Subject:	BIOL
Course Number:	78
Descriptive Title:	Quality and Regulatory Compliance in the Biosciences
Division:	Natural Sciences
Department:	Biology
Course Disciplines:	Biology, Biotechnology
Catalog Description:	This course will cover quality assurance and regulatory compliance for the bioscience industries. Topics will span quality control and Food Drug Administration (FDA) regulations for the biotechnology, biopharmaceutical, biomedical device, and food industries. Theories and application of quality assurance and quality control will be presented and several different quality systems will be discussed such as GMP (good manufacturing practices), ISO9000 (International Standards Organization), Six Sigma, and Lean.
Prerequisite:	None
Co-requisite:	None
Recommended Preparation:	None
Enrollment Limitation:	None
Hours Lecture (per week):	2
Hours Laboratory (per week):	0
Outside Study Hours:	4
Total Course Hours:	36
Course Units:	2
Grading Method:	Letter Grade only
Credit Status:	Credit, degree applicable
Transfer CSU:	Yes
Effective Date:	Fall 2023
Transfer UC:	No
Effective Date:	
General Education ECC:	
Term:	
Other:	
CSU GE:	
Term:	
Other:	
IGETC:	
Term:	

Other:	
Student Learning Outcomes:	**1. SLO #1 Knowledge:** Students will be able to demonstrate knowledge of the history and current state of regulatory compliance and quality assurance in the bioscience industry. **2. SLO #2 Scientific Communication:** Students will be able to express and communicate knowledge of the regulations concerning product quality. **3. SLO #3 Career Proficiency:** Students will be able to demonstrate a proficiency in the techniques used for QMS documentation.
Course Objectives:	1. Evaluate the history of regulations concerning product quality and the current state of the biotechnology industry. 2. Appraise methods of managing variation during production. Properly employ statistical process control charts. 3. Compare product quality and the regulatory environment. 4. Examine the role of the FDA in the biosciences industry including laws, regulations, and good practices. 5. Evaluate how the ISO applies to the field of biotechnology. 6. Analyze the quality management system and its components as it applies to biotechnology. Establish proper QMS documentation.
Major Topics:	**I. Quality Regulations – Abbreviated History and Influences (Lecture, 2 hours)** A. Quality Evolution: Influential People B. Regulations Evolution: Landmark Laws and Origin of the FDA (Food and Drug Administration) **II. Biotechnology Industry Overview and Production Considerations (Lecture, 3 hours)** A. Research and development B. Commercialization and the manufacturing process **III. Variation – Impacts on Quality (Lecture, 3 hours)** A. Quality Assurance (QA) and Quality Control (QC) concepts B. Quality Assurance (QA) and Quality Control (QC) functions **IV. Statistical Process Control Charts: Continuous and Monitoring (Lecture, 3 hours)** A. Six Sigma B. Lean **V. Quality and Regulatory Relationships (Lecture, 3 hours)** A. Government oversight B. International oversight **VI. Food and Drug Administration (Lecture, 5 hours)** A. Overview B. Organization

	C. Biotech product jurisdiction D. Regulated product approvals for drugs and medical devices including classification and substantial equivalence E. FDA website resources F. FDA inspection **VII. The Laws (U.S. Code) and Federal Regulations (Lecture, 5 hours)** A. Laws to regulations B. Laws to impacting the FDA C. FD&C Act overview D. 21 CFR (Code of Federal Regulation) Overview E. Summary of select CFR parts F. Good Practices (GXPs) G. Good Laboratory practices (GLPs) H. Good Manufacturing practices (GMPs) including medical device GMPs (21 CFR 820), FDA QSR-Introduction, and GMP design controls **VIII. ISO (International Organization of Standardization) (Lecture, 4 hours)** A. Governing body B. 9000 Series Standards Family C. ISO 9001 Quality Management System requirements **IX. Quality Management Systems (QMS) (Lecture, 4 hours)** A. Key elements of quality B. Controlling and improving quality C. Vocabulary D. Plan-Do-Check-Act (PDCA) cycle E. Quality activities F. QMS Process Model G. Understanding teams including the purpose of a team, team member roles, team success, and team stages **X. Quality Management System (QMS) Documents (Lecture, 4 hours)** A. Types of QMS documents B. Examples of QMS documents C. Writing QMS documents - Standard Operating Procedures (SOPs) D. Considerations of QMS documents E. Validating QMS documents (SOPs) F. Inspections and audits
Total Lecture Hours:	36
Total Laboratory Hours:	0
Total Hours:	36
Primary Method of Evaluation:	2) Problem solving demonstrations (computational or non-computational)

Typical Assignment Using Primary Method of Evaluation:	Develop a section of a Quality Assurance Plan including the following: 1. Mission Statement 2. Quality Objectives with related Quality Goals Key components of instructor evaluation: • Are the Quality Objectives driven from the Mission Statement? • Are the Quality Objectives clearly defined? • Are the Quality Goals measurable?
Critical Thinking Assignment 1:	Develop the following section of a Quality Assurance Plan: *Responsibility, Authority, and Communication.* PART 1: Create an Organizational Chart that relates to the company type (company type provided by the instructor). PART 2: Using the Organizational Chart, create a Management Responsibilities Table to determine the Personnel or Department, and the Quality Related Responsibilities for that Individual or Department.
Critical Thinking Assignment 2:	PART 3: Using your completed Organizational Chart and Management Responsibilities Table, answer the following questions: 1. Are all departments covered in the responsibilities assigned? 2. Describe the process of Internal Communication for ensuring the effectiveness of the Quality Management System of instructor provided company. 3. Describe the process (start to finish) of initiating external communication to the FDA based on internal company discussions. 4. What type of topics would need to be communicated to the FDA?
Other Evaluation Methods:	Completion, Homework Problems, Matching Items, Multiple Choice, Other Exams, Quizzes, Reading Reports, Term or Other Papers, True/False, Written Homework
If Other:	
Instructional Methods:	Demonstration, Discussion, Field trips, Group Activities, Guest Speakers, Lecture, Multimedia presentations, Role play/simulation
If other:	
Work Outside of Class:	Answer questions, Problem solving activity, Required reading, Study, Written work (such as essay/composition/report/analysis/research)
If Other:	
Up-To-Date Representative Textbooks:	2021 U.S. Code of Federal Regulation: Title 21, U.S. Food and Drug Administration, U.S. Department of Health and Human Services, ISBN: 20181234567891
Alternative Textbooks:	None
Required Supplementary Readings:	None

Other Required Materials:	None
Requisite	
Category	
Requisite course:	None
Requisite and Matching skill(s): Bold the requisite skill. List the corresponding course objective under each skill(s).	None
Requisite Skill:	None
Requisite Skill and Matching skill(s): Bold the requisite skill(s). if applicable	None
Requisite course:	None
Requisite and Matching skill(s): Bold the requisite skill. List the corresponding course objective under each skill(s).	None
Requisite Skill:	None
Requisite Skill and Matching skill(s): Bold the requisite skill. List the corresponding course objective under each skill(s). if applicable	None
Enrollment Limitations and Category:	None
Enrollment Limitations Impact:	None
Course Created by:	Mia Dobbs
Date:	December 7th, 2021
Board Approved:	6/20/2022