Course Syllabus

Department: Science and Technology

Date: 2/3/12

I. Course Prefix and Number: BIO 287

Course Name: Introduction to Biomanufacturing I

Credit Hours and Contact Hours: 1 credit hour and 1.5 contact hours

Catalog Description including pre- and co-requisites: supporting data required for grade prerequisite of ‘C’ or higher. Students in the Introduction to Biomanufacturing I course 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

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

This is a required course 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 the course, students will be able to:

- Demonstrate their understanding of the steps required to bring a biopharmaceutical product to market.
- Select appropriate protein separation methods (chromatography) using knowledge of protein structure and function.
- Demonstrate their ability to perform aseptic technique.
- Demonstrate an ability to follow GMP regulations and procedures.
- Write a Standard Operating Procedure (SOP) that meets industry standards.
- Properly assemble and run an SDS-PAGE gel for protein separation.

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

- [x] writing
- [ ] computer literacy
- [ ] oral communications
- [ ] ethics/values
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.

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<thead>
<tr>
<th>List identified College Learning Outcomes(s)</th>
<th>Specific assessment measure(s)</th>
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<tbody>
<tr>
<td><strong>Writing</strong></td>
<td>Students will demonstrate their ability to keep a proper laboratory notebook and will demonstrate their ability to write an SOP that meets industry standards. Students will be provided opportunities to produce drafts of these documents and receive feedback.</td>
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<td><strong>Mathematics</strong></td>
<td>Students will demonstrate their ability to perform calculations necessary for producing specific formulations and buffers.</td>
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<tr>
<td><strong>Critical Thinking</strong></td>
<td>Students will demonstrate their ability to design an experiment and analyze the results of the experiment.</td>
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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
   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. Scale Up: Sartorius 5L bioreactor
c. 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