Advanced Process Intensification in Upstream 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 paradigm shift, driven by the imperative to reduce Cost of Goods Sold (COGS) and accelerate Time-to-Market for novel biologics and advanced therapies. This is where Advanced Process Intensification (PI) in upstream bioprocessing the strategic use of technology to significantly increase productivity per unit time, volume, or footprint becomes paramount. Advanced Process Intensification in Upstream Bioprocessing Training Course provides a deep dive into the Next-Generation Biomanufacturing toolbox, focusing on High Cell Density Cultures, Perfusion Systems, and the seamless integration of Process Analytical Technology (PAT) and Digital Twins. Master the techniques to transform traditional batch-based manufacturing into efficient, scalable, and Sustainable Bioprocessing workflows that deliver superior yields, improved product quality, and a reduced facility Footprint.

This program is essential for bioprocess leaders seeking to implement Biomanufacturing 4.0 principles. Participants will gain practical, model-driven skills in designing, optimizing, and scaling intensified upstream processes, particularly for Monoclonal Antibodies (mAbs), Viral Vectors, and Cell & Gene Therapies (CGT). Through real-world Case Studies and hands-on simulation, the course directly addresses key challenges in Seed Train Intensification and Continuous Upstream Processing (CUP). Upon completion, attendees will be equipped to drive process innovation, reduce Operational Expenditure (OPEX) and Capital Expenditure (CAPEX), and navigate the evolving Regulatory Landscape to future-proof their manufacturing strategies.

Programme Curriculum

Advanced Process Intensification in Upstream Bioprocessing Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Strategically Implement various High Cell Density (HCD) culture techniques, including N-1 Perfusion, to dramatically shorten the seed train and increase bioreactor inoculation density.
2. Design, operate, and control Intensified Perfusion Bioreactor Systems utilizing advanced cell retention devices for long-term, stable, high-yield production runs.
3. Apply Process Analytical Technology (PAT), including advanced in-line and at-line sensors, to enable Real-Time Monitoring and control of Critical Process Parameters
4. Develop Mechanistic Models and Hybrid Modeling approaches to predict process performance and optimize feeding strategies for Maximum Volumetric Productivity.
5. Master the fundamentals of Continuous Upstream Processing (CUP) and its seamless integration with Multi-Column Chromatography (MCC) for an end-to-end continuous process.
6. Utilize Quality by Design (QbD) principles to establish robust Design Spaces for intensified processes, ensuring consistent Critical Quality Attributes (CQAs).
7. Deploy Digital Twin technology for virtual experimentation, process simulation, and Predictive Maintenance in a Biomanufacturing 4.0 environment.
8. Analyze the Techno-Economic Feasibility (TEA) of PI strategies, calculating the impact on COGS, CAPEX, and OPEX versus traditional batch operations.
9. Formulate and manage Chemically Defined, Highly Concentrated Media and feed strategies optimized for Ultra-High Cell Density cultures.
10. Adapt PI principles for emerging modalities, including Viral Vector Manufacturing and the complex requirements of Cell & Gene Therapy (CGT) production.
11. Design and implement Advanced Process Control (APC) systems, such as Model Predictive Control (MPC), for dynamic process optimization.
12. Navigate the Global Regulatory Landscape for continuous and intensified bioprocesses, focusing on control strategies and validation.
13. Drive Sustainable Bioprocessing by using PI to minimize waste, reduce facility footprint, and lower energy consumption, aligning with Circular Bioeconomy goals.

Target Audience

1. Process Development Scientists/Engineers.
2. Biomanufacturing/Operations Managers.
3. R&D/Tech Transfer Leads.
4. Automation & Data Science Engineers
5. Quality Assurance (QA) & Regulatory Affairs Specialists.
6. Biotech Consultants & Vendors.
7. Senior Researchers & Principal Scientists
8. Chemical/Biochemical Engineering Post-Docs & PhDs.

Course Modules

Module 1: Foundational Principles of Process Intensification (PI)

- Metrics and the drive for COGS reduction.
- Comparing traditional Batch and Fed-Batch against Intensified Fed-Batch and Perfusion strategies.
- Connected Upstream-Downstream workflows.
- Introduction to the Techno-Economic Analysis (TEA) framework for PI selection.
- The Regulatory Landscape and Quality by Design (QbD) for intensified processes.
- Case Study: TEA comparison of a 10,000L batch facility vs. a 1,000L perfusion facility for mAb production.

Module 2: High Cell Density (HCD) Culture & Media Optimization

- Bioreactor operation strategies for Ultra-High VCD.
- Developing Highly Concentrated and Chemically Defined Media formulations.
- Optimizing feeding and nutrient delivery to sustain HCD while managing metabolite buildup
- Impact of high shear stress and mass transfer limitations in intensified systems.
- Advanced strategies for managing culture viability and Cell-Specific Productivity
- Case Study: Optimization of a basal media and feed combination to achieve a 4x VCD increase in a CHO fed-batch process.

Module 3: N-1 Perfusion and Seed Train Intensification

- The critical role of Seed Train Intensification in reducing facility footprint and time.
- Designing the N-1 Perfusion step for optimal inoculum size and quality.
- Selection and operation of Cell Retention Devices in the N-1 step
- N?êÆX steps elimination and the impact of high-density cryopreservation.
- Scale-up principles for intensified seed train transfer to the production bioreactor.
- Case Study: Implementing N-1 perfusion to reduce a 14-day seed train to a 7-day process for a mAb candidate.

Module 4: Advanced Perfusion Bioreactor Design & Operation

- In-depth mechanics of Cell Retention Technologies.
- Determining optimal Perfusion Rate, Dilution Rate, and Medium Exchange strategy.
- Strategies for maintaining Long-Term Stability and culture health over 30+ days.
- Minimizing membrane fouling/clogging and membrane cleaning/regeneration strategies.
- Design considerations for Single-Use Perfusion Systems at scale.

- Case Study: Troubleshooting and mitigating TFF filter fouling to sustain a 60-day perfusion run in a pilot-scale bioreactor.

Module 5: Process Analytical Technology (PAT) and Advanced Sensing

- Integrating In-line, At-line, and On-line measurement technologies.
- Application of advanced sensors
- Data Aggregation and analysis for process understanding and control.
- Using PAT to monitor CQAs and CPPs in real-time.
- Regulatory expectations for PAT in commercial manufacturing.
- Case Study: Using an in-line Raman probe to monitor and automatically control a critical nutrient concentration in a perfusion bioreactor.

Module 6: Mechanistic & Hybrid Bioprocess Modeling

- Fundamentals of Mechanistic Modeling
- Developing and calibrating kinetic models for cell growth, substrate consumption, and product formation.
- Combining mechanistic models with Data-Driven approaches.
- Model parameter estimation, sensitivity analysis, and model validation.
- Utilizing models for Scale-Down Model (SDM) qualification and Tech Transfer.
- Case Study: Building a simple Monod kinetic model to predict peak VCD and optimize the timing of a late feed addition.

Module 7: Digital Twins and Process Simulation

- Defining the Digital Twin in biomanufacturing and its various levels of complexity.
- Designing a First-Principles-based digital twin for upstream unit operations.
- Application of simulation for Process Optimization and "What-If" Analysis.
- Integrating the digital twin with MES and control systems
- Using digital twins for training, operator guidance, and real-time decision support.
- Case Study: Using a digital twin to simulate DO fluctuations during a scale-up event to inform bioreactor control strategy and sparger design.

Module 8: Advanced Process Control (APC) and Soft Sensors

- Limitations of traditional PID Control in highly intensified bioprocesses.
- Fundamentals of Model Predictive Control (MPC) and its application to perfusion rate and feed control.
- Developing and validating Soft Sensors to estimate unmeasured parameters in real-time.
- Control strategies for long-term stability in Continuous Bioprocessing.
- Integrating APC systems with PAT data streams.
- Case Study: Implementing an MPC loop to dynamically adjust perfusion rate to maintain a constant viable cell density (VCD) setpoint.

Module 9: Quality by Design (QbD) in Intensified Upstream

- Identifying and linking Critical Material Attributes (CMAs) and CPPs to CQAs.
- Applying Design of Experiments (DoE) to efficiently map the intensified process Design Space.
- Risk assessment for new PI equipment and control strategies.
- Establishing a robust Control Strategy for high-risk parameters.
- Developing and maintaining the Knowledge Management System for intensified processes.

- Case Study: Using DoE to characterize the impact of perfusion rate and pO2?Çï on mAb glycosylation and aggregation (CQAs).

Module 10: Continuous Upstream Processing (CUP) and Hybrid Systems

- Fundamentals of Integrated Continuous Biomanufacturing (ICB).
- Steady-state and dynamic operation and operational challenges.
- The crucial interface and control strategies for connecting CUP to Multi-Column Chromatography
- Process variability, residence time distribution, and product quality risk in continuous systems.
- Design of a hybrid intensified process combining high-titer fed-batch with continuous capture.
- Case Study: Designing the control loop for a continuous mAb production train, managing the CUP overflow to the MCC loading tank.

Module 11: PI for Monoclonal Antibodies (mAbs)

- Specific PI strategies for achieving 10+ g/L titers in mAb production.
- The impact of high cell density on product quality (CQA) attributes
- Strategies for managing high product concentration and aggregate formation.
- Optimization of harvest and clarification for high-density, high-titer broths
- Case studies of successful mAb facilities transitioning from batch to intensified processes.
- Case Study: Comparing product quality data from a high-titer fed-batch vs. a 30-day perfusion process.

Module 12: PI for Viral Vector Manufacturing

- The unique challenges of Viral Vector production and PI.
- Application of intensified Cell Culture for adherent cell lines.
- Strategies for maximizing Viral Titer and vector quality under intensified conditions.
- Scalability and flexibility of Single-Use platforms for Viral Vector production.
- Regulatory considerations for novel PI technologies in gene therapy.
- Case Study: Optimizing transfection conditions and perfusion rate in a hollow fiber bioreactor for maximizing AAV vector yield.

Module 13: Techno-Economic Analysis (TEA) and Cost Modeling

- Detailed CAPEX and OPEX modeling for intensified vs. traditional facilities.
- Quantifying the financial impact of reduced facility Footprint and utility consumption.
- Evaluating the risk of key variables on COGS.
- Cost-benefit analysis of PAT and APC investments.
- Developing a Business Case for PI technology adoption and capital investment.
- Case Study: Performing a TEA to determine the break-even point for a PI investment based on projected increases in Space-Time Yield (STY).

Module 14: Scale-Up, Scale-Down, and Tech Transfer

- Developing and qualifying robust Scale-Down Models for intensified processes.
- Ensuring Geometric and Kinetic Similarity between scales.
- Managing Shear Stress, mixing, and gas transfer during scale-up of HCD cultures.
- Designing the Tech Transfer package and risk mitigation plan for a PI process.
- Process Validation and Continued Process Verification in an intensified environment.
- Case Study: Using an SDM to predict the kL?Çïa requirements and mixing profiles in a 2,000L HCD bioreactor.

Module 15: Future Trends and Regulatory Strategy

- Modular/Podular Facilities and mini-bioreactors.
- The role of Artificial Intelligence (AI) and Machine Learning (ML) in bioprocess control and design.
- Strategies for navigating global regulatory submissions for continuous and intensified operations.
- PI's role in achieving Sustainable Biomanufacturing and reducing the Carbon Footprint.
- The evolving landscape of PI in personalized medicine and Decentralized Manufacturing.
- Case Study: Review of an FDA or EMA submission for a continuously manufactured biologic, focusing on the control strategy and data integrity.

Training Methodology

The course will employ a rigorous, blended-learning approach combining theoretical principles with practical application:

- Interactive Lectures & Discussions.
- Model-Based Learning.
- Case Study Analysis.
- Virtual Lab/Simulation Exercises.
- Design & Strategy Workshops

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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