

BIOPHARMACEUTICALS (HCB-917)

Credit hours 3 (3-0)

Educational Objectives:

1. This course provides an understanding of the interrelated activities throughout the drug development cycle and is designed for R&D, mechanism or drugs actions, 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. An increasing number of pharmaceuticals in human and veterinary medicine are being developed using advanced genetic and other methods and therefore, this course will provide a balanced approached knowledge to the students. 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:

2. Demonstrate a proficiency of knowledge in the areas of biopharmaceuticals and intellectual property related to the pharmaceutical regulatory approval processes. Students will have in depth knowledge about the different stages in the processing of the biopharmaceuticals and will find jobs in pharmaceutical industries.

3. Course contents:

- a. Introduction to the drugs
- b. Active pharmaceutical ingredients and drug produced specifications
- c. Regulatory Compliance for Biopharmaceuticals and Biologics
- d. Sources of biopharmaceuticals
- e. Biomanufacturing of Therapeutic Proteins
- f. Adverse Drug events, reporting & regulatory requirements
- g. Problems in manufacturing
- h. Chiral Pharmaceuticals: Analysis and separation
- i. Stability Testing of Proteins, Peptides & Other Biomolecules
- j. Drug design and development
- k. Immunogenicity of Biopharmaceuticals
- l. Antibodies

- (1) Monoclonal
 - (2) bi-specific
- m. Enzymes
 - (1) DNAase
 - (2) Asparaginase
- n. Biopharmaceuticals used in blood homeostasis
- o. Hormones
 - (1) Insulin
 - (2) Growth hormone
- p. Vaccines

Recommended Journals:

1. **Modern Biopharmaceuticals: Design, Development and Optimization** by Jörg Knäblein.
2. **Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs** by Rodney J.Y. Ho and Milo Gibaldi.
3. **Biopharmaceuticals: Biochemistry and Biotechnology** by Gary Walsh.
4. **Sterile Product Facility Design and Project Management**, by Jeffrey N. Odum.
5. **Advanced Technologies in Biopharmaceutical Processing** by Roshni Dutton (BioProcess Assist (BPA) Ltd.) and Jenö Schärer (University of Waterloo)
6. **Immunogenicity of Biopharmaceuticals Biotechnology: Pharmaceutical Aspects VIII** by van de Weert, Marco; Møller, Eva Horn (Eds.)
7. **Advanced Gene Delivery: From Concepts to Pharmaceutical Products (Drug Targeting and Delivery)** by Alain Rolland.