Course Title: Pharmaceutical Chemistry

Course Code: CH-828

Credit Hours: 3-0

Prerequisite: Nil

Course Objectives

An increasing number of pharmaceuticals in human and veterinary medicine are being developed using advanced genetic and other methods that focus on modification of somatic and embryonic cells. These methods, in the setting of drug manufacture, call for new processes that go beyond the traditional unit processes of chemical and biological production, such as batch submerged culture. The course explains how technologies developed in the last decade function similarly to unit operations for producing advanced biopharmaceuticals, such as hormones, cytokines, therapeutic enzymes, modified proteins, and transgenic products.

Course Outcomes

This course provides an understanding of the interrelated activities throughout the drug development cycle and is designed for R&D, operations and/or marketing and sales management. This course serves as an introduction to the drug development process and will familiarize students with the steps involved in developing a drug from Discovery to Commercialization.

Course Contents

a. A Practical Introduction to Design of Experiments

b. Active Pharmaceutical Ingredient (API) and Drug Product Specifications

c. Drug design and Development

d. Drug Metabolism in Drug Discovery

e. Adverse Drug Events Reporting & Regulatory Requirements

f. Analytical Method Validation for Pharmaceutical, Biopharmaceutical, and Biologics Quality Control

g. Aseptic Processing in the Manufacture of Biotech and Pharmaceutical Products

h. Bio Manufacturing of Protein Therapeutics: Rewards and Challenges

i. Chiral Pharmaceuticals: Analysis and Separation

j. GMP for Quality Assurance and Quality Control of Pharmaceuticals, Biopharmaceuticals, and Biologics

k. Clean room Microbiology for the Non-Microbiologist

l. Discrete Automation in Bio Processing Unit Operations

m. Good Monitoring Practices for Medical Devices

n. Genomics, Proteomics, and Metabolomics - Impact on Biopharmaceutical Processing

o. Immunogenicity of Biopharmaceuticals

p. Regulatory Compliance for Biopharmaceuticals and Biologics

q. Comprehensive Overview of FDA Regulatory Compliance for Drugs and Biotech Products

r. Generic Drug Approvals: Preparing an ANDA for First-Cycle Approval

s. Generic Drug Approvals: Preparing an ANDA for First-Cycle Approval Generic Drug Approvals: Preparing an ANDA for First-Cycle Approval

t. Pharmaceutical Counterfeits and Intellectual Property Rights Infringement

u. Photostability of Drug Substances

v. Quality System Regulation for the Medical Device & Biotech Industries

w. Sterilization Procedures: Technology, Equipment and Validation

x. Stability Testing of Proteins, Peptides & Other Biomolecules

y. Validation of Computer Systems th ACM-23 Jan 2023 WP No.26-64 112

z. Financial Fundamentals; How Financial Issues Impact Business

Recommended Books

1. Modern Biopharmaceuticals: Design, Development and Optimization by Jörg Knäblein (Hardcover - Dec 6, 2005)
2. Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs by Rodney J.Y. Ho and Milo Gibaldi (Jun 27, 2003)
3. Biopharmaceuticals: Biochemistry and Biotechnology by Gary Walsh (Sep 19, 2003)
4. Sterile Product Facility Design and Project Management, Second Edition by Jeffrey N. Odum (Mar 29, 2004)
5. Advanced Technologies in Biopharmaceutical Processing By: Roshni Dutton (BioProcess Assist (BPA) Ltd.) and Jeno Scharer (University of Waterloo) (2007)

6. Immunogenicity of Biopharmaceuticals Biotechnology: Pharmaceutical Aspects VIII van de Weert, Marco; Møller, Eva Horn (Eds.) 2008, XII
7. Advanced Gene Delivery: From Concepts to Pharmaceutical Products (Drug Targeting and Delivery) by Alain Rolland (2006)