Downstream Processing for Complex Biologics 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

Downstream Processing (DSP) is the critical and often rate-limiting step in biopharmaceutical manufacturing, directly determining the quality, yield, and purity of life-saving therapeutics. The transition from traditional monoclonal antibodies (mAbs) to complex biologics such as antibody-drug conjugates (ADCs), bispecific antibodies, gene therapies, and viral vectors presents unprecedented purification challenges due to their structural heterogeneity and sensitivity. This advanced training course provides participants with the next-generation bioprocessing strategies required to overcome the downstream bottleneck. We focus on cutting-edge technologies like continuous chromatography, process intensification, and Process Analytical Technology (PAT) to design robust, scalable, and cost-effective DSP workflows that ensure compliance with stringent cGMP and Quality-by-Design (QbD) principles.

Downstream Processing for Complex Biologics Training Course is designed to transform process scientists and engineers into DSP experts capable of innovating and troubleshooting complex purification trains. By integrating hands-on exercises with real-world case studies on Host Cell Protein (HCP) and DNA clearance, viral clearance/inactivation, and advanced Tangential Flow Filtration (TFF) techniques, attendees will master the principles of high-resolution separation. Mastering these skills is essential for accelerating time-to-market and sustaining the competitive edge of biomanufacturing operations in the rapidly evolving landscape of advanced therapeutic development.

Programme Curriculum

Downstream Processing for Complex Biologics Training Course

Introduction

Downstream Processing (DSP) is the critical and often rate-limiting step in biopharmaceutical manufacturing, directly determining the quality, yield, and purity of life-saving therapeutics. The transition from traditional monoclonal antibodies (mAbs) to complex biologics such as antibody-drug conjugates (ADCs), bispecific antibodies, gene therapies, and viral vectors presents unprecedented purification challenges due to their structural heterogeneity and sensitivity. This advanced training course provides participants with the next-generation bioprocessing strategies required to overcome the downstream bottleneck. We focus on cutting-edge technologies like continuous chromatography, process intensification, and Process Analytical Technology (PAT) to design robust, scalable, and cost-effective DSP workflows that ensure compliance with stringent cGMP and Quality-by-Design (QbD) principles.

Downstream Processing for Complex Biologics Training Course is designed to transform process scientists and engineers into DSP experts capable of innovating and troubleshooting complex purification trains. By integrating hands-on exercises with real-world case studies on Host Cell Protein (HCP) and DNA clearance, viral clearance/inactivation, and advanced Tangential Flow Filtration (TFF) techniques, attendees will master the principles of high-resolution separation. Mastering these skills is essential for accelerating time-to-market and sustaining the competitive edge of biomanufacturing operations in the rapidly evolving landscape of advanced therapeutic development.

Course Duration

10 days

Course Objectives

1. Master the principles of Continuous Chromatography and Process Intensification for high-titer feed streams.
2. Design robust, scalable, and integrated DSP workflows for non-mAb complex modalities like ADCs and Bispecifics.
3. Apply Process Analytical Technology (PAT) for real-time monitoring and control to achieve true continuous bioprocessing.
4. Optimize high-resolution separation using multi-modal chromatography to effectively remove product-related impurities
5. Implement risk-based strategies for efficient Host Cell Protein (HCP) and Host Cell DNA (HCD) clearance.
6. Develop robust and compliant viral clearance and inactivation steps in complex DSP trains.
7. Leverage Design of Experiments (DoE) methodologies for process characterization and defining the Design Space.
8. Evaluate the economic and operational feasibility of Single-Use Technologies (SUT) in large-scale DSP.
9. Troubleshoot common TFF and ultrafiltration/diafiltration (UF/DF) challenges, including flux decline and membrane fouling.
10. Define and monitor Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) according to QbD principles.
11. Formulate stable Drug Substance (DS) intermediates and final Drug Product (DP) solutions for complex biologics.
12. Scale-up and Validate purification processes efficiently to meet cGMP regulatory requirements.
13. Integrate upstream-downstream optimization for maximum process yield and throughput.

Target Audience

1. Downstream Process Development Scientists/Engineers.

2. Manufacturing & Operations Personnel.
3. Quality Assurance (QA) & Quality Control (QC) Specialists.
4. Research Scientists/Formulation Specialists.
5. Bioprocess Technology Managers
6. Vendors and Suppliers.
7. Process Validation Professionals.
8. Recent Graduates.

Course Modules

Module 1: Introduction to Complex Biologics & DSP Challenges

- Defining the purification landscape for non-mAb molecules
- Managing Product Heterogeneity
- Overview of the classical "Platform Process" and customized DSP trains.
- Setting Critical Quality Attributes.
- Case Study: Developing a DSP platform for a Bispecific Antibody with multiple affinity tags.

Module 2: High-Resolution Chromatography Principles

- In-depth mechanics of affinity, ion exchange, and hydrophobic interaction chromatography
- Selecting the optimal chromatography resin for complex impurity removal.
- Understanding and optimizing bind/elute, flow-through, and gradient modes.
- Column packing, integrity testing, and lifetime studies.
- Case Study: Using multi-modal resin to remove a highly acidic Host Cell Protein

Module 3: Continuous Chromatography & Process Intensification

- Principles of Periodic Counter-Current Chromatography and Multi-Column Chromatography
- Designing an integrated, continuous capture step to handle high-titer feeds.
- System design: switching valves, pumps, and process control.
- Economic models for comparing batch vs. continuous DSP.
- Case Study: Implementation of a 3-column PCC system for MAb capture to halve resin usage.

Module 4: Primary Recovery: Clarification and Cell Harvest

- Principles of Centrifugation and high-capacity Depth Filtration.
- Optimization of Flocculation and precipitation to improve harvest efficiency.
- Strategies for handling high-density cell culture and cell debris.
- Filter sizing, pre-filtration, and managing filter capacity/fouling.
- Case Study: Designing a scalable harvest train for an E. coli inclusion body product.

Module 5: Impurity Clearance Strategy

- Sources and impact of Host Cell Protein, Host Cell DNA, and process-related impurities.
- Developing wash and elution buffers for effective impurity separation.
- Integration of membrane adsorbers and flow-through polishing steps.
- Analytical methods for monitoring impurity removal
- Case Study: Achieving 6-log reduction of residual DNA using a controlled pH precipitation step.

Module 6: Tangential Flow Filtration (TFF) for Concentration & Buffer Exchange

- Theory of Ultrafiltration and Diafiltration.
- Optimizing membrane selection for different biologics.
- Design and operation of TFF systems.
- Cleaning, sanitization, and membrane integrity testing.
- Case Study: UF/DF optimization to concentrate a labile fusion protein while minimizing aggregation.

Module 7: Viral Clearance and Inactivation

- Regulatory expectations for viral safety and Log Reduction Value calculation.
- Designing and validating low pH viral inactivation steps.
- Principles of Nanofiltration/Viral Filtration.
- Orthogonal clearance steps contribution to viral reduction.
- Case Study: Validation study for a viral filtration unit on an ADC process with high viscosity.

Module 8: Single-Use Technologies (SUT) in DSP

- Economics and operational benefits of single-use systems
- Challenges of leachables and extractables and regulatory assessment.
- Design and integration of SUT systems.
- Risk assessment for contamination and supply chain management.
- Case Study: Transitioning a legacy stainless steel DSP train to an all-single-use facility.

Module 9: Quality-by-Design (QbD) and Process Characterization

- Defining the Quality Target Product Profile and CQAs.
- Utilizing Design of Experiments for efficient process parameter screening.
- Mapping Critical Process Parameters to CQAs and defining the Design Space.
- Risk Management tools in DSP.
- Case Study: Using DoE to optimize the load-to-resin ratio and wash pH for a polishing step.

Module 10: Process Analytical Technology (PAT) Implementation

- Introduction to PAT tools for real-time monitoring.
- In-line and at-line monitoring of protein concentration, pH, and conductivity.
- Data acquisition, multivariate data analysis, and control strategies.
- PAT's role in enabling process control and continuous manufacturing.
- Case Study: Implementing in-line UV monitoring to automate chromatography pool cutting and maximize yield.

Module 11: Scale-Up and Technology Transfer

- Principles of hydrodynamic similarity and scaling DSP unit operations.
- Developing a robust Tech Transfer package for commercial manufacturing.
- Engineering calculations: bed height, column diameter, and flow rate proportionality.
- Regulatory expectations and documentation for Process Validation (PPQ).
- Case Study: Calculating and validating a scale-up from pilot to commercial-scale TFF.

Module 12: Advanced Protein Analysis and Formulation

- Analytical techniques for characterizing purity, aggregation, and charge variants
- Principles of Drug Substance (DS) and Drug Product (DP) formulation.
- Buffer selection, pH effects, and excipient impact on stability.

- Managing the stability of complex and fragile biologics.
- Case Study: Investigating the cause of protein aggregation during low-conductivity diafiltration.

Module 13: Non-Conventional Bioseparations

- Strategies for purifying non-antibody biologics.
- Application of precipitation, aqueous two-phase extraction, and crystallization.
- Membrane chromatography and expanded bed adsorption (EBA).
- New trends: Fiber-based chromatography and spatial flow chromatography.
- Case Study: Developing a purification strategy for a Lentiviral Vector for gene therapy.

Module 14: cGMP and Regulatory Compliance in DSP

- Good Manufacturing Practice (cGMP) requirements for bioprocessing facilities.
- Understanding ICH Guidelines: Q7 (API GMP), Q11 (Development), and Q13
- Data integrity, electronic batch records, and audit readiness.
- Change control and deviation management in DSP.
- Case Study: Simulating a regulatory audit of a chromatography skid's cleaning and validation logs.

Module 15: DSP Troubleshooting and Process Economics

- Systematic approach to troubleshooting DSP failures.
- Root Cause Analysis (RCA) techniques for process deviations.
- Modeling and calculation of the Cost of Goods Sold (COGS) for DSP trains.
- Identifying cost drivers and process debottlenecking.
- Case Study: RCA for a batch failure caused by increased host cell DNA carry-over after harvest.

Training Methodology

The course employs a highly interactive and practical methodology:

- Interactive Lectures
- Hands-on Case Studies & Problem-Solving.
- Group Discussion & Peer Learning.
- Scenario-Based Simulations.
- 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

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

Register Online Now

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