



C-ID Descriptor

Quality and Regulatory Compliance

Descriptor Details

- **Descriptor Title:** Quality and Regulatory Compliance
- **C-ID Number:** 210
- **Suffix:**
 - Community College Use Only (X)
- **Units:** 2.0
- **Hours:** 0000
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General Description

Introduces concepts of quality control and validation as it relates to manufacturing in regulated industries. Includes GLP, cGMP, Quality Assurance and Quality Control

Prerequisites

No information provided

Corequisites

None

Advisories

Introductory Biotechnology with Laboratory (C-ID BIOT 101), or Biotechnology with Laboratory (C-ID BIOT 150B)

Content

- History of Regulation
- Government oversight, including FDA (Food and Drug Association) and other agencies
- International oversight regulations and their application
- Concept of GMP (Good Manufacturing Practice)
- Concept of GLP (Good Laboratory Practice)
- Concept of GCP (Good Clinical Practice)
- Product development and commercialization as related to GMP, GLP, GCP
- Rationale of writing SOP (Standard Operating Procedure)
- Quality Assurance and Quality Control (functions and concept)
- Validation: Equipment, Process, Computer, Analytical, Cleaning
- Environmental Health & Safety

Inspections & Audits

Practice of writing SOP's (includes steps, procedures products, standards, objectives, formats, development procedures, review processes, implementation, evaluation)

- Investigations
- SPC (Statistical Process Control) & Continuous monitoring
- Interpret sample FDA citations

Lab Activities

No information provided

Objectives

At the conclusion of this course, the student should be able to:

1. Demonstrate understanding of inspection and verification of the quality of a product
2. Identify key validation concepts including equipment, process, computer, analytical and cleaning validation
3. Demonstrate good documentation practices

4. Recognize the importance of following established procedures
5. Explain the role of government oversight in development and manufacturing, including applicable federal, state, local and industry regulations
6. Assess the importance of corrective action and preventive action in continuous improvement
7. Demonstrate competency in terminology and acronyms applicable to the topic

Evaluation Methods

Case study assignments

Written assignments

Quizzes/ Written exams

Presentations

Textbooks

1. Moorpark College and Industry Partners. Industrial Biotechnology: A Training Manual. Cengage Learning, 2001.
2. Friedman, Yali: Building Biotechnology
3. Biomanufacturing Laboratory Manual, 2nd ed: Published by Northeast Blomanufacturing Center and Collaborative, 2010.
4. FDA.gov