Advanced Downstream Chromatography Techniques Training Course

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

In the rapidly evolving biopharmaceutical landscape, the efficiency and fidelity of Downstream Processing are paramount to delivering safe and efficacious therapeutic products, particularly monoclonal antibodies and Novel Drug Modalities like Cell and Gene Therapies. Modern biomanufacturing demands a shift from empirical methods to data-driven and integrated strategies. This advanced course is meticulously designed to equip scientists and engineers with expert-level proficiency in next-generation chromatographic separation technologies. Participants will master complex techniques such as Multicolumn Chromatography, High-Throughput Process Development, and the implementation of Quality by Design principles, moving beyond traditional batch processing to embrace Continuous Bioprocessing.

Advanced Downstream Chromatography Techniques Training Course emphasizes mechanistic modeling, process optimization, and troubleshooting for challenging biotherapeutic purifications, directly addressing industry needs for process intensification and enhanced yield and purity. The curriculum integrates real-world Case Studies focusing on product-related impurities and process-related impurities, leveraging Process Analytical Technology for Real-Time Release Testing. Upon completion, attendees will possess the technical authority to design, scale-up, and validate robust Advanced Chromatography methods, driving their organizations toward Biomanufacturing 4.0 standards, ensuring both regulatory compliance and a significant competitive advantage in the global market.

Programme Curriculum

Advanced Downstream Chromatography Techniques Training Course

Introduction

In the rapidly evolving biopharmaceutical landscape, the efficiency and fidelity of Downstream Processing are paramount to delivering safe and efficacious therapeutic products, particularly monoclonal antibodies and Novel Drug Modalities like Cell and Gene Therapies. Modern biomanufacturing demands a shift from empirical methods to data-driven and integrated strategies. This advanced course is meticulously designed to equip scientists and engineers with expert-level proficiency in next-generation chromatographic separation technologies. Participants will master complex techniques such as Multicolumn Chromatography, High-Throughput Process Development, and the implementation of Quality by Design principles, moving beyond traditional batch processing to embrace Continuous Bioprocessing.

Advanced Downstream Chromatography Techniques Training Course emphasizes mechanistic modeling, process optimization, and troubleshooting for challenging biotherapeutic purifications, directly addressing industry needs for process intensification and enhanced yield and purity. The curriculum integrates real-world Case Studies focusing on product-related impurities and process-related impurities, leveraging Process Analytical Technology for Real-Time Release Testing. Upon completion, attendees will possess the technical authority to design, scale-up, and validate robust Advanced Chromatography methods, driving their organizations toward Biomanufacturing 4.0 standards, ensuring both regulatory compliance and a significant competitive advantage in the global market.

Course Duration

10 days

Course Objectives

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

1. Design and optimize purification protocols for Novel Drug Modalities, including bispecific antibodies and viral vectors.
2. Implement Quality by Design principles for robust chromatography method development and Design Space establishment.
3. Execute Multicolumn Chromatography and other Continuous Bioprocessing strategies to enhance productivity and reduce cost.
4. Master High-Throughput Process Development using automated systems for resin screening and DoE.
5. Apply Mechanistic Modeling and In Silico Simulation to predict chromatographic performance and guide scale-up/scale-down.
6. Effectively manage and clear Process-Related Impurities and Product-Related Impurities
7. Integrate Process Analytical Technology tools for real-time monitoring and Automated Process Control in chromatography.
8. Select and apply Advanced Ligand Chemistries for challenging separations.
9. Troubleshoot complex peak asymmetry, fouling, and system-related issues in Large-Scale Biomanufacturing.
10. Develop and validate methods compliant with global Regulatory Guidelines for Biologics purification.
11. Perform Techno-Economic Analysis on continuous versus batch chromatography to justify new technology adoption.
12. Utilize Ultra-High-Performance Liquid Chromatography for High-Resolution Analytical Purity Assessments.
13. Establish a foundation for Digital Twin implementation in downstream process simulation and optimization.

Target Audience

1. Process Development Scientists/Engineers.
2. Manufacturing Science & Technology (MS&T) Professionals.
3. R&D Researchers
4. Analytical and Quality Control (QC) Scientists
5. Chemical/Biochemical Engineers.
6. Technical Managers/Group Leaders.
7. Automation/Data Scientists.
8. Regulatory Affairs Specialists.

Course Modules

Module 1: Foundations of Advanced Bioseparations

- Review of chromatographic modes.
- In-depth analysis of van Deemter and Resolution equations for Biopolymers.
- Understanding resin particle morphology: Porous, Superficially Porous, Monoliths.
- Case Study: Troubleshooting low HCP clearance due to incorrect IEX resin selection.
- Impact of mobile phase on ligand binding and selectivity.

Module 2: Quality by Design (QbD) and DoE in Chromatography

- Defining Quality Targeted Product Profile and Critical Quality Attributes for purification.
- Utilizing Design of Experiments for method robustness and Design Space mapping.
- Risk assessment tools applied to chromatography steps.
- Case Study: Establishing the Design Space for a Polishing IEX step for mAb charge variants.
- Linking DoE results to process understanding and regulatory documentation.

Module 3: High-Throughput Process Development

- Principles and advantages of HTPD screening.
- Automated resin screening and High-Throughput DoE execution.
- Accurate scale-down model development and qualification.
- Case Study: Rapid screening of 10 Multimodal resins to find the optimal aggregate clearance step.
- Data analysis and visualization from HTPD experiments for decision-making.

Module 4: Mechanistic Modeling and Simulation

- Fundamentals of Mechanistic Modeling for process dynamics.
- Estimating Adsorption Isotherms
- Using simulation software to predict breakthrough curves and elution profiles.
- Case Study: Utilizing In Silico Modeling to predict performance of a Protein A column at large scale.
- Model calibration, validation, and its use in QbD submissions.

Module 5: Continuous Chromatography Fundamentals

- Introduction to Process Intensification and the drivers for Continuous Bioprocessing.
- Multicolumn Chromatography
- Improved productivity, reduced cost of goods, and smaller footprint.
- Case Study: Comparing batch vs. column MCC for a Protein A capture step.
- Design considerations for system integration and buffer management in MCC.

Module 6: Implementation of Multicolumn Chromatography

- Detailed design and operation of 3-column and 4-column PCC systems.
- Cycle time optimization and setting valve switching logic.
- PAT and control strategies for robust MCC operation.
- Case Study: Optimization of a 4-column BioSMB system for Viral Vector purification.
- Techno-Economic Analysis.

Module 7: Advanced Protein A and Affinity Chromatography

- Next-generation Protein A resins.
- Strategies for effective Host Cell Protein and DNA removal during elution/wash.
- Optimizing elution conditions for stability and elution pool management.
- Case Study: Developing a novel elution buffer for acid-sensitive mAb variants.
- Cleaning-in-Place and column lifetime extension protocols.

Module 8: Multimodal and Hydrophobic Interaction Chromatography

- Theory of Multimodal Chromatography and its superior selectivity.
- Practical selection and operation of key Multimodal resins
- HIC method development for monomer/aggregate separation and ADC purification.
- Case Study: Using a Multimodal column to replace two separate polishing steps
- Troubleshooting HIC peak splitting and protein precipitation.

Module 9: Purification of Novel Drug Modalities

- Chromatography challenges for Viral Vectors and mRNA products.
- Techniques for plasmidDNA and empty-full capsid separation.
- Strategies for purifying Antibody-Drug Conjugates using HIC and SEC.
- Case Study: Developing an AAV purification platform using Affinity and IEX for Full Capsid enrichment.
- Scalability and regulatory aspects of NDM purification processes.

Module 10: Process Analytical Technology (PAT) and APC

- UV, Fluorescence, Raman, and Spectroscopy for DSP.
- Implementing Soft Sensors and predictive models for real-time quality monitoring.
- Automated Process Control strategies for dynamic pool cut decisions.
- Case Study: Using inline UV monitoring and APC to control the elution pool cut in IEX.
- Data integrity, PAT validation, and its role in Real-Time Release Testing

Module 11: Scaling and Technology Transfer

- Principles of hydrodynamic similarity and scale-up/scale-down calculations.
- Mitigating axial dispersion and column packing irregularities at large scale.
- Protocol development and documentation for seamless Technology Transfer
- Case Study: Successful Tech Transfer of an MCC process from PD lab to CMO pilot scale.
- Validation requirements for scale-down models and process control strategies.

Module 12: HPLC, UHPLC, and High-Resolution Analysis

- Advanced operation of UHPLC for high-speed, high-resolution purity analysis.
- Method development for aggregate and fragment quantification via SEC-UHPLC.
- Coupling LC with Mass Spectrometry for Product-Related Impurity characterization.
- Case Study: Using UHPLC with Charge Variant analysis to evaluate process stability.

- Regulatory expectations for Method Validation and system suitability.

Module 13: Column Performance, Packing, and Maintenance

- Best practices for column packing and Unpacking procedures.
- Determining Column Efficiency and Acceptance Criteria.
- Advanced Troubleshooting for peak tailing, fronting, and pressure drops.
- Case Study: Identifying and resolving resin compression issues in a large-diameter column.
- Long-term column storage, regeneration, and sanitization protocols.

Module 14: Viral Safety and Clearance Strategies

- Overview of regulatory requirements for Viral Safety in DSP.
- Chromatography's role in Viral Inactivation and Removal
- Process design for achieving required Log Reduction Value targets.
- Case Study: Designing a chromatography train that achieves 12 LRV for Model Virus Removal.
- Strategies for virus filter optimization and integration with chromatography.

Module 15: Future Trends in DSP and Biomanufacturing 4.0

- The rise of Integrated and Fully Continuous Biomanufacturing Flowsheets.
- Digital Twins and their application for Predictive Maintenance and Process Optimization.
- Emerging separation technologies.
- Case Study: Assessing the feasibility of converting a batch DSP suite to a Continuous Biomanufacturing Facility.
- Ethical and regulatory challenges of Artificial Intelligence in process control.

Training Methodology

The course employs a **Blended Learning** approach combining:

- Interactive Lectures.
- Hands-on/Virtual Labs.
- Software Workshops.
- Industry Case Studies.
- Group Problem-Solving.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com