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 / 3320 / Introduction To Quality Control/Quality Assurance
   - Instructional Area / Course Number / Short Course Title (30 characters max.)
     BTEC / 3320 / QUALITY CONTROL/ASSURANCE
   - SCH: 3.00 Level: JR 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 (3-0), Prerequisites: CHEM 3331 and 3221, BTEC2320, 2321 Description (30 words max.): Quality control techniques, quality assurance issues, and quality management methods. Quality in design and planning, quality in the constructed project, and quality in production of goods and services.
11. Dean's Signature: [redacted] Date: 10/12/06

    Print/Type Name: Fred D. Lewallen

University of Houston
Proposed Course Outline for Quality Control and Quality Assurance

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

- Identify the key components of Quality Systems currently in use in the Biotechnology industries
- Understand role of pertinent regulatory agencies as they relate to Quality Systems in the industry.
- Describe the critical regulatory guidance's issued by the International Committee on Harmonization, and Food & Drug Administration of the USA, and its equivalents in Europe and Japan.
- Gain a thorough knowledge of quality by design as it applies to the manufacture of drugs for human clinical use.
- Understand the regulatory and legal importance of Quality as it applies to the pre-clinical, clinical, and post commercialization for drugs for human use.

Course Outline

1. **Introduction:**
    a. What is the Quality System and why it is important to the pharmaceutical and biotechnology industry.
2. **The cGMP and the cGLP Regs**
    a. Introduction
    b. Review of the cGMP and cGLP regs.
    c. Importance of implementation of the cGMPs and cGLPs
3. **Quality Systems (as described by FDA)**
    a. Types
    b. Components of Quality Systems
4. **Quality Assurance**
    a. What is Quality Assurance?
    b. Role of Quality Assurance in Pharmaceutical Industry
    c. Personnel Responsibilities in cGMP environment
5. **Drug Manufacture**
    a. Process as it applies to Small Molecules, biologics, industrial enzymes, and devices
    b. Supply chain considerations
    c. Process validations
    d. Application of cGMPs and cGLPs
6. **Quality Control of Products**
    a. Analytical methods and development
    b. Test equipment
7. **Drug Manufacture (II)**
    a. Supply chain considerations
    b. Process validation
    c. Application of cGMPs and cGLPs

8. **Drug Development**
    a. Pre-Clinical
    b. Clinical
9. **Control of components:**
    a. Process control.
    b. Packaging in labeling.
    c. Holding in distribution.
    d. Records and reports.
    e. Returned goods.
10. **Commercial lunch and Commercial Production**
    a. What is commercial lunch and commercialization? Why were the cGXPs enacted and their relation to commercial lunch and commercialization?
    b. Review the activities and practices of commercially lunching a product.
    c. Quality Systems application to commercial launch and post- launch commercial activities.
11. **Corporate Quality Systems:**
    a. Quality Systems as they relate to corporate governance and practices
    b. Global Quality Systems