Miami Dade College

Course Competencies Template – Form 112

GENERAL INFORMATION	
Course Prefix/Number: ETI-XXXX	Course Title: Introduction to Bioscience Manufacturing
Number of Credits: 3	
Degree Type	☐ B.A. ☐ B.S. ☐ B.A.S ☐ A.A. ☒ A.S. ☐ A.A.S. ☒ C.C.C. ☒ A.T.C. ☐ V.C.C
Date Submitted:	Effective Year/Term:
☒ New Course Competency ☐ Revised Course Competency	
Course Description (limit to 50 words or less): This course introduces students to the field of bioscience manufacturing. Topics will include basic principles of the industry, large-scale process development and the future of the bioscience industry. Current Good Manufacturing Practices (cGMPs), and the nature and delivery system of products will also be discussed.	
Prerequisite(s):None	Corequisite(s): None

Course Competencies: (for further instruction/guidelines go to: http://www.mdc.edu/asa/curriculum.asp)

Competency 1: Upon successful completion of this course, students 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. Describing major steps of such commercial product transformation from the perspectives of research and development, scale-up, pilot plant production and quality control/quality assurance (QC/QA).
3. Summarizing the concepts of Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs).
4. Comparing and contrasting the three cultures within a bioscience company: Research and Development (R & D), production, and (QC/QA).
5. Explaining the functions of the departments in a bioscience company.
6. Distinguishing functions of the workplaces and/or departments in a bioscience company.
7. Describing the processes by which bioscience products are transitioned from concept to market.

Competency 2: Upon successful completion of this course, students will demonstrate knowledge of the bioscience industry by:

1. Summarizing the history of the bioscience industry.

2. Comparing and contrasting academic research, biotechnology, pharmaceutical and medical devices manufacturing industries.

3. Analyzing the biosciences companies' role in the public health, industry and the economy.

4. Analyzing the future outlook of the bioscience industry.

5. Listing the major bioscience companies on the market.

6. Describing the life cycle of a bioscience product.

7. Discussing the major biosciences products in the pipeline and their potential impact towards animal or human health.

Competency 3: Upon successful completion of this course, students will demonstrate knowledge of the bioscience industry workplace by:

1. Defining safety in the manufacturing areas.

2. Describing hazard and risk assessment.

3. Defining actions directed to risk reduction in the research or production facilities.

4. Comparing and contrasting aseptic and sterile processing techniques.

5. Listing the different gowning areas of a production facility.

6. Explaining methods to control contamination in aseptic, sterile, and controlled processing areas.

7. Designing a plant facility to examine how contamination in manufacturing areas is controlled.

8. Summarizing the role and organization of agencies, contractors and departments responsible for product regulation and compliance.

9. Summarizing the process and regulations of packaging and distribution of bioscience product materials.

10. Explaining the electronic records and signatures process.

11. Categorizing bioscience industry production systems and technical issues relating to those systems.

12. Analyzing the issues of environmental protection and its importance to the industry.

Competency 4: Upon successful completion of this course, students will demonstrate knowledge of the production process in bioscience companies by:

1. Explaining different aspects of production in a bioscience company.

2. Explaining how technology and informatics can be applied in the production of biotherapeutics, medical devices, or pharmaceutical products.

3. Describing the process of production, cultivation, downstream and upstream processing, and commercial scale development.

4. Illustrating the different areas of the production facilities, equipment, and raw materials handling.

5. Categorizing the different gowning levels and microbial contamination restrictions standardized in production facilities.

6. Comparing and contrasting specifications for raw materials and products.

7. Defining principles of labeling, documentation, and housekeeping.

8. Summarizing the major processing steps to make a product.

Competency 5: Upon successful completion of this course, students will demonstrate knowledge of the product design and manufacturing process by:

1. Explaining basics of current Good Manufacturing Practices (cGMPs).

2. Distinguishing the global regulations governing bioscience industries.

3. Describing production facility principles and how the pilot plant design can be utilized to optimize manufacturing.

4. Describing principles and methods relevant to manufacturing biotherapeutics, pharmaceuticals, or medical devices.

5. Summarizing the issues involved when formulating/designing different types of products.

Competency 6: Upon successful completion of this course, students will demonstrate knowledge of bioscience industry skills by:

1. Identifying the different duty areas, tasks performed, specific competencies required, tools and equipment used, and behavioral traits needed by the workforce.

2. Demonstrating common tasks performed in the manufacturing areas including interpreting charts and graphs, reading a tape measure, performing math calculations, and record keeping.

3. Categorizing job titles in a bioscience company.

4. Explaining the role of the various members of a bioscience company.

5. Explaining the reasons and necessity of continuous training in the industry.

Competency 7: Upon successful completion of this course, students will demonstrate knowledge of the purpose of validation in a bioscience organization by:

1. Describing the purpose of validating equipment and processes.

2. Explaining the steps of equipment and system validation: Installation, Performance and Operation Quality procedures (IQ, PQ, OQ).

3. Explaining the role of validation and documentation.

4. Writing validation protocols.

5. Listing the different types of validation.

6. Summarizing the validation standards for cleaning of equipment and systems.

7. Stating the different requirements for calibration of equipment and systems.