Downstream Bioprocessing Techniques Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Downstream bioprocessing is a critical component of modern biopharmaceutical manufacturing, biotechnology production, and industrial bioprocessing, focusing on the recovery, purification, and formulation of biological products. As the global demand for monoclonal antibodies (mAbs), vaccines, recombinant proteins, cell and gene therapies, and biosimilars continues to grow, organizations are investing heavily in advanced downstream technologies to improve product quality, yield, purity, and regulatory compliance. Downstream Bioprocessing Techniques Training Course provides participants with comprehensive knowledge of downstream processing operations, including cell harvest, filtration technologies, chromatography systems, ultrafiltration/diafiltration, viral clearance, and final product formulation. Participants will gain practical insights into process optimization, contamination control, and scalable purification strategies used in state-of-the-art biomanufacturing facilities.

The course emphasizes industry best practices, Quality by Design (QbD), Process Analytical Technology (PAT), continuous bioprocessing, digital biomanufacturing, and GMP-compliant operations. Through real-world case studies and hands-on exercises, participants will learn how to design robust purification processes, troubleshoot operational challenges, enhance process efficiency, and meet stringent regulatory requirements. The program integrates current trends in single-use technologies, automation, AI-driven process optimization, and sustainable manufacturing approaches to prepare professionals for the future of biopharmaceutical production and advanced biotechnology industries.

Programme Curriculum

Downstream Bioprocessing Techniques Training Course

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Course Objectives

By the end of this training course, participants will be able to:

1. Understand the fundamentals of downstream bioprocessing and product recovery.
2. Apply advanced purification strategies for biologics and biopharmaceutical products.
3. Optimize cell harvesting and clarification operations for improved yields.
4. Evaluate filtration technologies for process efficiency and product quality.
5. Design and operate chromatography systems for large-scale purification.
6. Implement ultrafiltration and diafiltration techniques for concentration and buffer exchange.
7. Utilize Process Analytical Technology (PAT) for real-time monitoring.
8. Apply Quality by Design (QbD) principles to downstream process development.
9. Develop viral clearance and contamination control strategies.
10. Integrate automation and digitalization into downstream operations.
11. Troubleshoot purification bottlenecks and process deviations.
12. Ensure GMP, FDA, EMA, and international regulatory compliance.
13. Enhance process scalability, sustainability, and manufacturing productivity.

Target Audience

This course is designed for:

1. Bioprocess Engineers
2. Biopharmaceutical Manufacturing Professionals
3. Biotechnology Scientists and Researchers
4. Process Development Specialists
5. Quality Assurance and Quality Control Personnel
6. Validation and Regulatory Affairs Professionals
7. Production and Operations Managers

8. Pharmaceutical and Life Sciences Consultants

Course Modules

Module 1: Introduction to Downstream Bioprocessing

- Overview of bioprocessing value chain
- Upstream vs downstream integration
- Product recovery principles
- Industry trends and innovations
- Regulatory landscape overview
- **Case Study:** Development of a purification process for a recombinant therapeutic protein.

Module 2: Cell Harvesting and Clarification

- Cell separation fundamentals
- Centrifugation technologies
- Depth filtration systems
- Flocculation techniques
- Clarification optimization
- **Case Study:** Improving harvest efficiency in monoclonal antibody production.

Module 3: Filtration Technologies

- Microfiltration principles
- Ultrafiltration applications
- Nanofiltration processes
- Filter integrity testing
- Single-use filtration systems
- **Case Study:** Reducing filtration fouling in vaccine manufacturing.

Module 4: Chromatography Fundamentals

- Chromatographic separation mechanisms
- Resin selection criteria
- Column packing techniques
- Process development methodologies
- Scale-up considerations
- **Case Study:** Chromatography optimization for biosimilar purification.

Module 5: Affinity Chromatography

- Protein A chromatography
- Ligand interactions
- Binding and elution optimization
- Resin lifetime management
- Cost reduction strategies
- **Case Study:** Enhancing antibody capture efficiency.

Module 6: Ion Exchange Chromatography

- Cation exchange purification

- Anion exchange applications
- Process parameter optimization
- Impurity removal strategies
- Scale-up techniques
- **Case Study:** Host cell protein reduction using ion exchange systems.

Module 7: Hydrophobic Interaction and Mixed-Mode Chromatography

- HIC fundamentals
- Mixed-mode separation technologies
- Selectivity optimization
- Process economics
- Industrial applications
- **Case Study:** Improving protein purity through mixed-mode chromatography.

Module 8: Ultrafiltration and Diafiltration (UF/DF)

- Membrane technology fundamentals
- Concentration processes
- Buffer exchange operations
- Membrane fouling control
- Process performance evaluation
- **Case Study:** UF/DF optimization for recombinant protein formulation.

Module 9: Viral Clearance and Safety Assurance

- Viral contamination risks
- Viral filtration systems
- Inactivation techniques
- Regulatory expectations
- Validation requirements
- **Case Study:** Viral clearance validation in biopharmaceutical manufacturing.

Module 10: Process Analytical Technology (PAT)

- PAT framework implementation
- Real-time monitoring tools
- Sensor technologies
- Data acquisition systems
- Process control applications
- **Case Study:** PAT deployment for chromatography monitoring.

Module 11: Quality by Design (QbD) in Downstream Processing

- Critical Quality Attributes (CQAs)
- Critical Process Parameters (CPPs)
- Risk assessment methodologies
- Design space development
- Lifecycle management
- **Case Study:** QbD implementation in a monoclonal antibody purification platform.

Module 12: Automation and Digital Biomanufacturing

- Automated purification systems
- Manufacturing Execution Systems (MES)
- Digital twins in bioprocessing
- AI-driven process optimization
- Industry 4.0 applications
- **Case Study:** Smart factory deployment in biologics manufacturing.

Module 13: Process Scale-Up and Technology Transfer

- Scale-up principles
- Equipment selection strategies
- Technology transfer planning
- Process comparability studies
- Commercial manufacturing readiness
- **Case Study:** Scaling purification from pilot to commercial production.

Module 14: GMP Compliance and Regulatory Requirements

- GMP regulations overview
- Documentation and data integrity
- Validation strategies
- Regulatory inspections
- Compliance management systems
- **Case Study:** Regulatory audit preparation for a biopharmaceutical facility.

Module 15: Future Trends and Sustainable Downstream Processing

- Continuous bioprocessing
- Single-use technologies
- Green biomanufacturing
- Advanced purification platforms
- Emerging biologics production
- **Case Study:** Implementing sustainable purification technologies to reduce manufacturing costs and environmental impact.

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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