California State University Channel Islands

NEW COURSE PROPOSAL

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

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

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:

- A-F Grades

-Credit/No Credit

Optional (Student Choice)

Repeatability:

- Repeatable for a maximum of

Course Level Information:

- Undergraduate

- Graduate

Total Completions Allowed

Multiple Enrollment in Same Semester

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

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<tr>
<th>Units</th>
<th>Hours per Unit</th>
<th>Benchmark Enrollment</th>
<th>Graded Component</th>
<th>CS &amp; HEGIS #</th>
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<tr>
<td>Lecture</td>
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<td>1</td>
<td>30</td>
<td>x</td>
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<td>Seminar</td>
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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
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 ☑ Elective for the Major/Minor
   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)*


8. **Tenure Track Faculty Qualified to Teach This Course.**

   Biology faculty

9. **Requested Effective Date:**

   9.15.08 km2
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.

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<thead>
<tr>
<th>Chair Name</th>
<th>Signature</th>
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<tbody>
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<td>Program Chair</td>
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<td>Program Chair</td>
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<td>Dean of Faculty</td>
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