

**NOVA COLLEGE-WIDE COURSE CONTENT SUMMARY
BIO 165 - PRINCIPLES IN REGULATORY AND QUALITY ENVIRONMENTS
FOR BIOTECHNOLOGY (2 CR.)**

Course Description

Prepares students to work effectively in a scientific field and explains the basics of the regulatory and quality environments encountered in a biotechnology or pharmaceutical field. Surveys the principles and practices used on a day-to-day basis in regulatory affairs and quality systems. Lecture 2 hours per week.

General Course Purpose

This course is designed to provide an introduction to the regulations and quality control procedures for the biotechnology industry. Students will be introduced to concepts and practices involved in maintaining quality control standards in the biopharmaceutical manufacturing industry. This course is designed to help students learn the importance of writing and following standard operating procedures (SOPs), complying with environmental health and safety standards, and complying with current good manufacturing practices (cGMPs). The course will also cover effective communication and documentation skills, information management, validation support, and the importance of equipment maintenance and troubleshooting.

Course Prerequisites/Corequisites

Prerequisites: Program placed, BIO 180 with a "C" or better or biotechnology program head permission

Course Objectives

Upon completing the course, the student will be able to:

- Work in compliance with environmental health and safety standards
- Work in compliance with cGMPs
- Clean and maintain production areas
- Maintain effective communication
- Properly collect and document samples
- Carry out appropriate laboratory work following SOPs
- Appropriately manage information and maintain proprietary information properly
- Provide technical and/or validation support
- Assist in the maintenance of laboratory equipment

Major Topics to be Included

- SOPs, written test procedures, safety, regulatory requirements, and approved license requirements
- Record keeping and documentation
- Proper material/sample collection
- Reagent and sample preparation
- Proper testing and validation of reagents, samples, raw materials
- Execution of laboratory testing and data analysis
- Records management
- Validation procedures, including troubleshooting technical problems, instrument malfunctions, and methodology problems