College of San Mateo
Official Course Outline

1. **COURSE ID:** BIOL 129 **TITLE:** Biotechnology: Research and Industrial Applications
   Units: 3.0 units **Hours/Semester:** 32.0-36.0 Lecture hours; 48.0-54.0 Lab hours; 64.0-72.0 Homework hours; 144.0-162.0 Total Student Learning hours
   Method of Grading: Letter Grade Only
   Recommended Preparation:
   College level introductory biology course such as BIOL 110, or BIOL 210 or BIOL 220 and a college chemistry course such as CHEM 210, and successful completion of Intermediate Algebra or equivalent.

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

3. **COURSE DESCRIPTIONS:**
   Catalog Description:
   This course prepares students for more successful transfer to baccalaureate programs and beyond in bioscience and biotechnology. This course provides students with hands-on lab experience and a thoughtful application of those skills with a thorough exploration of the underlying scientific concepts and by employing necessary practices from a regulated industry. Students practice skills necessary for lab work in a research or production lab setting. Applications of current Good Manufacturing Process (cGMP), Good Laboratory Practice (GLP), Quality Control, Quality Assurance, documentation, and the use of Standard Operating Procedures are practiced at each stage of the course so students develop good practices. Topics include the necessary skills and knowledge to successfully carry out measurements, DNA and protein preparation and purification and their analysis. Included are applications of Polymerase Chain Reaction (PCR), the immunoassays ELISA and Western Analysis. Good communication practices, team work, and work-readiness skills are emphasized through group project design, execution, analysis and presentation.

4. **STUDENT LEARNING OUTCOME(S) (SLO'S):**
   Upon successful completion of this course, a student will meet the following outcomes:
   1. Compare and contrast current regulated industries in pharmaceuticals, agriculture, devices, food, cosmetics and analytical services.
   2. Demonstrate, through practice, current Good Lab Practices of documentation, lab notebooks and record keeping, and writing and editing Standard Operating Procedures
   3. Perform and analyze preparations of nucleic acids (DNA), proteins and other molecules from cells and tissues.
   4. Practice and demonstrate good communication and team skills and leadership.
   5. Practice and demonstrate an understanding of lab safety and ethical considerations in the field of biotechnology.

5. **SPECIFIC INSTRUCTIONAL OBJECTIVES:**
   Upon successful completion of this course, a student will be able to:
   1. Compare the requirements and expectation of the government agencies, USDA, EPA, FDA on regulated industries.
   2. In model research or industrial lab activities, fulfill the government regulatory requirements and expectations of documentation and safety.
   3. Successfully carry out a project using DNA that includes sample preparation, extraction, purification and analysis.
   4. Successfully carry out a project using protein that includes sample preparation, extraction, purification and analysis.
   5. Use common lab equipment and common lab math to measure and analyze volumes, concentrations, and purity of DNA and protein.
   6. Research, write, and analyze case studies of ethical and safety issues in the industries studied in this course.

6. **COURSE CONTENT:**
   Lecture Content:
   1. Defining biotechnology and practices

A. Scientific Method and experimental design
B. Academic research laboratories
C. Industry research, development and manufacturing laboratories
D. Laboratories and Industries regulated by FDA, EPA, USDA, and Public Health Agencies
E. Outsourcing

2. Cell Biology, structure and function
   A. Cell metabolism
   B. DNA
   C. Protein
3. Understanding Regulation
   A. History and oversight agencies
   B. Quality Control and Quality Assurance
   C. Good Laboratory and Good Manufacturing Practices
4. Implementing QC and QA
   A. Required Documentation and Record Keeping
   B. Batch Records
5. Manufacturing and production process in biotechnology industry
   A. Compared to academic research laboratories
   B. Preclinical discovery and development
   C. Clinical and after market research
   D. Other regulated industries
   E. Biomolecule upstream and downstream processes
   F. Efficiency, problem identification and solutions
   G. DNA examples and case studies
   H. Protein example and case studies
6. Communication
   A. Internal reports and presentations
   B. External reports and presentations
   C. Trade secrets, intellectual property,
   D. Information security
   E. Patents
   F. Collaborations
7. Environmental Health and Safety
8. Ethics
   A. Business case studies
   B. Research case studies
   C. Clinical Case studies
9. Careers

Lab Content:

1. General lab procedures and Health and Safety
   A. MSDS/SDS
   B. Personal Protection Equipment
   C. Monitoring for and correction of bacterial contamination
2. Measurement and math
   A. Lab tools, volume, mass
   B. Units of Measurement and converting between units (Metric System)
   C. Graphical methods of analysis and data display and reporting
   D. Various methods and math of expressing concentration
   E. Standard Operating Procedures
   F. Lab instrumentation
   G. spectrophotometry,
   H. DNA and protein methods
   I. Microscopes
   J. pH meter
   K. centrifuge
   L. filtration
   M. chromatography
3. Manufacturing models
   A. Supply chain,

B. Quality control, quality assurance,
C. Documentation, batch record
D. Practice of writing SOP's (includes steps, procedures products, standards, objectives, formats, development procedures, review processes, implementation, evaluation)

4. Manufacturing: growth media,
   A. Aseptic technique
   B. QC, QA
   C. Documentation, batch record
5. Manufacturing: growth media with antibiotics
   A. Aseptic technique
   B. QC, QA
   C. documentation, batch record
6. DNA preparation
   A. from cells and tissues for analysis
   B. PCR, restriction (bacteria, human, fish, plant)
   C. For cloning
7. Protein preparation from cells and tissues for analysis
   A. gel electrophoresis (bacteria, human, fish, plant)
   B. ELISA, Western blotting.
8. Protein preparation and purification for activity
   A. Specific activity
9. Bioinformatics
   A. DNA
   B. Protein
10. Work-readiness skills
   A. Oral communication
   B. Written communication
   C. Teamwork and leadership

TBA Hours Content:
none

7. **REPRESENTATIVE METHODS OF INSTRUCTION:**

Typical methods of instruction may include:
A. Lecture
B. Lab
C. Activity
D. Discussion
E. Experiments
F. Guest Speakers
G. Observation and Demonstration

8. **REPRESENTATIVE ASSIGNMENTS**

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

Writing Assignments:
Laboratory Notebooks, Batch Records, Equipment Log Books, Standard Operating Procedures, Research Reports, etc

Reading Assignments:
Textbooks, research reports and reviews, lab manuals, instrument documentation and instructions, Standard Operating Procedures, laboratory notebooks, Material Data Safety Sheets, Government regulations, policy, and guidance documents

Other Outside Assignments:
Presentation of lab results, research, and identification, tracking and correcting manufacturing errors.
Document evaluation, editing, updating of Standard Operating Procedures, Batch Records, manufacturing progress reports, oversight and inspection requirements.
Interpreting graphs and other data presentation

9. **REPRESENTATIVE METHODS OF EVALUATION**

Representative methods of evaluation may include:
A. Class Participation

B. Class Work
C. Exams/Tests
D. Group Projects
E. Homework
F. Lab Activities
G. Oral Presentation
H. Papers
I. Projects
J. Quizzes
K. Research Projects
L. Simulation

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

Possible textbooks include:

A. Thieman, William. Palladino, Michael. *Introduction to Biotechnology*, 4th ed. London: Pearson, 2019
B. Seidman, L. A.. *Basic Laboratory Methods for Biotechnology*, 3rd ed. San Francisco: Benjamin Cummings, 2020
C. Daugherty, Ellen. *Biotechnology: Science for the New Millennium*, 1st ed. Saint Paul: EMC Paradigm Publishing, 2017
D. Joseph P. Stalder (Editor) CRC Press 2022. *Project Management for Drug Developers (Drugs and the Pharmaceutical Sciences)*, 1st ed. Boca Raton: CRC Press, 2022
E. Bryans, Maggie. *Biomanufacturing Laboratory Manual, 1st ed.*, 1st ed. Bluebell, PA: The Northeast Biomanufacturing Center and Collaborative, 2016
F. Simon, F.. *Managing Biotechnology: From Science to Market in the Digital Age*, 1st ed. Hoboken, NJ: Wiley, 2017

Other:

A. US Food and Drug Administration website for case study, guidelines, policy and recommendations.

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.

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Course Originator: Christopher Smith