BTEC 120 - BUSINESS AND REGULATORY PRACTICES IN BIOTECHNOLOGY

Units Lecture	3.00	**Units Lab**	0.00	**Units Total**	3.00
Total Hrs Lecture	50.00	**Total Hrs Lab**	0.00	**Total Course Hrs**	50.00

COURSE DESCRIPTION

This course examines basic business principles and practices utilized in the discovery, development, and production phases of new product development. It explores the role of governmental oversight and regulation in assuring the safety, efficacy, and quality of a biotechnology product.

ENROLLMENT RESTRICTIONS

PREREQUISITES	*COREQUISITES*	*ADVISORIES*
None	None	None

OUTLINE OF COURSE CONTENT

The course will address the following topics:

I. History of regulation in the United States of drugs intended for human use
A. Development of the Food and Drug Administration (FDA) and the need for drug efficacy, safety, and quality
B. Product quality attributes.

II. Business practices related to the development of a model human therapeutic
A. Stages of product development: discovery, development, and production
B. Market sectors of biotechnology
C. Funding biotechnology product development
D. Risk analysis and risk management.

III. Regulatory requirements related to the development of a model human therapeutic
A. Preclinical studies and Good Laboratory Practices (GLPs)
B. Clinical studies: Phases I, II, III, and IV
C. Regulatory filings (IND, NDA).

IV. Quality systems
A. Good manufacturing practices (GMPs)
B. Quality management and consequences of noncompliance
C. International efforts to harmonize quality and regulatory requirements: International Conference on Harmonization (ICH)
D. International Organization for Standardization (ISO).

V. Process control for human therapeutic
A. Control of process inputs: man, machine, materials, methods, environment
B. Documentation: policies, procedures, records, and change control
C. Validation: qualification and process validation
D. Quality control: analytical and microbiological
E. Quality assurance (QA): corrective and preventive actions (CAPA), investigations, root cause analysis.

VI. Intellectual property
A. Patents, trademarks, and copyrights
B. Trade secrets.

VII. Inspections and audits
A. Regulatory inspections
B. Supplier audits
C. Internal audits
D. Reporting requirements for regulated therapeutics

E. Product labeling and promotional violations.

VIII. Organizational operations
A. Facilities: manufacturing, quality control laboratory, warehouse, and distribution
B. Personnel: independence of manufacturing and quality
C. Materials management: material and vendor controls.

PERFORMANCE OBJECTIVES

Upon successful completion of this course, students will be able to do the following:

1). Describe and assess the impact of tragedy, regulatory reform, and voter will in establishing requirements for drug product efficacy, safety, and quality
2). Contrast the business practices during the stages of product development and apply principles of risk management towards the goal of a marketed therapeutic
3). Evaluate the regulatory requirements in bringing a regulated therapeutic to market
4). Examine the standardization of quality and regulatory practices in the production of a regulated therapeutic and the role of harmonization in a global health care market
5). Appraise the need for process control in the production of a quality product whereby end users have the reasonable expectation that it is safe and effective for the intended use
6). Describe the various forms of intellectual property and relate their importance in a technology-based industry
7). Evaluate the role of an auditor in assessing compliance with regulatory and internal requirements
8). Describe the operational aspects of a biotechnology manufacturer and assess the unique roles of manufacturing and quality in producing a safe and effective product