

Dept: Science & Technology

Date: February 26, 2009

I. General Information

Course Name: Introduction to Biomanufacturing II

Prefix and Number: BIO 288

Credit hours: 1 credit hour

Catalog Description: Introduction to Biomanufacturing II is a continuation of Introduction to Biomanufacturing I. While part I introduced students to the process of bringing a biopharmaceutical from “bench to bottle,” this course focuses on the many functional areas specific to a biomanufacturing operation. Through a combination of lecture and laboratory (hands-on) activities, students will be introduced to the roles of these functional areas in the manufacturing process. Included in this exploration are the roles of technicians working in Environmental Health and Safety, Quality Control, Quality Assurance, and Validation. In addition, students will be exposed to basic analytical tools used in a manufacturing environment (RCA and FMEA). Students will continue the application of regulatory affairs introduced in part I of the course, and will follow proper documentation procedures as outlined in the Good Laboratory and Good Manufacturing Practices (Food and Drug Administration). **Prerequisites:** BIO 121, 122, BIO 287 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:

Introduction to Biomanufacturing II is a continuation of Introduction to Biomanufacturing I. While part I introduced students to the process of bringing a biopharmaceutical from “bench to bottle,” this course focuses on the many functional areas specific to a biomanufacturing operation. Through a combination of lecture and laboratory (hands-on) activities, students will be introduced to the roles of these functional areas in the manufacturing process. Included in this exploration are the roles of technicians working in Environmental Health and Safety, Quality Control, Quality Assurance, and Validation. In addition, students will be exposed to basic analytical tools used in a manufacturing environment (RCA and FMEA). Students will continue

the application of regulatory affairs introduced in part I of the course, 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 – Critical Thinking Skills
 - a. Root Cause Analysis (RCA) and RCA tools
 - b. Failure Mode and Effects Analysis (FMEA)
 - c. Corrective and Preventative Action Plans
 - d. Industry-specific safety regulations
- II. Week Two – Safety and Permitting
 - a. Confined Space Entry
 - i. Permitting
 - ii. Confined space Evaluation
 - b. LOTO
 - c. HAZCOM Programs
 - i. Safety Audits
 - ii. Labeling and MSDS
- III. Week Three – Quality in Biomanufacturing
 - a. Quality Control
 - i. Microbiology
 - ii. Chemistry
 - b. Quality Assurance
 - c. Popcorn GMP Laboratory

- IV. Week Four – Quality Control Microbiology Part I
 - a. Endotoxin Testing
 - b. LAL assay, colorimetric endpoint, microplate method
- V. Week Five – Quality Control Microbiology Part II
 - a. Mycoplasma Testing, PCR method
- VI. Week Six – Quality Control Chemistry
 - a. QC Chemistry sample and solution prep for HPLC
 - b. HPLC
 - i. Caffeine
 - ii. OTC drug active ingredients
 - iii. GFP
- VII. Week Seven – Validation
 - a. Validation and GMPs
 - b. IQ, OQ, PQ
 - c. Process Validation – Bradford Assay

Quality Control Microbiology: What Do Technicians Do?

Guest lecturers from Lonza Biologics delineate various roles of QC Microbiology technicians and their relationship in the biomanufacturing process.

Time = 72:41 File size = 33 meg

http://www.biomanufacturing.org/movies/QC_Micro092397_web.wmv

Quality Control Biochemistry: What Do Technicians Do?

Guest lecturers from Lonza Biologics delineate various roles of QC Biochemistry technicians and their relationship in the biomanufacturing process.

Time = 68:41 File size = 61 meg

http://www.biomanufacturing.org/movies/QC_Biochem_web_022608.wmv