BIOT 160: ENVIRONMENTAL MONITORING AND QUALITY OPERATIONS IN BIOMANUFACTURING

Citrus College Course Outline of Record

Heading	Value
Effective Term:	Fall 2025
Credits:	2
Total Contact Hours:	72
Lecture Hours :	18
Lab Hours:	54
Hours Arranged:	0
Outside of Class Hours:	36
Total Student Learning Hours:	108
Prerequisite:	BIOT 110, BIOT 150.
Strongly Recommended:	Intermediate algebra or higher; ENGL C1000.
Transferable to CSU:	No
Transferable to UC:	No
Grading Method:	Standard Letter

Catalog Course Description

This course builds on the concepts and laboratory techniques introduced in Biotechnology II: Biomanufacturing and Quality Principles. Students will examine the roles of Environmental Monitoring and Quality Control Microbiology in the context of biomanufacturing to ensuring the safety of biological drug products. Routine facility, personnel, and utilities environmental monitoring plans and procedures will be highlighted in the context of a comprehensive quality system. This course will review detection, analysis, and control of both viable and non-viable contaminants with an emphasis on aseptic technique and interpretation of testing data. This course includes a significant laboratory component which emphasizes the selection of appropriate equipment and procedures for non-viable particle monitoring in air, bioburden assessment of air, water, surfaces, and personnel, microbial identification, endotoxin testing, and aseptic gowning procedures. 18 lecture hours, 54 lab hours.

Course Objectives

- Discuss the Code of Federal Regulations and how they apply to the biomanufacturing industry
- Summarize the importance of and rating system for clean room environments
- Construct and follow an environmental monitoring plan for a facility
- Distinguish between the various strategies available for sterilization and disinfection in a biomanufacturing facility
- Don/doff clean room garments in the correct sequence and with the appropriate technique necessary for work in a clean room
- Demonstrate appropriate technique for performing tasks in a clean room
- Prepare disinfectant solutions of the correct concentration, and clean bench tops and floors in a manner appropriate for a clean room environment
- Clean tanks or vessels with chemical disinfectants and perform quality testing on rinse water
- Prepare, sterilize, assess for viability, and properly store bacteriological media
- Aseptically sample surfaces and water sources for microbial contamination using swabs, contact plates, and filtration units
- Obtain samples from incoming materials for inspection, and store materials in compliance with safety regulations and Good Manufacturing Practice (cGMP) standards
- Perform basic bacteriological identification using Gram stain and biochemical testing for microbial contaminants
- Operate particulate counters and air samplers for testing air quality
- Perform and interpret the LAL assay for endotoxin detection
- Assess a work area for cGMP and GDP compliance, identify safety and/or process improvement, and compose an oral and/or written report of the audit
- Explain the significance of Good Documentation Practice (GDP) and Good Manufacturing Practice (cGMP) for biomanufacturing operations and their role in maintaining FDA compliance
- Evaluate a variety of completed records, forms, and logs for errors in Good Documentation Practices (GDP)

Major Course Content

1. Foundational microbiology concepts
   a. Variety and ubiquitousness of microorganisms
   b. Bacteria (Gram + vs Gram -)
2. Environmental monitoring program/plan design
   a. Purpose, components, and organization
   b. Cleanroom classifications
   c. Testing site identification and sample frequency
   d. Response/investigation procedures
   e. Data management
3. Types of contamination in a biomanufacturing facility
   a. Nonviable vs Viable
   b. Sources of Contamination
4. Strategies for reducing contamination.
   a. Facility design
   b. Cleaning, disinfection, and sterilization procedures
   c. Personnel (aseptic techniques and gowning)

Lab Content

1. Environmental monitoring (EM) plan design
   a. Purpose, components, and organization
   b. Cleanroom Classifications
   c. Testing site identification and sample frequency
   d. Response/investigation procedures
   e. Evaluate and design EM plans.
2. Aseptic Gowning and Techniques
   a. Personal protective equipment
   b. Gowning procedures for ISO 5 (Class 100), ISO 7 (Class 10,000), and ISO 8 (Class 100,000)

c. Cleanroom behavior
d. Working is a Biosafety Cabinet

3. Testing Methodology
   a. Non-viable air particle monitoring
   b. Microbial air monitoring (active and passive)
   c. Surface monitoring (equipment and personnel)
   d. Utility monitoring
   e. Endotoxin screening
   f. Microbial Identification

Suggested Reading Other Than Required Textbook

Students will read and complete supplemental handouts given in the laboratory.
Students will read technical articles, news items, and/or online resources relating to Quality operations in the biotechnology industry and specific course content.

Examples of Required Writing Assignments

Students will write a short report on a resent FDA inspection report/ warning letter, focusing on quality operations failures and providing specific suggestions for remediation to bring the quality plan into compliance.
Students will write a performance evaluation for him/herself or a team member.

Examples of Outside Assignments

Students will prepare for exams covering principles of environmental monitoring in a biomanufacturing facility, such as the rating systems used to classify clean room environments.
Students will complete homework assignments with questions, such as: (1) Describe the structural differences between Gram negative and Gram positive bacterial cells. (2) Propose an environmental monitoring plan directed at the attached facility blueprint. (3) Explain the purpose of pyrogen testing prior to final sterile-filled product release.
Students will perform online research in preparation for class discussions. Topics to include: published FDA inspection reports regarding quality operations violations.

Instruction Type(s)

Lab, Lecture, Online Education Lecture