Syllabus

BIO 287 - Introduction to Biomanufacturing I

General Information

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Course Prefix BIO

Course Number 287

Course Title Introduction to Biomanufacturing I

Course Information

Catalog Description 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).

Credit Hours 1

Lecture Contact Hours 1

Lab Contact Hours 0

Other Contact Hours 0

Grading Scheme Letter

Prerequisites

Bio 121

Co-requisites

None

First Year Experience/Capstone Designation

This course DOES NOT satisfy the outcomes applicable for status as a FYE or Capstone.

SUNY General Education

This course is designated as satisfying a requirement in the following SUNY Gen Ed category
None

FLCC Values

Institutional Learning Outcomes Addressed by the Course
Vitality, Inquiry, Perseverance, and Interconnectedness

Course Learning Outcomes

Course Learning Outcomes

1. Demonstrate their understanding of the steps required to bring a biopharmaceutical product to market
2. Describe the upstream and downstream steps involved in the manufacturing of a biopharmaceutical.
3. Follow Good Manufacturing and Good Laboratory practices when performing laboratory tasks.
4. Use chromatographic methods to separate proteins.
5. Write a Standard Operating Procedure (SOP) that meets industry standards

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