

**Pharmaceutical Biotechnology Virtual Lab:
Student Learning Objectives / Desired Outcomes**

Module 1: PBVL Company Orientation and Native Protein Purification

1. Understands the basic organization of the work units in a pharmaceutical company.
 - 1.1 Describes the interrelationships of the work units in a pharmaceutical company.
 - 1.2 Describes the role of each work unit in the pharmaceutical biotechnology drug development process.
2. Understands the Scientific Method as a strategy to solve problems.
 - 2.1 Applies the Scientific Method to scientific and clinical problems.
 - 2.2 Applies the Scientific Method to solving everyday problems.
3. Describes the scientific steps of the pharmaceutical biotechnology drug research and development process.
4. Understands several chromatographic techniques used for small scale protein sequencing.
 - 4.1 Describes HPLC size-exclusion chromatography.
 - 4.2 Interprets the results of a SDS-Page gel.
 - 4.3 Describes affinity chromatography.
5. Understands the scientific process of protein sequencing.
 - 5.1 Discriminates between SDS-Page and Reverse-Phase HPLC for peptide purification.
 - 5.2 Writes the one-letter amino acid code for peptides.
 - 5.3 Describes the possible pitfalls in a protein sequencing experiment

Module 2: Cloning of the Gene Encoding the Protein

1. Rationally selects and designs a scientific approach for the isolation of mRNA.
 - 1.1 Discriminates between traditional and contemporary mRNA isolation methods.
 - 1.2 Describes mRNA quantitation and purity techniques.
 - 1.3 Identifies possible pitfalls in mRNA isolation.
2. Understands three basic gene cloning strategies.
 - 2.1 Discriminates between direct synthesis of cDNA versus RT-PCR versus RACE-PCR.
 - 2.2 Designs a virtual PCR experiment
 - 2.2.1 Designs oligonucleotide primers.
 - 2.2.2 Designs PCR conditions.
 - 2.2.3 Describes PCR product purification.
3. Selects a cloning vector based on the experimental requirements and constraints.
4. Describes to screen transformed bacteria harboring the recombinant cloning vector.

Module 3: Development of an Expression System

1. Understands strategies to select transformed bacteria harboring the cloned gene.
 - 1.1 Designs probes for colony screening.
 - 1.2 Describes transformed bacterial colony selection and testing.
 - 1.3 Describes protein expression experiments as a validation test.
2. Describes approaches for the development of a stable expression system.

Module 4: Protein Isolation and Purification

1. Designs experiments to isolate, concentrate and decontaminate the recombinant protein produced by the stable expression system.
2. Designs a three-step protein purification approach to obtain recombinant proteins in high yield and purity.

Module 5: Recombinant Protein Dosage Form Design

1. Describes the physicochemical tests unique to recombinant proteins.
2. Designs and formulates a recombinant protein dosage form.
3. Describes stability testing strategies for assessment of the final dosage form.

Module 6: Preclinical and Clinical Testing for FDA Approval

1. Describes the preclinical tests necessary to obtain an FDA IND.
2. Describes the FDA review process for an IND.
3. Describes the clinical tests necessary to obtain an FDA BLA.
4. Describes the FDA review process and various FDA decisions in reviewing a BLA application.