

Process Development Ready Track* (190 hours):

Mammalian Cell Culture

- Aseptic/Sterile Techniques
- Thawing - Cell Culture Maintenance
- Cell Culture Microscopy (Enumeration and Viability), Passage (Cell Counting and Splitting)
- Cryopreservation (Harvest and Freeze cells)
- Understanding of Cell metabolism
- Sterility Testing; Solutions for contaminant and impurity testing

Protein Purification and Analysis

- Understanding Protein Structure, function and role in Homeostasis, 3D structures, - (up regulate, down regulate, create novel function - Biologics and therapeutics.
- Protein Purification methods and assays (ELISA, Western Blots, SDS-page, MALDI-TOFF, HPLC, etc.)
- Protein Identification methods and assays (FPLC-AKTA, etc.)

HPLC: Principles of Chromatography

- Scientific Hypothesis; Experimental Design
- Basic Principles in HPLC, separation techniques
- Quantitative and Qualitative Strategies
- Sample Preparation strategies for analysis, Quality Control

Microscopy

- Principles and Fundamentals of Light Microscopy
- Histology
- Principles and fundamentals of Live Microscopy

Introduction to Bioprocessing and Instrumentation

- Introduction to QC Measures and Molecular Testing Methods
- Cell Culture and Bioreactor Sterile Methods
- Materials and Management
- Introduction to Molecular Testing and Quality Control; QC measures, PCR, ELISA
- Equipment and Instrument, maintenance, sterilization, Disassembly, Cleaning, pH, Oxygenation and temperature monitoring

Regulatory Compliance and Inspection

- Quality and Regulatory: cGMP, critical quality attributes, critical process parameters, efficacy, safety, environmental monitoring, Upstream and Downstream Processes
- Regulatory Audits; Inspections and Observations, Records of Regulatory findings
- Recall Process, Complaint Handling
- Regulatory Agencies such as FDA

Cell and Gene Therapy

- Cell and Gene Therapy
- Human Gene Editing
- Cell and Gene Therapeutics
- Cell Therapy Workflow and testing solutions
- Process Control; characterizing viral vectors, environmental monitoring
- Data Analysis

Workplace Competency; Communications and Presentation Skills, Poster Presentation (30 hours)

***Intern Ready & Research Associate Ready Courses are prerequisites for Process Development Track.*