# Continuous Biomanufacturing and Process Intensification Training Course

Professional Development Training Course Outline

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| **Category** | Biotechnology and Pharmaceutical Development | **Duration** | 10 Days |
| **Base Fee** | $4,000 USD | **Delivery Mode** | Online / On-site Hybrid |

## Course Introduction

Continuous Biomanufacturing and Process Intensification Training Course is designed to equip biopharmaceutical professionals with the knowledge and practical skills to implement next-generation biomanufacturing strategies. Continuous Biomanufacturing and Process Intensification represent a fundamental paradigm shift away from traditional, large-scale batch processing toward more agile, efficient, and sustainable production models. This evolution is driven by the urgent need to reduce Cost of Goods, accelerate time-to-market, and meet the increasing global demand for biologics with enhanced product quality and consistency. Participants will master the principles of upstream intensification, including perfusion cell culture and high-density seed train, and seamlessly integrate these with continuous downstream processing technologies like multi-column chromatography and continuous filtration to achieve an end-to-end continuous workflow.

The curriculum provides an in-depth exploration of the theoretical foundations and real-world applications of these advanced technologies, focusing on a "do more with less" approach to bioprocess design. Key enabling technologies like Process Analytical Technology (PAT), Quality by Design, and Bioprocess Modeling are emphasized for establishing robust, automated, and steady-state operations. By focusing on facility footprint reduction, optimizing resource consumption, and leveraging single-use technologies (SUT), this course directly addresses the industry's twin goals of operational efficiency and environmental sustainability. Successfully implementing these strategies is crucial for securing a competitive edge and establishing the flexible, modular, multi-product facilities of Biomanufacturing 4.0.

## Programme Curriculum

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**Introduction**

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**Course Duration**

10 days

**Course Objectives**

1. Master the principles of Continuous Bioprocessing and the strategic drivers for Process Intensification (PI).
2. Design and implement end-to-end integrated biomanufacturing workflows for enhanced efficiency.
3. Develop expertise in Perfusion Cell Culture techniques for high-density, high-yield upstream processing.
4. Apply High-Throughput Process Development tools and Design of Experiments (DoE) for rapid process optimization.
5. Utilize Quality by Design (QbD) and Risk Assessment methodologies to ensure process robustness.
6. Implement Process Analytical Technology (PAT) for real-time monitoring and control of Critical Process Parameters (CPPs).
7. Evaluate and select advanced Single-Use Technologies (SUT) for modular and flexible facility design.
8. Master the operation and scale-up of Multi-Column Chromatography (MCC) and Simulated Moving Bed systems.
9. Integrate and intensify downstream unit operations, including continuous filtration and viral clearance.
10. Apply Bioprocess Modeling and in silico simulation for predictive performance and process design.
11. Perform comprehensive Techno-Economic Analysis (TEA) and Cost of Goods (CoG) modeling for intensified processes.
12. Establish practices for Sustainable Biomanufacturing, focusing on PMI reduction and Green Metrics.
13. Explore the future of Biomanufacturing 4.0 through Automation, Digitalization, and the role of AI/ML.

**Target Audience**

1. Process Development Scientists/Engineers.
2. Manufacturing & Operations Professionals.
3. R&D Scientists.

4. Automation & IT Specialists.
5. Quality Assurance (QA) & Regulatory Affairs
6. Biotech/Pharma Managers & Directors.
7. Equipment & Technology Vendors.
8. Chemical/Biochemical Engineering Graduates.

**Course Modules**

**Module 1: Foundations & Strategy for PI/CB**

- Principles of Continuous and Batch bioprocessing and their economic drivers.
- Defining and quantifying Process Intensification (PI)
- Overview of the End-to-End Integrated Biomanufacturing workflow.
- Regulatory landscape for Continuous Biomanufacturing
- Case Study: Comparing TEA/CoG of a traditional 20,000 L fed-batch facility versus a 200 L perfusion/continuous facility.

**Module 2: Quality by Design (QbD) for Continuous Processes**

- Establishing the Quality Target Product Profile and Critical Quality Attributes
- Conducting Process Risk Assessments in a continuous context.
- Defining the Design Space and implementing Control Strategy for steady-state operation.
- Documentation and filing strategies for a continuous process with regulatory bodies.
- Case Study: Using QbD principles to define the control strategy for continuous viral inactivation to ensure viral clearance is maintained.

**Module 3: Upstream Intensification: High-Density Seed Train**

- Fundamentals of N-1 Perfusion and its role in process intensification.
- Methods for achieving High-Density Cell Culture.
- Optimization of Seed Train steps for accelerated manufacturing timelines.
- Impact of high cell density on cell culture media and nutrient feeding strategies.
- Case Study: Accelerating a mAb seed train from 14 days to 5 days using a perfusion N-1 bioreactor strategy.

**Module 4: Perfusion Production Bioreactors**

- Detailed design and operation of different Perfusion Bioreactor systems.
- Selection and optimization of Cell Retention Devices.
- Strategies for managing cell viability, metabolite build-up, and process longevity.
- Process control for achieving and maintaining steady-state cell culture.
- Case Study: Achieving volumetric productivity of >5 g/L/day for a CHO cell line using a 20 L perfusion bioreactor.

**Module 5: Principles of Continuous Downstream Processing**

- The need for Downstream Intensification to match upstream productivity.
- Challenges in continuous purification.
- Design and operation of integrated, pool-less downstream workflows.
- Impact of high-titer/low-volume harvests on clarification and initial capture.
- Case Study: Designing a fully connected mAb purification train with no intermediate holding tanks.

**Module 6: Continuous Chromatography I: Multi-Column Systems**

- Theory and operation of Multi-Column Chromatography (MCC).
- Detailed review of 2-Column and 3-Column systems.
- Optimization of Protein A capture using MCC for increased resin utilization.
- Dynamic binding capacity vs. batch static binding capacity in continuous mode.
- Case Study: Implementation of MCC for Protein A capture leading to a 60% reduction in resin volume and buffer consumption.

**Module 7: Continuous Chromatography II: SMB & Polishing**

- Advanced continuous systems: Simulated Moving Bed chromatography.
- Application of MCC for polishing steps.
- Strategies for flow-through and bind-elute continuous polishing.
- Scale-up and equipment considerations for commercial-scale continuous chromatography.
- Case Study: SMB system design for purifying a complex molecule with multiple impurity variants.

**Module 8: Continuous Filtration & Viral Clearance**

- Continuous operation of Tangential Flow Filtration for concentration and diafiltration
- Principles of continuous Viral Filtration and validation in an integrated process.
- Integrating Viral Inactivation as a continuous, inline step.
- Strategies for buffer and media management in a continuous filtration train.
- Case Study: Developing a continuous UF/DF step that is 50% faster than the equivalent batch process.

**Module 9: Single-Use and Modular Facility Design**

- Role of Single-Use Technologies in enabling PI and CB.
- Design of Modular, Small-Footprint Facilities for enhanced flexibility.
- Infrastructure and utility requirements for a continuous facility.
- Comparison of capital investment for batch vs. continuous facilities.
- Case Study: Designing a modular continuous facility for the simultaneous production of two different biologics.

**Module 10: Process Analytical Technology (PAT) & Real-Time Control**

- Principles and components of a comprehensive PAT system.
- Selection and integration of real-time sensors
- Implementation of Advanced Control Strategies
- Data acquisition, management, and establishing golden batch profiles in a continuous context.
- Case Study: Using Raman spectroscopy for real-time monitoring of cell culture media components to adjust the feed rate automatically.

**Module 11: Bioprocess Modeling & Simulation**

- Fundamentals of Bioprocess Modeling.
- Using modeling for Process Design, Optimization, and identification of CPPs.
- In Silico Simulations for risk analysis and rapid scale-up decisions.
- Model validation and lifecycle management in a regulated environment.
- Case Study: Building a predictive model to optimize the column loading and switching points in a PCC system.

**Module 12: Digitalization and Biomanufacturing 4.0**

- The foundation of Biomanufacturing 4.0.
- Application of Artificial Intelligence and Machine Learning for process optimization.
- Data integrity, cyber security, and regulatory compliance in a digital environment.
- LIMS, MES, and ERP systems integration for end-to-end data flow.
- Case Study: Workshop on using a Machine Learning algorithm to predict and mitigate potential fouling in a TFF unit.

**Module 13: Scale-Up and Technology Transfer**

- Strategies for transferring intensified processes from PD to GMP manufacturing.
- Scale-Down Models for continuous processes and validation of process parameters.
- Equipment selection, vendor qualification, and process validation protocols.
- Strategies for managing scale-up of perfusion systems and MCC.
- Case Study: Developing a qualified scale-down model for an MCC step to support commercial validation.

**Module 14: Advanced Modalities & Intensification**

- Applying PI and CB to non-mAb products.
- Challenges and solutions for intensifying oligonucleotide and mRNA manufacturing.
- Development of Continuous Affinity Precipitation and other novel purification techniques.
- Integrating upstream and downstream in a Viral Vector production process.
- Case Study: Development of an intensified AAV viral vector production process for gene therapy.

**Module 15: Sustainability and Green Metrics**

- Calculating and minimizing the Process Mass Intensity and Water Related Impact of Energy
- Strategies for reducing buffer and media consumption through innovative systems.
- Waste reduction and solvent management in intensified processes.
- Adopting Green Chemistry principles in biomanufacturing.
- Case Study: Evaluating the sustainability profile of a continuous process against a batch process using PMI as the key metric

**Training Methodology**

The course employs a holistic, blended learning approach that maximizes knowledge transfer and practical skill development:

- Interactive Lectures.
- Real-World Case Studies & Debates.
- Hands-on Workshops/Simulation.
- Group Problem-Solving & Design Exercises.
- Q&A Sessions with Expert Instructors.

**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**