Advanced Mammalian Cell Culture Bioprocessing 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 industry is undergoing a rapid transformation, driven by the emergence of complex therapeutics like ATMPs and the demand for faster, more cost-effective manufacturing. Traditional fed-batch processes are being surpassed by Process Intensification and Continuous Bioprocessing strategies. Advanced Mammalian Cell Culture Bioprocessing Training Course is meticulously designed to bridge the skills gap by providing a deep, practical understanding of next-generation upstream technologies. Participants will move beyond foundational concepts to master areas critical for modern bio manufacturing, including high-density CHO cell culture, advanced bioreactor control, and the implementation of real-time monitoring tools.

This intensive training focuses heavily on the integration of Digitalization and QbD principles to ensure Process Robustness and Regulatory Compliance. Key topics like Perfusion Systems, Single-Use Technologies, and advanced Cell Line Engineering strategies are covered to equip attendees with the expertise needed to design, optimize, and execute state-of-the-art bioprocesses. By emphasizing Case Studies and Hands-on Simulation, the course prepares professionals to drive COGS Reduction and accelerate time-to-market for life-saving bio therapeutics in a highly competitive global landscape.

Programme Curriculum

Advanced Mammalian Cell Culture Bioprocessing Training Course

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Course Objectives

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

1. Implement and Optimize Perfusion systems, including ATF and Tangential Flow Filtration, to achieve Process Intensification and Volumetric Productivity gains.
2. Design and execute DoE studies for multivariable process optimization, ensuring Process Robustness and a comprehensive Design Space.
3. Apply Process Analytical Technology tools for Real-Time Monitoring and control of critical process parameters
4. Formulate and modify Chemically Defined Media to support High-Density Cell Culture and minimize Waste Metabolites.
5. Evaluate the economics and implementation strategies of Single-Use Systems versus traditional stainless-steel bioreactors for Scalability.
6. Master the principles of Metabolic Engineering and CHO Cell Line Development for enhanced Titer and desired Product Quality Attributes.
7. Develop robust upstream processes specific to the manufacturing of Viral Vectors and ATMPs.
8. Utilize Bioprocess Modeling and Digital Twins to simulate, predict, and control cell culture behaviour.
9. Ensure compliance with global cGMP and regulatory expectations for Continuous Bioprocessing submissions.
10. Troubleshoot complex bioreactor deviations, focusing on Mass Transfer limitations, Shear Stress, and Foaming control.
11. Integrate Automation and Data Management platforms to facilitate Digital Biomanufacturing.
12. Compare and select appropriate Cell Retention Devices for specific process requirements
13. Execute a comprehensive strategy for Process Validation and technology transfer from Development to GMP Manufacturing.

Target Audience

1. Upstream Process Development (PD) Scientists/Engineers
2. Manufacturing Science & Technology (MSAT) Specialists
3. Bioprocess Engineers
4. R&D Scientists focused on Cell Line Development

5. Quality Assurance (QA) and Regulatory Affairs (RA) Professionals interested in QbD and PAT applications.
6. Biomanufacturing Operator.
7. Project Managers.
8. Academic Researchers/Post-Doc.

Course Modules

1. Next-Generation Upstream Strategies

- Evolution from Batch to Fed-Batch to Continuous Bioprocessing.
- Principles and economics of Process Intensification.
- Case Study: Analyzing the productivity gain of switching a mAb process from Fed-Batch to Perfusion.
- Introduction to High-Density Cell Culture and Cell Line Development improvements.
- Defining Volumetric Productivity and its impact on COGS.

2. Advanced Cell Line Engineering

- Strategies for engineering CHO cells for enhanced Titer and Survival.
- Gene Editing techniques for target protein expression and Glycosylation control.
- Case Study: Using Cell Line Engineering to remove a co-eluting Host Cell Protein impurity, simplifying DSP.
- Understanding Post-Translational Modifications and CQAs.
- Rapid clone screening and selection using Automated Systems.

3. Principles of Perfusion Culture

- Mechanism and operational modes of Perfusion
- Selection and operation of Cell Retention Devices
- Case Study: Optimizing a Perfusion process for Long-Term Continuous Protein Production
- Media and feeding strategies for High-Cell Viability and density.
- Impact on Downstream Processing and facility fit.

4. Design of Experiments (DoE) and QbD

- Developing a Control Strategy and defining the Design Space.
- Using Factorial, Fractional Factorial, and Response Surface Methodologies.
- Case Study: A DoE approach to simultaneously optimize Temperature Shift and Feed Rate for maximum mAb expression.
- Identifying CPPs and CQAs.
- Tools for statistical analysis and Process Understanding.

5. Advanced Bioreactor Control and PAT

- Implementing Process Analytical Technology for real-time process monitoring.
- In-line and At-line sensors: Raman, Dielectric Spectroscopy, and Near-Infrared.
- Case Study: Utilizing Dielectric Spectroscopy to automatically trigger a Feed Adjustment based on Cell Viable Density.
- Advanced control loops and Set-Point management.
- Gas Transfer dynamics, kLa measurement, and pCO_2 control.

6. Bioprocess Media and Feed Optimization

- Chemically Defined Media formulation and raw material control.
- Strategies for mitigating Waste Metabolite accumulation.
- Case Study: Developing a customized, Serum-Free Medium to eliminate a specific PTM issue in CHO cells.
- Advanced feed strategies for Intensified processes.
- Impact of Osmolality and Trace Elements on Cell Performance.

7. Single-Use Technologies (SUTs) and Facility Design

- Advantages and limitations of Single-Use Bioreactors in cGMP manufacturing.
- Leachables and Extractables risk assessment and Tox testing.
- Case Study: Comparing Capital Cost and Operating Expense of SUT vs. Stainless Steel for a new facility build.
- Sterile Connection and Aseptic Transfer techniques in SUT workflows.
- Waste management and sustainability in a Single-Use environment.

8. Data Science, Modeling, and Digital Twins

- Introduction to Digital Biomanufacturing and Industry 4.0 concepts.
- Developing Mechanistic and Hybrid Models for Bioprocess Prediction.
- Case Study: Using a Digital Twin to predict the outcome of a Bioreactor Scale-Up before execution.
- AI and Machine Learning applications for Cell Culture Optimization.
- Data integrity, Data Historians, and MES integration.

9. Cell and Gene Therapy Bioprocessing (ATMPs)

- Unique challenges and requirements for Autologous and Allogeneic therapies.
- Manufacturing of Viral Vectors using HEK293 or Producer cell lines.
- Case Study: Scaling-Up a Lentiviral Vector process from Nunc Cell Factory to a Stirred Tank Bioreactor.
- Closed and Automated Systems for Cell Therapy manufacturing.
- Critical Quality Attributes for ATMPs

10. Scale-Up and Technology Transfer

- Principles of Scaling-Up.
- Scaling-Down models and their use in Troubleshooting and Process Characterization.
- Case Study: Tech Transfer documentation for Upstream Process from PD to cGMP manufacturing site.
- Tip Speed, Power per Volume, and Oxygen Transfer.
- Process Performance Qualification (PPQ) and Validation requirements.

11. Process Risk Assessment and Deviations

- Conducting a FMEA for Upstream operations.
- Root Cause Analysis for common bioprocessing deviations
- Case Study: Investigating a Batch Failure due to an unexpected raw material variability.
- Contamination Control strategies, Mycoplasma, and Viral Safety.
- Implementing CAPAs.

12. Quality and Regulatory Compliance (cGMP)

- Global Regulatory Frameworks for Biologics and ATMPs.
- Understanding ICH Guideline on QbD and Risk Management.

- Case Study: Preparing the CMC Section of a Biologic Investigational New Drug submission.
- Process Validation and Change Control requirements.
- Good Documentation Practices in a cGMP environment.

13. Advanced Harvest and Clarification

- Methods for High-Density Culture Harvest.
- Optimizing Microfiltration and Ultrafiltration for Cell Clarification.
- Case Study: Improving Mammalian Cell Harvesting yield and throughput using TFF filters with optimized Shear Rates.
- Minimizing Product Loss and Product-Related Impurities
- Interfacing Upstream and Downstream for Continuous Processing Integration.

14. Troubleshooting Nutrient and Metabolite Challenges

- Detailed Metabolic Flux Analysis to understand cellular energy pathways.
- Addressing Oligosaccharide Synthesis and Protein Folding issues.
- Case Study: Solving a Lactate accumulation problem through Temperature Shift and Nutrient Modulation.
- Strategies for Apoptosis and Cell Viability maintenance in Prolonged Cultures.
- Amino Acid catabolism and its impact on Ammonia formation.

15. Future Trends and Industry Outlook

- Personalized medicine and the future of small-batch bioprocessing.
- Emerging cell culture platforms and their manufacturing challenges.
- Case Study: The bioprocess implications of developing a novel Bispecific Antibody versus a standard mAb.
- The role of Sustainability and **Eco-Friendly** practices in biomanufacturing.
- Industry Collaboration and Standardization in the era of Continuous and Intensified bioprocessing.

Training Methodology

The course employs a Blended Learning approach combining expert-led instruction with highly practical, application-focused sessions, ensuring deep knowledge transfer and skill acquisition:

1. Interactive Lectures.
2. Hands-on Bioreactor Simulation.
3. Data-Driven Workshops.
4. In-depth Case Studies.
5. Group QbD Project.

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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