CALIFORNIA STATE UNIVERSITY CHANNEL ISLANDS

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.**

	Units	Hours per Unit	Benchmark Enrollment
Lecture	3	1	30
Seminar			
Laboratory			
Activity			

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)	
B (Mathematics & Sciences)	**X**
C (Fine Arts, Literature, Languages & Cultures)	
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

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.]*

Thomas, G. *Medicinal Chemistry: An Introduction*, John Wiley & Sons,2000.
Patrick, G. *Medicinal Chemistry: An Introduction*, Oxford 2001.
From Test Tube to Patient: Improving Health through Human Drugs, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Special Report, 1999.
Werth, B. *The Billion Dollar Molecule*, Touchstone, 1995.
Drews, J. and Drews, J. *In Pursuit of Tomorrow's Medicines*, Springer, 2002.
Getz, K. *et al. Informed Consent: The Consumer's Guide to the Risks and Benefits of Volunteering for Clinical 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.

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

Consultation:

_____

Prof. Dennis Muraoka Date

_____

Prof. William Cordeiro Date