CBM003 ADD/CHANGE FORM

☒ Undergraduate Council	or	☐ Graduate/Professional Studies Council
☒ New Course ☐ Course Change		☐ New Course ☐ Course Change
Core Category: NONE Effective Fall 2007		Effective Fall __

1. Department: ET College: TECH

RECEIVED OCT 1 3 2006

2. Person Submitting Form: Rupa Iyer Telephone: 713-743-4076

APPROVED JAN 2 4 2007

3. Course Information on New/Revised course:
   - Instructional Area / Course Number / Long Course Title:
     BTEC / 2321 / Good Manufacturing Practices
   - Instructional Area / Course Number / Short Course Title (30 characters max.)
     BTEC / 2321 / GOOD MANUFACTURING PRACTICES
   - SCH: 3.00 Level: SO CIP Code: 2612010002 Lect Hrs: 3.0 Lab Hrs: 0
4. Justification for adding/changing course: **To provide for new discipline areas**
5. 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): _____
6. Is this course offered for undergraduate credit only? ☒ Yes ☐ No
7. 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
8. Grade Option: Letter (A, B, C ...) Instruction Type: lecture
9. 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.): Current Good Manufacturing Practices (GPM) as they apply in the biotechnology workplace. Examine the history, rationale, purpose, and GMP requirements applicable to the manufacuring, packaging and labelling, testing, and control of pharmaceutical products and consequence of inaction.
11. Dean's Signature: [redacted] Date: 10/12/06

    Print/Type Name: Fred D. Lewallen

University of Houston

Proposed Course Outline for BTEC 2321, Good Manufacturing Practices

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

- Be familiar with FDA regulations that guide companies to manufacture safe and effective products
- Gain a basic understanding of GMP concepts and key requirements for proper implementation of a GMP program in a biotechnology or pharmaceutical industry
- Apply basic principles of GMP facility design and operation, product development and process and product evaluation

Course Outline

1. **Introduction to GMPs**
   a. What are cGMPs
   b. History of GMPs
   c. Drug laws and regulations
   d. Definition of Drugs and Biologics
   e. Definitions Used in cGMP Manufacturing
   f. Sections of Manufacturing Governed by GMPs
   g. Compliance and Legal Consequences of Non Compliance
2. **Validation**
   a. Definitions
   b. Importance
   c. Areas that need Validation
3. **Quality**
   a. Importance of Quality
   b. What is Quality Control/Quality Assurance?
   c. Role of Quality Assurance in the Pharmaceutical Industry
   d. Personnel Responsibilities in cGMP environment
4. **Documentation and Guidelines**
   a. Record Keeping
   b. Batch Records
   c. Standard Operating Procedures / Work Instructions
   d. Unacceptable Documentation Practices
   e. Importance of Specifications

5. **Safety and Labeling**
    a. General Laboratory Safety
    b. Receiving, Labeling, Handling and Storing Chemicals and Biological Products
    c. Spills and Emergencies
    d. Hazardous and Medical Waste Disposal
    f. Product labeling requirements
6. **Cleaning and Maintenance**
    a. Importance of Cleaning
    b. Mechanisms of Cleaning
    c. Cleaning Agents
    d. Preventive Maintenance and Calibration
7. **Annual Inspections and Audits**
    a. Steps in the Inspection Process
    b. Audits

Recommended Text: Moorpark College, Industrial Biotechnology, 2001, 1st Edition, Thompson Learning