College of San Mateo
Official Course Outline

1. **COURSE ID:** BIOL 680MB **TITLE:** Biotechnology: Manufacturing Experience
   Units: 1.0 units **Hours/Semester:** 16.0-18.0 Lecture hours; 32.0-36.0 Homework hours; 48.0-54.0 Total Student Learning hours
   Method of Grading: Letter Grade Only

2. **COURSE DESIGNATION:**
   Degree Credit
   Transfer credit: CSU

3. **COURSE DESCRIPTIONS:**
   Catalog Description:
   This course provides students with experience in a simple manufacturing project. Students learn manufacturing expectations of an FDA regulated industry. Through experiencing this project students are exposed to and are responsible for Quality Assurance, Quality Control, Supply Line and Material Control, Manufacturing Process Control and Production, and Project Management. Students experience teamwork and leadership through a team approach to the project. Bio-manufacturing safety, responsibility and ethics are discussed. Opportunities exist for discussions with industry representatives.

4. **STUDENT LEARNING OUTCOME(S) (SLO'S):**
   Upon successful completion of this course, a student will meet the following outcomes:
   1. Work with a team to accomplish course related tasks to model the structure and functioning of the modern workplace.
   2. Define and demonstrate the importance of both Quality Control and Quality Assurance and provide examples from the biotechnology industry.
   3. Demonstrate an understanding of supply line, process control and project management in the biotechnology industry.
   4. Explain the importance of ethics and responsibilities in a manufacturing industry regulated by the US FDA.

5. **SPECIFIC INSTRUCTIONAL OBJECTIVES:**
   Upon successful completion of this course, a student will be able to:
   1. Experience the manufacturing process of an industry regulated by the US FDA through a model project.
   2. Work with a team to address work expectations and problems.
   3. Investigate US FDA warning letters and discuss case studies to understand responsibilities and ethical obligations in the bio-manufacturing industry.

6. **COURSE CONTENT:**
   Lecture Content:
   1. Introduction to the biotechnology industry.
   2. Types of biotechnology industry: pharmaceuticals, devices, agriculture.
   3. Types of industry regulated by the US FDA: food, pharmaceutical, cosmetics.
   4. Manufacturing process including, Quality Control, Quality Assurance, Supply line and Material Control, Process Control, Production, Project Management.
   5. Team design, responsibilities and expectations in the biotechnology industry.
   6. Ethics and responsibilities in the biotechnology industry.

   Lab Content:
   This course does not have a lab, but is a workshop experience.
   TBA Hours Content:
   none

7. **REPRESENTATIVE METHODS OF INSTRUCTION:**
   Typical methods of instruction may include:
   A. Lecture
   B. Activity
   C. Discussion
   D. Guest Speakers

E. Observation and Demonstration

8. **REPRESENTATIVE ASSIGNMENTS**

Representative assignments in this course may include, but are not limited to the following:

Writing Assignments:

Keeping a notebook as part of Good Laboratory Practice and Good Manufacturing Practice.

Keeping equipment performance log books.

Writing and editing Standard Operating Procedures

Keeping records to create a Batch Record.

Writing a summary of experience for use in a Resume or job application.

Reading Assignments:

Reading Standard Operating Procedures

Read Case Studies.

Read Resume or Curriculum Vitae

9. **REPRESENTATIVE METHODS OF EVALUATION**

Representative methods of evaluation may include:

A. Class Participation
B. Class Performance
C. Class Work
D. Exams/Tests
E. Group Projects
F. Homework
G. Oral Presentation
H. Papers
I. Portfolios
J. Projects
K. Quizzes

10. **REPRESENTATIVE TEXT(S):**

Possible textbooks include:

A. Bryans, Maggie. *Biomanufacturing Laboratory Manual*, 1st ed. Bluebell, PA: The Northeast Biomanufacturing Center and Collaborative, 2016

Other:

A. 1. US Food and Drug Administration website for case study.

2. Code of Federal Regulations Title21 - This database includes a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

3. ISO 9000, a set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements needed to maintain an efficient quality system.

Origination Date: August 2023
Curriculum Committee Approval Date: December 2023
Effective Term: Fall 2024
Course Originator: Christopher Smith