

CBM003 ADD/CHANGE FORM

Undergraduate Council
 New Course Course Change
 Core Category: NONE Effective Fall 2007

or Graduate/Professional Studies Council
 New Course Course Change
 Effective Fall ____

RECEIVED OCT 13 2006

APPROVED JAN 24 2007

- Department: ET College: TECH
- Person Submitting Form: Rupa Iyer Telephone: 713-743 4076
- Course Information on New/Revised course:
 - Instructional Area / Course Number / Long Course Title:
BTEC / 2320 / Biotechnology Regulatory Environment
 - Instructional Area / Course Number / Short Course Title (30 characters max.)
BTEC / 2320 / BIOTECH REGULATORY ENVIRONMENT
 - SCH: 3.00 Level: SO CIP Code: 2612020002 Lect Hrs: 3.0 Lab Hrs: 0
- Justification for adding/changing course: To provide for new discipline areas
- Was the proposed/revised course previously offered as a special topics course? Yes No
 If Yes, please complete:
 - Instructional Area / Course Number / Long Course Title:
____ / ____ / ____
 - Content ID: _____ Start Date (yyyy3): _____
- Is this course offered for undergraduate credit only? Yes No
- Authorized Degree Program(s): BS, Biotechnology
 - Does this course affect major/minor requirements in the College/Department? Yes No
 - Does this course affect major/minor requirements in other Colleges/Departments? Yes No
 - Are special fees attached to this course? Yes No
 - Can the course be repeated for credit? Yes No
- Grade Option: Letter (A, B, C ...) Instruction Type: lecture
- If this form involves a change to an existing course, please obtain the following information from the course inventory: Instructional Area / Course Number / Long Course Title
 ____ / ____ / ____
 • Start Date (yyyy3): _____ Content I.D.: _____

10. Proposed Catalog Description:
 Cr: (3-0) Prerequisites: BIOL1361/1161 and CHEM 1332/1112. Description (30 words max.): Structure of FDA and other regulatory agencies, steps in the approval processes and role of government oversight and regulation during the discovery, development and manufacture of new biotechnology products.

11. Dean's Signature:  Date: 10/12/06
 Print/Type Name: Fred D. Lewallen

University of Houston
Proposed Course Outline for BTEC 2320, Biotechnology Regulatory
Environment

Course Objectives: Students who successfully complete this course will be able to:

- Correlate changes in biotechnology and pharmaceutical production.
- Correlate quality, safety, and regulatory issues in biotechnology to practices employed in total quality management to assure excellence and safety.
- Understand FDA (Food and Drug Administration) regulations in regard to cGMP (current Good Manufacturing Practices) and cGLP (current Good Laboratory Practices) practices.
- Evaluate compliance of laboratories and manufacturing facilities in accordance with FDA and other governing regulations.
- Interpret and evaluate validation procedures.
- Prepare and evaluate SOPs (standard operating procedures) as they relate to development and processing of products.
- Recognize, appraise and assess a wide variety of manufacturing documents and their respective uses.

Course Outline

- 1. Introduction to total quality management: how sound business practices assure quality and safety:**
- 2. Current good manufacturing practices (cGMP):**
 - a. Assuring and proving product safety, identity, strength, quality, purity.
 - b. Standards of formation, fermentation, sterilization, lyophilization, and depyrogenation.
- 3. Issues in quality assurance and quality control:**
 - a. Calibration and automation.
 - b. Quality assurance practices.
 - c. ISO 9000: international quality standards for manufacturing.
- 4. The Food and Drug Administration:**
 - a. Background and history.
 - b. Clinical trials.
 - c. Interaction with industry
- 5. Validation:**
 - a. Retrospective validation.
 - b. Prospecting validation.
- 6. The Environmental Protection Agency:**
- 7. Agricultural biotechnology and the United States Department of Agriculture:**
- 8. Issues in Organization and personnel, buildings and facilities, and equipment:**
- 9. Control of components:**
 - a. Process control.

- b. Packaging in labeling.
- c. Holding in distribution.
- d. Records and reports.
- e. Returned goods.

10. Control and monitoring operations:

11. Automation issues:

- a. Information systems

12. Intellectual property, patents in biotechnology:

13. The future in biotechnology industry: economic trends and social consideration

Required Text: Moorpark College, *Industrial Biotechnology*. Thompson Learning, 2001. ISBN: 0 7593 0514 5