California State University Channel Islands

NEW COURSE PROPOSAL

Courses must be submitted by November 2, 2009, for priority catalog review.

DATE (*Change if modified and redate file with current date)*) 9-22-09; REV 12.11.09; REV 1.13.10
PROGRAM AREA(S) BIOLOGY

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

Prefix(es) (Add additional prefixes if cross-listed) **and Course No. BIOL 516**
Title: CLINICAL TRIALS AND QUALITY ASSURANCE Units: 3
xxx Prerequisites BIOL 503
Corequisites
Consent of Instructor Required for Enrollment
Catalog Description (Do not use any symbols): An introduction to the foundational knowledge and skills necessary to successfully conduct clinical trials for new drugs, biologics, and medical devices, including *in vitro* diagnostics. Topics include a broad overview of the product development process in the pharmaceutical, biopharmaceutical, and medical device industries, the regulatory and operational requirements for clinical study setup and management, monitoring, data management, and closure of clinical trials, the principles of Good Clinical Practice (GCP), and the applications of quality control and quality assurance. The integration of quality assurance throughout the medical product development process will be discussed.

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: This is an elective course for the MS Biotechnology and Bioinformatics program. Through this course, students will learn important aspects of clinical trials and quality assurance in the field of biotechnology.

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. You may wish to use the following resource in utilizing measurable verbs: http://senate.csuci.edu/comm/curriculum/resources.htm*)

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

- Explain the structure and function of the U.S. Food and Drug Administration (FDA) and its history
- Participate in the medical product development process
- Apply ethical considerations in clinical trials, incorporating current and historical perspectives
- Comply the U.S. regulatory requirements for clinical testing of new drugs, biologics, and medical devices, including *in vitro* diagnostics, and combination products
- Demonstrate an understanding of the application and importance of Good Clinical Practice (GCP)
- Engage in the clinical trials process from planning to study close-out
- Implement clinical trial monitoring, study and data management best practices
- Identify the concepts of quality control and assurance as related to GCP and other areas of medical product development

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

- Introduction to the structure and function of the U.S. Food and Drug Administration (FDA) and its history
- Review of the medical product development processes
- Comprehensive overview of the U.S. regulatory requirements for clinical testing of new drugs, biologics, and medical devices, including *in vitro* diagnostics, and combination products
- Ethical issues in clinical trials
- Application and importance of Good Clinical Practice (GCP)
- Institutional Review Board (IRB) requirements and best practices
- Informed Consent history and requirements
- The processes of planning, initiating, executing, and closing clinical trials
- Review of the key elements and importance of the study Protocol and Investigator Brochure (IB)
- Function and importance of Case Report Forms (CRFs) or equivalent, database development and validation, and data management
- Clinical trial monitoring best practices
- Statistical analysis in clinical trials
- Requirements for preparation of the Clinical Study Report
- Quality control and assurance (Quality Systems) as related to GCP and other areas of medical product development

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]*

Guide to Drug Development: A Comprehensive Review and Assessment by Burt Spilker, Publisher: Lippincott Williams & Wilkins, 2009, ISGN-10: 0781774241.

A Manager's Guide to the Design and Conduct of Clinical Trials (Manager's Guide Series) by Phillip I. Good, Publisher: Wiley-Liss; 2nd edition, 2006, ISBN-10: 0471788708.

Clinical Trials: A Methodologic Perspective Second Edition (Wiley Series in Probability and Statistics) by Steven Piantadosi, Publisher: Wiley-Interscience; 2 edition, 2005, ISBN-10: 0471727814.

Biologics Development: A Regulatory Overview, edited by Mark Mathieu, Publisher: PAREXEL International Corporation, 3rd edition, 2004, ISBN: 1-882615-67-0

New Drug Development: A Regulatory Overview, edited by Mark Mathieu, Publisher: PAREXEL International Corporation, 8th edition, 2008, ASIN: B0013AMIII.

Principles and Practices of Clinical Research by John I. Gallin and Frederick P. Ognibene, Publisher: Elsevier, Inc., 2007, ISBN-10: 012369440X.

Clinical Trials & Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky, JD, MPH, and Rodney K. Adams, Publisher: John Wiley & Sons, 2003, ISBN: 0-7879-6570-7.

Introduction to Statistical Methods for Clinical Trials (Texts in Statistical Science) by Thomas D. Cook and David L. DeMets, Publisher: Chapman & Hall/CRC; 1 edition, 2007, ISBN-10: 1584880279.

The Pharmaceutical Regulatory Process, Second Edition by Ira R. Berry and Robert P. Martin, Publisher: Informa Healthcare USA, Inc., 2008, ISBN-10: 1420070428.

Preclinical Safety Evaluation of Biopharmaceuticals, edited by Joy A. Cavagnaro, Publisher: John Wiley & Sons, 2008, ISBN: 978-0-470-10884-0.

Quality Systems and Control for Pharmaceuticals by Dipak Kumar Sarker, Publisher: John Wiley & Sons Ltd., 2008, ISBN-10: 0470056932.

8. Tenure Track Faculty Qualified to Teach This Course.

Biology faculty

9. Requested Effective Date:

First semester offered: S11

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

A. Computer Needs (data processing, audio visual, broadcasting, other equipment, etc.)

B. Library Needs (streaming media, video hosting, databases, exhibit space, etc.)

C. Facility/Space/Transportation Needs

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 5, 2009 of preceding year.
Priority deadline for Course Proposals and Modifications: November 2, 2009, of preceding year.
Last day to submit forms to be considered during the current academic year: April 15th.

Ching-Hua Wang 10-5-09

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