Advanced Single-Use Chromatography Systems 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

The biopharmaceutical landscape is undergoing a paradigm shift toward flexible, cost-effective, and contamination-risk mitigating manufacturing processes. Advanced Single-Use Chromatography Systems (ASUCS), often referred to as disposable chromatography, represent a critical enabler in the modern downstream processing of biologics, including monoclonal antibodies (mAbs), vaccines, and cell and gene therapies. Advanced Single-Use Chromatography Systems Training Course is meticulously designed to move beyond fundamental concepts, focusing on the sophisticated design, operation, and validation of these systems. Participants will gain cutting-edge expertise in leveraging ASUCS to significantly enhance process economics, speed-to-market, and cGMP compliance in a rapidly evolving biomanufacturing environment.

This course provides a deep dive into process optimization and advanced regulatory considerations unique to single-use platforms. A strong emphasis will be placed on next-generation chromatography techniques, such as continuous chromatography, multi-modal resins, and the integration of Process Analytical Technology (PAT). By mastering the complexities of single-use fluid path integrity, leachables and extractables (L&E) management, and digital integration, attendees will be equipped to spearhead the deployment of high-throughput, scalable purification strategies. The curriculum is essential for professionals aiming to drive operational excellence and ensure product quality in a future dominated by flexible bioprocessing.

Programme Curriculum

Advanced Single-Use Chromatography Systems Training Course

Introduction

The biopharmaceutical landscape is undergoing a paradigm shift toward flexible, cost-effective, and contamination-risk mitigating manufacturing processes. Advanced Single-Use Chromatography Systems (ASUCS), often referred to as disposable chromatography, represent a critical enabler in the modern downstream processing of biologics, including monoclonal antibodies (mAbs), vaccines, and cell and gene therapies. Advanced Single-Use Chromatography Systems Training Course is meticulously designed to move beyond fundamental concepts, focusing on the sophisticated design, operation, and validation of these systems. Participants will gain cutting-edge expertise in leveraging ASUCS to significantly enhance process economics, speed-to-market, and cGMP compliance in a rapidly evolving biomanufacturing environment.

This course provides a deep dive into process optimization and advanced regulatory considerations unique to single-use platforms. A strong emphasis will be placed on next-generation chromatography techniques, such as continuous chromatography, multi-modal resins, and the integration of Process Analytical Technology (PAT). By mastering the complexities of single-use fluid path integrity, leachables and extractables (L&E) management, and digital integration, attendees will be equipped to spearhead the deployment of high-throughput, scalable purification strategies. The curriculum is essential for professionals aiming to drive operational excellence and ensure product quality in a future dominated by flexible bioprocessing.

Course Duration

10 days

Course Objectives

1. Master the principles of Single-Use Chromatography (SUC), contrasting its process economics and environmental sustainability against traditional stainless-steel systems.
2. Design and Engineer ASUCS flow paths for multi-product facilities, emphasizing flexibility and rapid changeover.
3. Optimize chromatographic separation using advanced single-use resins and multi-modal chromatography for challenging protein purification
4. Implement and Control Continuous Chromatography (PCC) and Integrated Downstream Processing using single-use hardware.
5. Develop robust Leachables and Extractables (L&E) risk mitigation and testing strategies for single-use assemblies under cGMP guidelines.
6. Validate and ensure the Sterility Assurance Level (SAL) and bioburden control of gamma-irradiated single-use components.
7. Integrate Process Analytical Technology (PAT) and real-time monitoring for automated process control and improved process understanding.
8. Evaluate and select appropriate single-use sensors, valves, and pump technologies for precise fluid handling and control.
9. Troubleshoot common chromatographic deviations and hardware issues unique to advanced single-use systems.
10. Apply Quality by Design (QbD) principles for developing and scaling-up single-use purification methods to commercial scale.
11. Conduct comprehensive Cost of Goods Sold (COGS) and Life Cycle Assessment (LCA) to justify single-use technology adoption.
12. Navigate Advanced Regulatory Submissions requirements related to single-use systems
13. Explore the future of bioprocessing 4.0 by integrating AI/Machine Learning for predictive maintenance and process optimization in ASUCS.

Target Audience

1. Process Development Scientists/Engineers.
2. Manufacturing/Operations Specialists.
3. Validation/Quality Assurance Professionals.
4. Bioprocess Automation Engineers.
5. Regulatory Affairs Specialists.
6. R&D Researchers.
7. Supply Chain/Procurement Managers.
8. Technical Directors/Managers.

Course Modules

Module 1: SUC Fundamentals and Strategic Justification

- Detailed Techno-Economic Analysis (TEA) and CapEx/OpEx comparison.
- Components of Advanced SUC Systems.
- Biologics Purification Economics, Facility Footprint, Disposable Technology.
- Regulatory landscape and cGMP compliance for SUC in Phase I/II/III.
- Case Study: Justification for adopting a complete SUC platform for a Vaccine manufacturing facility build-out.

Module 2: Advanced Single-Use Resin and Media Selection

- Selection criteria for high-binding capacity and high-flow single-use resins.
- In-depth focus on Multi-modal Chromatography and Hydrophobic Interaction Chromatography (HIC) media in SU columns.
- High-Throughput Screening, Multi-Modal Resins, Adsorption Isotherms.
- Impact of resin particle size and column geometry on Scale-up and Scale-down.
- Case Study: Optimizing a purification step by replacing a traditional resin with a SU membrane adsorber for viral vector clearance.

Module 3: SUC System Design and Engineering Principles

- Modular design philosophy for flexible single-use skid integration.
- Best practices for Tubing, Connection, and Sterile Welding of disposable assemblies.
- Fluid Path Integrity, Aseptic Connections, Gamma Sterilization.
- Design considerations for pressure, flow rate, and back-pressure management in SU systems.
- Case Study: Designing a closed-system SU chromatography train from capture to polishing for a bispecific antibody.

Module 4: Leachables and Extractables (L&E) Management

- Fundamentals of polymer chemistry and L&E profile generation for SU components.
- Regulatory expectations and risk assessment frameworks for L&E.
- Toxicology Assessment, Material Compatibility, Risk Mitigation Strategy.
- Methodology for conducting Worst-Case-Scenario L&E studies and subsequent toxicological evaluation.
- Case Study: Investigating and mitigating a critical leachable identified during the process validation of a new single-use bioreactor bag.

Module 5: Principles of Continuous Chromatography (PCC)

- Theory and benefits of Continuous Chromatography
- Differences between batch and continuous operation in terms of productivity and resin utilization.
- Process Intensification, High Productivity, Simulated Moving Bed (SMB).
- Hardware and software requirements for SU-PCC system operation and control.
- Case Study: Transitioning a traditional batch Protein A capture step to a three-column PCC system using single-use pre-packed columns to halve column size.

Module 6: Advanced Control Strategies and Automation

- Integration of Advanced Automation for auto-tuning and self-correction of chromatographic runs.
- Implementation of Feed Forward and Feed Back control loops for gradient and flow rate precision.
- SCADA Systems, Control Algorithms, Data Integrity.
- System control architecture and data integrity challenges in single-use environments.
- Case Study: Developing an automated control sequence for in-line buffer dilution integrated with the ASUCS for hands-off operation.

Module 7: Process Analytical Technology (PAT) in SUC

- Selection and validation of Single-Use Sensors for real-time monitoring.
- Integration of in-line/at-line analytical tools for critical quality attribute (CQA) prediction.
- Real-Time Release (RTRT), Quality by Design (QbD), Spectroscopic Analysis.
- Data acquisition, processing, and leveraging chemometrics for process understanding.
- Case Study: Using an in-line UV sensor and a PAT analyzer to achieve real-time pool cut determination in a polishing step.

Module 8: Single-Use Filtration and Virus Clearance Integration

- Integration of single-use Depth Filtration and Sterile Filtration units upstream and downstream of chromatography.
- Design of a robust, single-use viral filtration train and its integrity testing protocols.
- Viral Clearance Strategy, Filter Sizing, Prefiltration Optimization.
- Regulatory expectations and log reduction value (LRV) requirements for viral removal.
- Case Study: Designing a pre-filter optimization strategy to maximize the capacity of a costly single-use viral filter in a high-titer mAb process.

Module 9: Qualification and Validation of ASUCS

- Developing a complete Validation Master Plan (VMP) for single-use chromatography skids and assemblies.
- Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) unique to SU systems.
- System Qualification, Change Control, Risk-Based Validation.
- Protocol development for validating gamma sterilization dose and extractables testing as part of qualification.
- Case Study: Executing the OQ protocol for a multi-column SUC system, focusing on pump accuracy and UV sensor calibration.

Module 10: Troubleshooting and Maintenance of ASUCS

- Identifying and resolving common operational issues.
- Protocols for integrity testing and leak detection of single-use bags and assemblies.

- System Diagnostics, Preventative Maintenance, Root Cause Analysis (RCA).
- Strategies for handling and disposal of contaminated single-use consumables.
- Case Study: Conducting a Root Cause Analysis on a consistently high back-pressure issue traced back to a specific component in the single-use flow path.

Module 11: Scale-Up and Technology Transfer

- Principles of linear velocity scaling for maintaining chromatographic performance.
- Strategies for successful technology transfer of a SUC process from development to a cGMP manufacturing suite.
- Geometric Scaling, Process Characterization, Design Space.
- Using Process Performance Indicators (PPIs) for monitoring and maintaining scale-up consistency.
- Case Study: Scaling a 20-cm diameter pre-packed column to an 80-cm single-use column and comparing the purification yield and quality metrics.

Module 12: Single-Use Systems for Cell and Gene Therapy

- Adaptation of SUC for purifying viral vectors and non-viral vectors.
- Challenges and solutions for low-titer, high-viscosity purification in SUC.
- Vector Purification, Exosome Isolation, Oligonucleotide Synthesis.
- Application of monolithic chromatography within a single-use platform.
- Case Study: Developing an all-single-use purification train for a Lentiviral vector, from harvest clarification to final sterile filtration.

Module 13: Supply Chain and Vendor Management

- Supplier qualification and audit requirements for single-use component manufacturers.
- Strategies for ensuring long-term supply security and managing material obsolescence.
- Business Continuity, Material Traceability, Dual Sourcing.
- Best practices for storage, inventory control, and shelf-life management of gamma-irradiated consumables.
- Case Study: Implementing a dual-sourcing strategy for critical single-use bags following a major supply chain disruption.

Module 14: Bioprocessing 4.0 and Digital Integration

- Concepts of Smart Manufacturing and the Digital Twin in bioprocessing.
- Integrating ASUCS data with LIMS and MES for seamless data flow and batch record generation.
- Industry 4.0, Artificial Intelligence (AI), Predictive Modeling.
- Introduction to AI/Machine Learning for predictive process monitoring and anomaly detection.
- Case Study: Implementing an AI-driven model to predict the optimal time for column sanitization based on real-time process data, reducing downtime.

Module 15: Regulatory Filing and Future Trends

- Specific sections of IND/BLA/NDA filings where single-use system data must be presented.
- Miniaturization, fully automated closed-loop systems, and in-situ monitoring.
- Advanced Regulatory Strategy, Single-Use Roadmap, Personalized Medicine.
- Global regulatory convergence on single-use technology adoption.
- Case Study: Preparing the chemistry, manufacturing, and controls (CMC) section of a BLA submission focusing on the validation and L&E data of a novel single-use chromatography system.

Training Methodology

This course employs an Advanced Blended Learning approach, ensuring deep theoretical understanding complemented by critical practical application and problem-solving skills.

1. Expert-Led Interactive Lectures.
2. Hands-on Virtual Simulations/Labs.
3. Real-World Case Studies and Group Projects.
4. Q&A and Regulatory Discussion Panels.
5. Technical Whitepaper Review.

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

Start Date	End Date	Location	Price
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

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

Register Online Now

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