery and Formulation
Scientific Advisory Boards

Business and Economic Aspects of the Drug Discovery and Development Process
Management of a Start-Up Company
Management of the Scientific Process
Economic Cost and Application to Drug Development
Critical Path Management

Clinical Development
The FDA and Drug Development: Investigational New Drug Application,
Treatment IND
Clinical Development
Clinical Trials, Study Design, Informed Consent
Patenting and Intellectual Property Rights
FDA Approval

Marketing and Manufacturing
IPO, Stock Market
Public Perception
Economy of Scale
Marketing
Drug Pricing Issues and Impact of Markets, Government Regulation, and Patents on Pricing
Process Development
Advertising, Direct-to-Consumer

Threats and Opportunities
Patent Expiration
Over-the-Counter
Generic Competition
Reformulation
On-going Research and Development
Health Insurance and Drug Coverage
Government Policies to Control Drug Pricing and the Effect of Controls on Drug Pricing and Availability
Ethical Issues in Drug Development
Orphan Drugs
Human Genome and Customized Pharmaceutical Drugs

6. References. [Provide 3 - 5 references on which this course is based and/or support it.]

From Test Tube to Patient: Improving Health through Human Drugs, U.S. Food and Drug Administration,
Trials, Centerwatch, 2002

7. List Faculty Qualified to Teach This Course.

Dr. Philip Hampton, Dr. William Cordeiro, Dr. Dennis Muraoka, Dr. Ashish Vaidja, Dr. Paul Rivera

8. Frequency.
a. Projected semesters to be offered: Fall _X_ Spring _X_ Summer _____

9. New Resources Required.
None.

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10. **Consultation.**
    Attach consultation sheet from all program areas, Library, and others (if necessary)
    *(See Attached Forms)*

11. If this new course will alter any degree, credential, certificate, or minor in your program, attach a program modification.

    ___________Philip Hampton__________________1/8/03__________________________
    Proposer of Course                  Date