Advanced Bio-Separation Techniques Training Course Outline

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The burgeoning field of biotechnology and biopharmaceuticals demands increasingly sophisticated and high-resolution separation techniques. As the industry scales up production of complex biologics including monoclonal antibodies (mAbs), recombinant proteins, and gene therapies the bottleneck often lies in achieving rapid, efficient, and cost-effective downstream processing (DSP). This introductory course provides a deep dive into the theoretical underpinnings and practical applications of cutting-edge bio-separation methodologies. Participants will master techniques essential for product purity, process intensification, and regulatory compliance, directly addressing the industry's critical need for skilled professionals who can optimize recovery yields and ensure critical quality attributes (CQAs) are met in a competitive global market.

Advanced Bio-Separation Techniques Training Course Outline is designed to equip bioprocess engineers and scientists with advanced skills in key separation modalities. We will cover the latest advancements in chromatography including affinity, hydrophobic interaction (HIC), and ion exchange (IEX) as well as emerging technologies like membrane chromatography and continuous bioprocessing. Crucially, the program emphasizes process development strategies, scale-up principles, and the integration of PAT (Process Analytical Technology) tools for real-time monitoring and control. By focusing on viral clearance, impurity removal, and process economics, this training ensures participants can immediately apply advanced knowledge to achieve regulatory excellence and drive innovation in the manufacture of life-saving therapeutics.

Programme Curriculum

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Introduction

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Course Objectives

Upon completion of this course, participants will be able to:

1. Evaluate the role of High-Resolution Separations in modern Biologics Manufacturing.
2. Optimize Chromatography Media selection for diverse Recombinant Proteins and mAbs.
3. Design efficient Capture Step and Polishing Step protocols.
4. Implement Continuous Chromatography for Process Intensification.
5. Master the principles of Hydrophobic Interaction Chromatography (HIC) and its application in Aggregation Control.
6. Apply Ultrafiltration/Diafiltration (UF/DF) for effective Buffer Exchange and Concentration.
7. Integrate Membrane Chromatography for high-throughput Viral Clearance and Impurity Removal.
8. Develop robust Viral Inactivation and Virus Filtration strategies.
9. Utilize Process Analytical Technology (PAT) for real-time Downstream Monitoring.
10. Analyze Process Economics to minimize Cost of Goods Sold (COGS) in DSP.
11. Troubleshoot common issues in Scale-Up from lab to Commercial Manufacturing.
12. Ensure regulatory compliance with ICH Guidelines for Product Purity.
13. Adapt separation techniques for emerging modalities like Gene Therapies

Target Audience

1. Bioprocess Engineers and Scientists
2. Downstream Process Development Specialists
3. Biomanufacturing Operations Personnel
4. Quality Assurance/Quality Control (QA/QC) Analysts
5. R&D Scientists in Biologics and Vaccines
6. Technical Project Managers in Biopharma

7. Academics and Post-doctoral Researchers
8. Regulatory Affairs Professionals involved in CMC

Course Modules

Module 1: Foundational Principles of Bio-Separation

- Understanding the challenge of biologics complexity and impurity profiles.
- Review of key separation drivers: size, charge, hydrophobicity, and affinity.
- Process flow overview: from harvest to final formulation.
- Defining and measuring Critical Quality Attributes (CQAs) and process performance indicators (PPIs).
- Case Study: The impact of host cell protein (HCP) and aggregate removal on therapeutic efficacy.

Module 2: Advanced Ion Exchange Chromatography (IEX)

- Mechanisms and selection of strong vs. weak exchangers (anion/cation).
- Salt and pH gradient optimization for high-resolution separation.
- Application of multimodal ligands for enhanced selectivity.
- Understanding binding capacity and flow rate limitations in scale-up.
- Case Study: Optimizing a Cation Exchange (CEX) polishing step for a bispecific antibody.

Module 3: Affinity Chromatography for High Selectivity

- Deep dive into Protein A/G and non-Protein A alternatives for mAb capture.
- Optimization of elution conditions to maintain product integrity and reduce aggregation.
- Strategies for media regeneration and lifetime extension.
- The role of affinity in emerging modalities like VLPs and gene therapy vectors.
- Case Study: Designing a high-yield, low-cost capture step using a novel synthetic ligand.

Module 4: Hydrophobic Interaction Chromatography (HIC)

- Theory of hydrophobic interactions and the role of kosmotropic salts.
- Method development for aggregate and variant separation.
- Impact of temperature and additives on HIC performance.
- Troubleshooting peak shape and resolution issues.
- Case Study: Using HIC as a robust polishing step for the removal of deamidated product variants.

Module 5: Size Exclusion Chromatography (SEC) and Gel Filtration

- Principles of separation based on hydrodynamic radius.
- Analytical vs. preparative SEC applications and limitations.
- Column selection and mobile phase optimization for accurate monomer sizing.
- Integration of SEC for formulation and buffer screening.
- Case Study: Utilizing preparative SEC for high-purity isolation of virus-like particles

Module 6: Principles of Ultrafiltration and Diafiltration (UF/DF)

- Theory and mechanism of convective mass transfer across membranes.
- Selecting the correct molecular weight cut-off (MWCO) and membrane material.
- Optimization of flux and recovery in tangential flow filtration (TFF) systems.
- System design and practical considerations for scale-up.

- Case Study: Developing an efficient 3-volume diafiltration process for a high-concentration therapeutic protein.

Module 7: Cutting-Edge Membrane Chromatography

- Comparison of traditional packed-bed columns vs. membrane adsorbers.
- Application in flow-through polishing and high-throughput impurity removal.
- Benefits for process intensification and single-use technologies.
- Strategies for maximizing dynamic binding capacity on membranes.
- Case Study: Replacing a secondary IEX column with a single-use membrane unit for cost savings.

Module 8: Robust Viral Clearance Strategies

- Regulatory requirements and guidelines for viral safety.
- In-depth analysis of viral inactivation methods
- Understanding the mechanism and validation of nanofiltration and virus filters.
- Designing an orthogonal viral reduction scheme
- Case Study: Validation and regulatory submission data for a multi-step viral clearance process.

Module 9: Process Analytical Technology (PAT) in DSP

- The role of PAT in meeting Quality by Design (QbD) principles.
- Real-time monitoring techniques.
- Integrating automation and feedback control for process consistency.
- Data analysis and implementation of chemometrics for process understanding.
- Case Study: Using in-line UV280?Çï and pH to automatically control a chromatography step cut-off.

Module 10: Process Scale-Up and Technology Transfer

- Principles of linear velocity vs. residence time in scale-up.
- Maintaining separation performance across different column diameters and systems.
- The critical role of mass transfer and mixing in large-scale systems.
- Developing a robust tech transfer protocol between R&D and manufacturing.
- Case Study: Scaling a 1-liter pilot chromatography column to a 300-liter manufacturing column.

Module 11: Continuous Chromatography and Process Intensification

- Introduction to Multi-Column Chromatography (MCC) principles
- Detailed analysis of Periodic Counter-Current (PCC) systems for capture.
- Benefits: reduced buffer usage, smaller column size, and increased productivity.
- Integration of continuous UF/DF and in-line mixing.
- Case Study: Converting a batch Protein A step to a 2-column PCC system for 40% reduction in resin cost.

Module 12: Separation for Novel Therapeutic Modalities

- Purification challenges for oligonucleotides and peptides.
- Specialized techniques for pDNA and mRNA purification
- DSP strategies for recombinant vaccines
- Separation of Cell and Gene Therapy products
- Case Study: Developing a high-yield purification train for an AAV-based gene therapy vector.

Module 13: Single-Use Systems in Bio-Separation

- The shift to single-use components in DSP.
- Advantages in reducing cleaning validation and cross-contamination risk.
- Integrating single-use chromatography columns and TFF cassettes.
- Evaluating extractables and leachables (E&L) for regulatory compliance.
- Case Study: Designing a fully disposable DSP suite for a clinical trial material.

Module 14: Documentation and Regulatory Compliance

- Developing robust Standard Operating Procedures (SOPs) and batch records.
- Understanding the regulatory framework for process validation (ICH Q7, Q11).
- The importance of change control and deviations in a GMP environment.
- Preparing the Chemistry, Manufacturing, and Controls section for regulatory submissions.
- Case Study: Responding to an FDA audit observation regarding cleaning validation of chromatography columns.

Module 15: Process Economic Analysis and Optimization

- Calculating key metrics: yield, purity, throughput, and cycle time.
- Analyzing the Cost of Goods Sold (COGS) contribution of DSP.
- Modeling and simulation tools for process optimization.
- Strategies for maximizing column utilization and media lifetime.
- Case Study: A comprehensive COGS analysis comparing batch vs. continuous bioprocessing.

Training Methodology

The course employs a highly interactive and practical methodology designed to foster deep understanding and immediate application:

- Interactive Lectures.
- Hands-on Workshops.
- In-Depth Case Studies.
- Group Problem-Solving.
- Expert Q&A Sessions.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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