California Sate University Channel Islands

NEW COURSE PROPOSAL

Courses must be submitted by November 3, 2008, for priority catalog review.

DATE (*Change if modified and redate file with current date)*) 10-7-08 REV 11.17.08
PROGRAM AREA(S) BIOLOGY

1. Course Information. *[Follow accepted catalog format.]*

Prefix(es) (Add additional prefixes if cross-listed) **and Course No. BIOL 500**
Title: : Introduction to Biopharmaceutical Production Operations Units: 3

Prerequisites
Corequisites
Consent of Instructor Required for Enrollment

Catalog Description (Do not use any symbols): **An** introduction to biopharmaceutical production systems and processes. Topics include manufacturing, unit operations and supporting infrastructures, product distribution, quality assurance and control, facility engineering and maintenance, utility operations, regulatory compliance, and laboratory support.

Grading Scheme:
x A-F Grades
Credit/No Credit
Optional (Student Choice)

Repeatability:
Repeatable for a maximum of units
Total Completions Allowed
Multiple Enrollment in Same Semester

Course Level Information:
Undergraduate
Post-Baccalaureate/Credential
x Graduate

Mode of Instruction/Components (*Hours per Unit are defaulted*).

	Units	Hours per Unit	Benchmark Enrollment	Graded Component	CS & HEGIS # (Filled in by the Dean)
Lecture	3	1	30	x	
Seminar		1			
Laboratory		3			
Activity		2			
Field Studies					
Indep Study					
Other Blank					

Leave the following hours per week areas blank. The hours per week will be filled out for you.
3 hours lecture per week
hours blank per week

2. Course Attributes:

General Education Categories: All courses with GE category notations (including deletions) must be submitted to the GE website: http://summit.csuci.edu/geapproval. Upon completion, the GE Committee will forward your documents to the Curriculum Committee for further processing.

A (English Language, Communication, Critical Thinking)
A-1 Oral Communication
A-2 English Writing
A-3 Critical Thinking

B (Mathematics, Sciences & Technology)
B-1 Physical Sciences
B-2 Life Sciences – Biology
B-3 Mathematics – Mathematics and Applications
B-4 Computers and Information Technology

C (Fine Arts, Literature, Languages & Cultures)
C-1 Art
C-2 Literature Courses

C-3a Language
C-3b Multicultural
D (Social Perspectives)
E (Human Psychological and Physiological Perspectives)
UDIGE/INTD Interdisciplinary
Meets University Writing Requirement
Meets University Language Requirement

American Institutions, Title V Section 40404: Government US Constitution US History
Refer to website, Exec Order 405, for more information: http://senate.csuci.edu/comm/curriculum/resources.htm
Service Learning Course (Approval from the Center for Community Engagement must be received before you can request this course attribute).

3. Justification and Requirements for the Course. (Make a brief statement to justify the need for the course)

A. Justification: The current curriculum of the MS in Biotechnology and Bioinformatics program was designed with a strong emphasis on the domains of Research and Product Development. It has strong basic science content and also addresses subjects such as law, regulatory compliance specifically with respect to product development, informatics, human resouce and project management. An opportunity that would enhance the program and render it more holistic is to address the world of Operations and Product Supply. This is particularly important given that 30% to 45% of total workforce of the biopharmaceutical industry is in Operations. The proposed course is an overview of the infrastructure, the regulations, the quality assurance and the science behind the processes that supply large quantities of biopharmaceuticals to the marketplace. This is going to be an elective course for the MS in Biotechnology and Bioinformatics program. It is going to be offered through Extended Education as part of a self-supported program.

B. Degree Requirement:
Requirement for the Major/Minor
x Elective for the Major/Minor
Free Elective

Note: Submit Program Modification if this course changes your program.

4. Learning Objectives. (*List in numerical order*)

Upon completion of the course, the student will be able to:

1. describe the processes, the facilities, the regulations, and the systems that are necessary for the production and supply of biopharmaceuticals;
2. communicate with experts in the domains of recombinant DNA technology, the unit operations associated with cell culture and fermentation, upstream recovery and downstream purification, formulation, and filling and packaging;
3. describe the international regulations associated with the industry, the scientific principles and rationale of the regulations, and draw the connections between the regulations, scientific principles and the quality systems that are put in place to assure the safety of the patients;
4. describe the concepts around the design and operation of facilities and the infrastructures that support their operation.

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

1. Biopharmaceutical Industry and Production Overview
    a. Understanding the Product Development Lifecycle
2. Manufacturing Unit Operations
    a. Cell Culture/ Fermentation
    b. Upstream Recovery Processes (Ex. Filtration, Centrifugation, Homogenization)
    c. Downstream Purification Processes (Ex. Precipitation, Diafiltration, Chromatography)
    d. Formulation, Filling and Packaging
3. Regulatory Requirements
    a. cGMPs and GDPs
4. Manufacturing Facility Design Maintenance
5. Manufacturing Supporting Systems and Processes
    a. Utilities
    b. Controls
6. Quality Systems
    a. Quality Assurance
    b. Quality Control
    c. Validation
    d. Raw Material Management

7. Distribution, Warehousing and Transportation

Does this course content overlap with a course offered in your academic program? **Yes** **No** x
If YES, what course(s) and provide a justification of the overlap.

Does this course content overlap a course offered in another academic area? **Yes** **No** x
If YES, what course(s) and provide a justification of the overlap.

Overlapping courses require Chairs' signatures.

6. Cross-listed Courses (*Please note each prefix in item No. 1)*

A. List Cross-listed Courses (Signature of Academic Chair(s) of the other academic area(s) is required).
List each cross-listed prefix for the course:

B. Program responsible for staffing: Biology

7. References. *[Provide 3 - 5 references]*

1. Biopharmaceuticals, Biochemistry and Biotechnology, by Gary Walsh, 2nd edition 2003, John Willey and Sons Ltd.
2. Fermentation and Biochemical Engineering Handbook: Principles, Process Design, and Equipment, by Henry C. Vogel and Celeste C. Todaro, Noyes Publications, 1997
3. Advanced Technology in Pharmaceutical Processing, by Roshni Dutton and Jeno Scharer, Blackwell Publishing 2007.
4. Protein Purification Techniques, by Simoon Roe, Oxford University Press, 2nd edition 2001.
5. Code of Federal Regulations, Food and Drug Administration 21 CFR
6. ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guideline for Active Pharmaceuticals Q7

8. Tenure Track Faculty Qualified to Teach This Course.

Biology faculty

9. Requested Effective Date:
First semester offered: 2009

10. New Resources Requested. Yes **No** x
If YES, list the resources needed.

A. Computer Needs (data processing, audio visual, broadcasting, other equipment, etc.)
No.

B. Library Needs (streaming media, video hosting, databases, exhibit space, etc.)
No.

C. Facility/Space/Transportation Needs
Using Extended Education's Thousand Oaks classroom.

D. Lab Fee Requested (please refer to Dean's Office for additional processing) **Yes** **No** x

E. Other

11. Will this new course alter any degree, credential, certificate, or minor in your program? Yes **No** x

If, YES attach a program update or program modification form for all programs affected.

Priority deadline for New Minors and Programs: October 6, 2008 of preceding year.

Priority deadline for Course Proposals and Modifications: November 3, 2008, of preceding year.

Last day to submit forms to be considered during the current academic year: April 15th.

Ching-Hua Wang	10-7-08
Proposer of Course (Type in name. Signatures will be collected after Curriculum approval)	Date

Approval Sheet

Program/Course:
If your course has a General Education Component or involves Center affiliation, the Center will also sign off during the approval process.

Multiple Chair fields are available for cross-listed courses.

Program Chair		
	Signature	Date
Program Chair		
	Signature	Date
Program Chair		
	Signature	Date
General Education Chair		
	Signature	Date
Center for International Affairs Director		
	Signature	Date
Center for Integrative Studies Director		
	Signature	Date
Center for Multicultural Engagement Director		
	Signature	Date
Center for Civic Engagement Director		
	Signature	Date
Curriculum Chair		
	Signature	Date
Dean of Faculty		
	Signature	Date