Advanced Bioreactor Control and Optimization 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 modern biopharmaceutical and biotechnology landscape is undergoing a radical transformation, driven by the demand for high-titer biologics, advanced therapies, and enhanced bioprocess efficiency. Bioreactors are the cornerstone of this industry, yet their operation at scale presents significant challenges in maintaining precision control over complex, dynamic biological systems. Advanced Bioreactor Control and Optimization Training Course is meticulously designed to equip professionals with cutting-edge skills in real-time monitoring, advanced process control (APC), and data-driven optimization. We bridge the critical gap between theoretical bioengineering principles and their industrial application, focusing on leveraging technologies like Process Analytical Technology (PAT), Machine Learning (ML), and Digital Twins to unlock peak performance. Mastering these strategies is no longer optional; it is essential for achieving Quality by Design, ensuring process robustness, minimizing Cost of Goods, and securing a competitive edge in biomanufacturing.

This intensive training delves into practical, scale-up methodologies and troubleshooting for both single-use and traditional stainless-steel bioreactors. Participants will gain actionable expertise in designing and implementing adaptive control strategies, optimizing fed-batch and perfusion operations, and conducting rigorous bioreactor characterization. The curriculum features a heavy emphasis on process intensification, including high cell density cultivation and continuous bioprocessing, directly addressing the industry's need for faster, more sustainable, and cost-effective production. By the end of this program, attendees will be proficient in transforming raw bioprocess data into actionable insights for predictive modeling, leading to unparalleled control over Critical Process Parameters (CPPs) and a dramatic increase in product yield and quality assurance. This is the definitive path for engineers and scientists committed to pioneering the next generation of smart bioprocessing.

Programme Curriculum

Advanced Bioreactor Control and Optimization Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the application of Process Analytical Technology for real-time bioprocess monitoring and data acquisition.
2. Implement Advanced Process Control and PID tuning techniques to stabilize Critical Process Parameters
3. Develop and validate Quality by Design (QbD) principles for robust and reproducible bioreactor operations.
4. Utilize Machine Learning (ML) and AI-driven algorithms for predictive modeling and dynamic feed control.
5. Design and apply Digital Twin concepts to simulate, optimize, and troubleshoot large-scale bioprocesses.
6. Formulate and execute high-efficiency Process Intensification strategies, including perfusion culture and high cell density fermentation.
7. Conduct comprehensive bioreactor characterization and scale-up studies using hydrodynamic and mass transfer principles.
8. Analyze and interpret complex multi-variate bioprocess data using advanced data analytics and statistical process control (SPC).
9. Optimize Mass Transfer and Oxygen Transfer Rate (OTR) in different bioreactor types
10. Apply metabolic modeling to precisely inform nutrient feeding and media optimization strategies.

11. Ensure Good Manufacturing Practice (GMP) compliance and Data Integrity in automated control systems.
12. Troubleshoot common bioreactor failures and implement Root Cause Analysis (RCA) and CAPA
13. Evaluate the economic feasibility and implementation of Continuous Bioprocessing (CB) in biomanufacturing.

Target Audience

1. Bioprocess Engineers and Scientists.
2. Process Development and R&D Scientists.
3. Manufacturing and Operations Technical Leads.
4. Automation and Control Engineers.
5. Quality Assurance (QA) and Regulatory Affairs professionals.
6. Technology Transfer Specialists.
7. Data Scientists and Bioinformaticians.
8. Project Managers.

Course Modules

Module 1: Bioreactor Fundamentals and Advanced Characterization

- Review of Stirred-Tank, Single-Use, and Perfusion Systems.
- Hydrodynamics and Mixing Characterization
- KLa Measurement and Oxygen Transfer Rate Optimization.
- Shear Stress Management for Sensitive Mammalian and Cell and Gene Therapy cultures.
- Case Study: Comparing KLa performance and power consumption between a stainless-steel STR and a SUB during scale-up.

Module 2: Advanced Process Control (APC) Strategies

- Theory and Application of PID Control and Auto-Tuning for CPPs
- Cascade Control and Feed-Forward Control implementation.
- Model Predictive Control (MPC) fundamentals and basic process models.
- Strategies for handling non-linear process dynamics and dead-time compensation.
- Case Study: Using feed-forward control to anticipate and compensate for pH shifts during high-density fermentation.

Module 3: Process Analytical Technology (PAT) Implementation

- Selection and Calibration of In-Line, At-Line, and On-Line Sensors
- Data Synchronization and integration of PAT sensors with the Distributed Control System
- Calibration and maintenance strategies for ensuring Data Integrity and sensor reliability.
- Real-time measurement of Biomass, Viability, and Metabolite concentration.
- Case Study: Implementing a Raman spectroscopy probe for real-time glucose and lactate monitoring to trigger automated feeding adjustments.

Module 4: Quality by Design (QbD) and Process Robustness

- Defining and linking Critical Quality Attributes to Critical Process Parameters
- Developing the Design Space and operating within the Proven Acceptable Range
- Risk Management and Mitigation in Bioreactor Operations.
- Establishing Control Strategy for commercial biomanufacturing.

- Case Study: Designing a QbD study to determine the acceptable range of DO and temperature variations that do not impact monoclonal antibody glycosylation.

Module 5: Bioprocess Data Analytics and Multivariate Analysis

- Cleaning, Pre-processing, and Visualization of large-scale historical bioprocess data.
- Introduction to Multivariate Data Analysis and Principal Component Analysis
- Developing Golden Batch profiles and deviation detection.
- Implementing Statistical Process Control for continuous process verification.
- Case Study: Using PCA to identify two previously unknown process variables that were contributing to batch-to-batch variability in product titer.

Module 6: Machine Learning and AI for Bioreactor Optimization

- Overview of Supervised and Unsupervised Learning in bioprocessing.
- Building Predictive Models for yield, titer, and cell viability.
- Using ML for Automated Anomaly Detection and early fault prediction.
- Reinforcement Learning concepts for dynamic, self-optimizing control loops.
- Case Study: Training a neural network model to predict final product titer 48 hours in advance based on a combination of sensor and feed data.

Module 7: Bioreactor Scale-Up and Technology Transfer

- Maintaining Geometric Similarity and Kinetic Similarity during scale-up.
- Scaling rules based on P/V (Power per Volume), vtip?Çï (Impeller Tip Speed), and KLa.
- Developing robust Scale-Down Models (SDMs) for industrial process replication.
- Documentation and regulatory requirements for a successful Tech Transfer package.
- Case Study: Troubleshooting an OTR limitation encountered during the transfer of a microbial fermentation from 100L to 1000L scale.

Module 8: Perfusion and Continuous Bioprocessing (CB)

- Fundamentals of Perfusion Culture and various cell retention devices .
- Optimizing Bleed Rate, Perfusion Rate, and Cell-Specific Perfusion Rate (CSPR).
- Implementation and benefits of Continuous Downstream Processing (DSP) integration.
- Addressing operational and regulatory challenges of a fully Continuous Train.
- Case Study: Economic analysis comparing a fed-batch process to a continuous perfusion process for monoclonal antibody production, focusing on facility footprint and productivity.

Module 9: Fed-Batch Strategies and Media Optimization

- Mathematical modeling of microbial and mammalian cell kinetics.
- Design of Constant-Rate vs. Variable-Rate feeding strategies.
- Metabolic burden and control of inhibitory byproducts.
- Advanced techniques in Media Design and nutrient spike management.
- Case Study: Developing a sophisticated, DO-stat-based fed-batch control loop to manage nutrient delivery and prevent oxygen limitation.

Module 10: Single-Use Bioreactor (SUB) Systems

- Design considerations, benefits, and limitations of SUBs vs. traditional stainless steel.
- Validation and regulatory compliance for Disposable Components and materials.

- Leachables and Extractables (L&E) studies and risk mitigation.
- Turn-around Time (TAT) and operational efficiency of SUBs.
- Case Study: Evaluating the total cost of ownership (TCO) for a single-use facility versus a multi-use facility for a multi-product biopharma pipeline.

Module 11: Aseptic Operations and Contamination Risk Management

- Advanced Sterilization-in-Place (SIP) and Cleaning-in-Place (CIP) protocols.
- Aseptic connection techniques and validation for Single-Use Systems.
- Monitoring and troubleshooting air, liquid, and CO2?Çï filter integrity.
- Rapid detection methods and Root Cause Analysis of contamination events.
- Case Study: Performing a mock investigation and CAPA for a Mycoplasma contamination detected late in a batch run.

Module 12: Bioreactor Process Modeling and Simulation

- Developing First-Principles Models for bioprocesses.
- Introduction to Computational Fluid Dynamics (CFD) for mixing and gas dispersion.
- Creating a simplified Digital Twin for process simulation and hypothetical scenario testing.
- Parameter estimation and model fitting to real experimental data.
- Case Study: Using a CFD model to redesign the sparger and impeller configuration in a new bioreactor to eliminate a localized CO2?Çï accumulation hotspot.

Module 13: Regulatory Compliance and Good Manufacturing Practice (GMP)

- FDA and EMA requirements for Process Validation.
- 21 CFR Part 11 and Data Integrity in automated systems.
- Audit readiness and documentation requirements for bioreactor operations.
- Change Control and Deviation Management procedures.
- Case Study: Preparing a comprehensive documentation package for the PQ of a newly scaled-up fed-batch process to support a BLA submission.

Module 14: Sensor and System Calibration and Maintenance

- Protocols for pH, DO, and conductivity sensor calibration and drift compensation.
- Routine maintenance schedules for probes, agitators, and pump systems.
- Validation of Control Loop performance and alarm settings.
- Impact of calibration on CPP assurance and batch release criteria.
- Case Study: Diagnosing and resolving a continuous DO reading drift issue over multiple batches, tracing it back to an incorrect probe storage protocol.

Module 15: Bioreactor Troubleshooting and Failure Analysis

- Systematic approach to diagnosing operational issues
- Applying Ishikawa Diagrams and 5 Whys for Root Cause Analysis.
- Developing and implementing robust Corrective and Preventive Actions.
- Strategies for maximizing recovery and minimizing loss after a major process deviation.
- Case Study: Analyzing a failed batch where cell viability dropped unexpectedly, determining if the cause was mechanical, metabolic, or contamination.

Training Methodology

The course employs a **Blended Learning** approach focusing on maximum practical retention and application:

1. Expert-Led Lectures and Interactive Discussions.
2. Case Studies and Scenario Analysis.
3. Hands-on Workshops/Simulations.
4. Group Problem-Solving.
5. Q&A and Peer-to-Peer Learning

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

Start Date	End Date	Location	Price
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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