BIOT 125: QUALITY AND REGULATORY PRACTICES IN BIOTECHNOLOGY

Citrus College Course Outline of Record

Heading	Value
Effective Term:	Fall 2024
Credits:	3
Total Contact Hours:	54
Lecture Hours :	54
Lab Hours:	0
Hours Arranged:	0
Outside of Class Hours:	108
Total Student Learning Hours:	162
Strongly Recommended:	Intermediate algebra or higher; ENGL 101.
Transferable to CSU:	Yes
Transferable to UC:	No
Grading Method:	Standard Letter

Catalog Course Description

This course serves as an introduction to basic quality principles and tools with an emphasis on their application in biotechnology. Students will explore concepts related to quality control, quality assurance, validation, documentation, and regulatory compliance within this industry. The course prepares students for examination through the American Society for Quality to become a Certified Quality Improvement Associate (CQIA). 54 lecture hours.

Course Objectives

- Define quality and apply the term appropriately.
- Differentiate between quality control and quality assurance in the bioscience industry.
- Explain the role of validation and its importance in regulatory compliance for the bioscience industry.
- Select, define, and apply basic quality improvement tools.
- Describe the importance of using data to drive continuous improvement, and identify key quality factors.
- Select and define various customer feedback mechanisms.
- Identify and assess supplier performance measures.
- Describe and distinguish between quality theories and philosophies.
- Identify key historical events that shaped FDA regulations and quality systems in the biosciences.
- Discuss how regulatory bodies (including FDA) impact bioscience company operations and the work performed by technicians.
- Explain why teams are an effective way to identify and solve problems.
- List the stages of team formation.
- Describe and distinguish the various types of teams, and identify which team is best suited for a particular situation.
- Explain the purpose of a quality management system (QMS), its major components, and how it benefits an organization.
- Describe the main types of QMS documentation used in the bioscience industry.

Major Course Content

Introduction to Quality Concepts

1. Definition of quality
2. History of quality
3. Pioneers of quality and their contributions
4. Overview of quality philosophies
5. Benefits of quality for organizations and stakeholders
6. Quality plans and their purpose
7. Applications of quality concepts

Team Basics

1. Value of teams
2. Types of teams
3. Roles and responsibilities of team stakeholders
4. Team formation and evolution
5. Decision-making and conflict resolution within teams

Introduction to Bioscience Regulations

1. History of the Food and Drug Administration (FDA)
2. FDA's mission and organizational structure
3. Overview of the Code of Federal Regulations (21 CFR)
4. Regulation of the pharmaceutical, medical device and food industries
5. Exploration of Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP)
6. Other regulatory bodies, including international oversight

Quality Management

1. Quality management and consequences of non-compliance
2. Definition of Quality Management Systems (QMS)
3. Supplier, input, process, output, customer (SIPOC)
4. ISO and Baldrige standards
5. Documentation: standard operating procedures, change control, and Good Documentation Practices (GDP)
6. Quality Control: analytical and microbiological
7. Quality Assurance: corrective and preventive actions, investigations, root cause analysis
8. Validation principles

Continuous Improvement Techniques

1. Continuous Improvement: brainstorming, plan-do-check-act (PDCA), internal audits
2. Process Improvement
   a. Six sigma and Lean
   b. Incremental and breakthrough improvement
3. Quality Improvement Tools
   a. Flowcharts
   b. Histograms
   c. Pareto charts
   d. Scatter diagrams
   e. Cause and effect diagrams

f. Check sheets
g. Control charts

Customer-Supplier Relations

1. Internal and external customers and suppliers
2. Customer feedback mechanisms
3. Using data to drive continuous improvement
4. Supplier performance measures

Suggested Reading Other Than Required Textbook

Students will read technical articles, news items, and online resources relating to the regulation of the biotechnology industry and specific course content. Students will access the FDA website to read about current regulations and recent FDA investigations.

Examples of Required Writing Assignments

Students will develop an audit checklist and write an audit report based on their evaluation of a laboratory or other appropriate work location. Students will create an investigation into a possible process failure, identify a potential root cause, and compose a memo to communicate this information and propose a corrective action.

Examples of Outside Assignments

Students will complete homework assignments with questions, such as (1) Analyze this statistical process control chart and determine if the fermentation temperature is out of specification. (2) Create a cause-and-effect diagram to identify factors that may explain why a flashlight does not turn on. Students will answer discussion questions, such as: (1) Explain the significance of the sulfanilamide incident in the development of FDA regulations. (2) Describe the philosophy behind the Shewhart cycle and how it relates to the concept of quality.

Instruction Type(s)

Lecture, Online Education Lecture