Miami Dade College

Course Description

ETI1040L | Introduction to Bioscience Manufacturing Lab | 2.00 credits

In this laboratory course students will learn the basic principles of the industry, large-scale process development and the future of bioscience. Students also learn about current Good Manufacturing Practices (GMPs), and the nature and delivery system of products. Corequisite: ETI 1040.

Course Competencies

Competency 1: The student will demonstrate knowledge of the organization and function of biosciences companies by:

1. Defining the concept of a bioscience company as a tool for transformation of scientific knowledge into commercial products
2. Summarizing the different duty areas, tasks performed, specific competencies required, tools and equipment used, and behavioral traits needed by the workforce
3. Researching major steps of commercial product transformation from the perspectives of research and development, scale-up, pilot plant production and quality control/quality assurance (QC/QA)
4. Using the concepts of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) by:
    a. Using Standard Operating Procedures (SOPs)
    b. Following a batch record
    c. Using the principles of labeling
    d. Interpreting an investigation report
5. Identifying functions of the manufacturing areas and/or departments in a bioscience company
6. Explaining the importance of process flow and process control
7. Discussing ethical issues that impact the manufacturing environment

Competency 2: The student will demonstrate knowledge of the bioscience industry workplace by:

1. Utilizing safety in the manufacturing areas according to Federal Drug Administration (FDA) and Occupational Safety and Health Administration (OSHA) guidelines
2. Performing industry procedures in accordance with risk reduction practices
3. Applying methods to control contamination in an aseptic area, sterile area, and controlled processing area level
4. Describing the electronic records and signatures process
5. Explaining the importance of inventory control and housekeeping

Competency 3: The student will demonstrate knowledge of the production process in bioscience companies by:

1. Delineating different aspects of production in a bioscience company
2. Performing the methods of cultivation, downstream and upstream processing, and scale development
3. Mapping the different areas of the production facilities, equipment, and raw materials storage
4. Demonstrating proper gowning techniques

Competency 4: The student will demonstrate knowledge of the product design and manufacturing process by:

1. Performing the steps of fermentation during the scale up process after the transformation of bacteria.
2. Preparing buffers
3. Conducting dialysis buffer exchange, ultrafiltration and diafiltration methods in order to change a product's conditions
4. Harvesting a protein product with the use of column chromatography

Competency 5: The student will demonstrate knowledge of bioscience industry skills by:

1. Performing common production tasks such as:
    a. Interpreting charts and graphs
    b. Using a tape measure

    c. Demonstrating record keeping practices
2. Utilizing the GMP terminology used in processing areas
3. Utilizing computer software and automation components of the equipment used in the fermentation and protein purification processes
4. Working in a team-oriented environment with the use of interaction and communication skills

Competency 6: The student will demonstrate knowledge of the purpose of validation in a bioscience organization by:

1. Reviewing the purpose of validating equipment and processes
2. Executing validation protocols
3. Utilizing Installation, Performance and Operation Quality procedures (IQ, PQ, OQ) to validate equipment and systems.
4. Summarizing the validation standards for cleaning of equipment and systems
5. Reviewing different requirements for calibration of equipment and systems
6. Listing examples of Corrective Action Preventive Action (CAPA) steps used to follow risk scenario investigations

Learning Outcomes:

- Solve problems using critical and creative thinking and scientific reasoning
- Formulate strategies to locate, evaluate, and apply information
- Create strategies that can be used to fulfill personal, civic, and social responsibilities