

Course Syllabus

Department: Science and Technology

Date: 2/3/13

I. Course Prefix and Number: BIO 288

Course Name: Introduction to Biomanufacturing II

Credit Hours and Contact Hours: 1 credit hour and 2 contact hours

Catalog Description including pre- and co-requisites: *supporting data required for grade prerequisite of 'C' or higher.*

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, BIO 122, BIO 287.

Relationship to Academic Programs and Curriculum including SUNY Gen Ed designation if applicable:

BIO 288 is required for the A.S. Biotechnology degree

II. Course Student Learning Outcomes: *State the student learning outcome(s) for the course (e.g. Student will be able to identify...)*

At the completion of this course the students should be able to:

- Demonstrate their understanding of the roles of Quality Assurance and Quality Control in a GMP environment.
- Use basic analytical tools in a manufacturing environment (RCA and FMEA).
- Apply regulatory affairs introduced in part I of the course.
- Follow proper documentation procedures as outlined in the Good Laboratory and Good Manufacturing Practices (Food and Drug Administration).
- Demonstrate sterile gowning technique to an industry standard.
- Apply Root Cause Analysis tools to solve problems

College Learning Outcomes Addressed by the Course: (check each College Learning Outcome addressed by the Student Learning Outcomes)

- | | |
|---|--|
| <input checked="" type="checkbox"/> writing | <input type="checkbox"/> computer literacy |
| <input type="checkbox"/> oral communications | <input type="checkbox"/> ethics/values |
| <input type="checkbox"/> reading | <input type="checkbox"/> citizenship |
| <input type="checkbox"/> mathematics | <input type="checkbox"/> global concerns |
| <input checked="" type="checkbox"/> critical thinking | <input type="checkbox"/> information resources |

III. Assessment Measures (Summarize how the college and student learning outcomes will be assessed): For each identified outcome checked, please provide the specific assessment measure.

List identified College Learning Outcomes(s)	Specific assessment measure(s)
<i>eg: writing</i>	<i>eg: student will complete a research paper</i>
Writing	Students will demonstrate their ability to produce an SOP that meets an industry standard. Students will have the opportunity for revision and improvement in their documents.
Critical thinking	Students will be given a case study and will apply Root Cause Analysis tools to analyze a problem. Students will be assessed on their ability to apply root cause analysis tools to solve the problem. Students will demonstrate their ability to design a sterile gowning procedure and then revise the design based on feedback from the class and the instructor

IV. Instructional Materials and Methods

Types of Course Materials:

Hard-bound laboratory notebook required
 Basic Laboratory Methods for Biotechnology, Lisa Seidman and Cynthia Moore, Prentice Hall
 – optional

Methods of Instruction (e.g. Lecture, Lab, Seminar ...):

Three hours of laboratory, one day per week, for seven weeks

V. 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

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