

**Dept:** Science & Technology

**Date:** February 26, 2009

## **I. General Information**

**Course Name:** Introduction to Biomanufacturing I

**Prefix and Number:** BIO 287

**Credit hours:** 1 credit hour

**Catalog Description:** Students in the Introduction to Biomanufacturing Course I will learn how a biopharmaceutical makes its way from “bench to bottle.” Upstream and downstream manufacturing processes will be introduced through a combination of lecture and laboratory (hands-on) activities. Students will be introduced to regulatory affairs and will follow proper documentation procedures as outlined in the Good Laboratory and Good Manufacturing Practices (Food and Drug Administration). Prerequisites: BIO 121 and 122, or permission from the instructor

### **Textbooks:**

Hard-bound laboratory notebook required

Basic Laboratory Methods for Biotechnology, Lisa Seidman and Cynthia Moore, Prentice Hall - optional

## **II. Course Outcomes and Objectives**

### **Learning Outcomes:**

Students in the Introduction to Biomanufacturing Course I will learn how a biopharmaceutical makes its way from “bench to shelf.” Upstream and downstream manufacturing processes will be introduced through a combination of lecture and laboratory (hands-on) activities. Students will be introduced to regulatory affairs and will follow proper documentation procedures as outlined in the Good Laboratory and Good Manufacturing Practices (Food and Drug Administration).

### **College Competencies Addressed by the Course:**

Writing, ethics/values, oral communication, citizenship, reading, global concerns, mathematics, information resources, problem-solving, professional competency, computer literacy.

## **III. Methods of Instruction**

**Types of Course materials:** Textbook, laboratory notebook

**Methods of instruction:** Three hours of laboratory, one day per week, for seven weeks

**Assessment measures:** Longitudinal assessment of student performance on quizzes, homework, lab work, laboratory notebooks; Classroom Assessment Techniques.

**Methods of Evaluation:** Quizzes, evaluation of laboratory notebook and SOPs and presentations, laboratory competencies.

#### **IV. General Outline of Topics Covered**

##### **I. Week One**

- a. Safety and Lab orientation
- b. Introduction to the FDA and regulatory affairs
  - i. History of the FDA and CDER/CBER
  - ii. cGMP
  - iii. GLP
  - iv. OSHA
  - v. EPA
- c. The drug development process
  - i. Pre-clinical
  - ii. Clinical Trials
  - iii. Post-market surveillance
  - iv. FDA applications (IND, BLA, NDA)
- d. The laboratory notebook
- e. Intro to methods of protein purification

##### **II. Week Two**

- a. Theory: Protein chemistry
- b. Theory: Protein separations
- c. Bioinformatics and Databases
  - i. BLAST searches and output interpretation
  - ii. Database management

##### **III. Week Three**

- a. Theory: Recombinant DNA technology
- b. Theory: The Standard Operating Procedure (SOP), writing SOPs
- c. Media Preparation
- d. Aseptic techniques and awareness
- e. Streaking plates (cloning)
- f. Scale-up, primary cultures
- g. Solution and dilution calculations

##### **IV. Week Four**

- a. Labeling and documentation procedures for solution preparation
- b. Solution preparation (chromatography solutions)
  - i. Ammonium sulfate dilutions series for HIC

- ii. Tris Buffer / NaCl solutions for IEX
    - iii. NaCl solutions for SEC
  - c. Evaluating SOPs, deviations, revisions
- V. Week Five
  - a. Process development: designing a purification strategy
  - b. Downstream: Protein purification
    - i. Gravity columns (IEX, HIC, SEC)
    - ii. LP system (IEX). Bio-Rad LP Biologic system
- VI. Week Six
  - a. Theory: Quality control
  - b. QC testing with SDS-PAGE electrophoresis
  - c. Process Development: Troubleshooting
- VII. Week Seven
  - a. Analysis of Clinical Trial Data
  - b. Bioethics