Bioreactor Scale-Up and Technology Transfer 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 demand for complex biologics like monoclonal antibodies and cell and gene therapies (CGT). Successful translation of a promising lab-scale bioprocess to a commercially viable manufacturing operation is the most critical and risk-intensive phase. Bioreactor Scale-Up and Technology Transfer Training Course directly addresses this challenge, providing an essential, data-driven roadmap for engineers and scientists. We bridge the gap between bench-scale science and cGMP manufacturing, focusing on engineering fundamentals like hydrodynamics, mass transfer (kL?Çïa), and shear stress to ensure process robustness and titer optimization across scales. Participants will master modern strategies, including Process Analytical Technology (PAT), Computational Fluid Dynamics (CFD), and the utilization of Single-Use Systems (SUS), to achieve predictive scale-up and seamless site-to-site transfer.

This program emphasizes the crucial role of Quality by Design (QbD) principles in mitigating technical and regulatory risks. In an era of increasing adoption of Continuous Bioprocessing and Industry 4.0 technologies, the ability to execute a compliant and efficient Tech Transfer is paramount for accelerating time-to-market and securing a competitive edge. Through a blend of theoretical expertise and practical industry case studies, attendees will acquire the bioprocess engineering and regulatory acumen necessary to navigate the complex landscape of biologics manufacturing, making them invaluable assets in today's biotech sector.

Programme Curriculum

Bioreactor Scale-Up and Technology Transfer Training Course

Introduction

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Course Objectives

1. Master Bioreactor Scale-Up fundamentals, emphasizing geometric, kinematic, and dynamic similarity.
2. Apply Quality by Design (QbD) principles to define Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).
3. Utilize Computational Fluid Dynamics (CFD) for predictive modeling of mixing and shear stress in large-scale vessels.
4. Optimize Mass Transfer (kL?Çïa) and oxygen transfer rate (OTR) to maximize titer and yield in high-density cultures.
5. Design and execute scientifically sound Scale-Down Models (SDMs) for process characterization and validation.
6. Develop a comprehensive Technology Transfer (Tech Transfer) Protocol, including a gap analysis and facility/equipment fit assessment.
7. Integrate Process Analytical Technology (PAT) and digital twins for real-time bioprocess monitoring and advanced control.
8. Navigate the regulatory landscape of process validation, including Process Performance Qualification (PPQ) and continued process verification.
9. Evaluate and justify the selection of Single-Use Systems (SUS) versus traditional stainless steel bioreactors for different modalities.
10. Troubleshoot common scale-up challenges related to cell viability, foam control, and nutrient gradient formation.
11. Implement risk management strategies (FMEA) for a smooth and compliant site-to-site process transfer.
12. Understand the impact of Continuous Bioprocessing on scale-up strategy and Tech Transfer documentation.
13. Formulate a final bioprocess control strategy that ensures batch consistency and product quality at the commercial scale.

Target Audience

1. Bioprocess Engineers
2. Process Development (PD) Scientists
3. Technology Transfer Specialists and Project Managers
4. Manufacturing Managers and Supervisors
5. Quality Assurance (QA) and Regulatory Affairs (RA) Professionals
6. R&D Scientists transitioning projects to the pilot plant
7. Automation and Control Engineers in Biomanufacturing
8. Biotech Consultants and new facility design teams

Course Modules

Module 1: Bioprocess Engineering Fundamentals and Scale-Up Theory

- Review of cell culture and microbial fermentation kinetics.
- Key engineering principles.
- The concept of Scale-Down Models (SDMs) and their qualification.
- Dimensionless numbers and their application in scaling.
- Case Study: Escherichia coli fermentation scale-up based on constant volumetric power input (P/V).

Module 2: Hydrodynamics and Mixing in Bioreactors

- Impact of impeller design on flow patterns.
- Quantifying mixing time (?ÿM?Çï) and its importance for pH and nutrient homogeneity.
- Understanding and mitigating high shear stress for fragile mammalian cells
- Gassing strategies.
- Case Study: Optimizing agitation strategy for a 10,000L mAb production bioreactor to reduce cell damage.

Module 3: Oxygen Mass Transfer and kL?Çïa Determination

- Theory of gas-liquid mass transfer and the volumetric mass transfer coefficient.
- Methods for kL?Çïa measurement and data interpretation.
- Factors influencing kL?Çïa.
- Scaling criteria based on constant kL?Çïa versus constant dissolved oxygen (DO) setpoint.
- Case Study: Process redesign to meet high oxygen demand for a high-cell-density Pichia pastoris fermentation at commercial scale.

Module 4: Practical Scale-Up of Upstream Processes

- Developing a robust and scalable seed train expansion protocol.
- Strategies for media and feed delivery for fed-batch and perfusion cultures.
- Temperature control, heat removal, and sterilization issues in large-scale vessels.
- Strategies for handling and troubleshooting foaming issues.
- Case Study: Scaling up a CHO cell culture process from 5L to 2,000L Single-Use Bioreactor (SUB) with successful titer and quality matching.

Module 5: Computational Fluid Dynamics (CFD) for Scale-Up

- Introduction to CFD methodology and software for bioprocess modeling.
- Simulating fluid flow, mixing zones, and kL?Çïa distribution within the vessel.

- Using CFD to predict zones of high shear stress and non-ideal mixing.
- Application of CFD for rapid bioreactor design and troubleshooting.
- Case Study: Using CFD to compare two impeller configurations for a new 15,000L stainless steel vessel design.

Module 6: Quality by Design (QbD) and Process Characterization

- Defining the Quality Target Product Profile (QTPP) and CQAs.
- Process mapping and identifying Critical Process Parameters (CPPs) and Key Process Parameters (KPPs).
- Designing Design of Experiments (DoE) studies using SDMs for operating range definition.
- Establishing the Design Space and the Control Strategy.
- Case Study: A QbD approach to determine the impact of inoculation density and temperature on a fusion protein's glycosylation profile.

Module 7: Introduction to Technology Transfer (Tech Transfer) Management

- The four phases of Tech Transfer.
- Defining the Technology Transfer Document (TTD) and its essential contents.
- Gap analysis, risk assessment, and defining the "sending unit" and "receiving unit" responsibilities.
- Regulatory expectations (ICH Q10) for Tech Transfer and change control.
- Case Study: A complete Tech Transfer checklist review for moving an intermediate drug substance process between two global manufacturing sites.

Module 8: Facility and Equipment Fit Assessment

- Reviewing the "receiving unit" facility layout, utility availability, and cleanroom classification.
- Equipment Fit assessment.
- Strategies for managing differences in raw materials, media, and buffer preparation capacity.
- Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Case Study: Assessing the feasibility of transferring a process designed for a 20L glass bioreactor to a 50L single-use bioreactor.

Module 9: Single-Use Systems (SUS) and Disposable Technologies

- Advantages and limitations of Single-Use Bioreactors and disposable fluid paths.
- Scale-up considerations for SUBs.
- Leachables and Extractables testing and regulatory requirements.
- Integration of disposable sensor technology
- Case Study: Implementing a fully Single-Use system from media prep to final purification to accelerate facility build-out.

Module 10: Process Analytical Technology (PAT) and Automation

- Introduction to PAT and its role in real-time quality assurance and control.
- Implementing spectroscopic and chromatographic sensors for in-situ process monitoring.
- Advanced control strategies.
- Data integrity, data management, and the role of LIMS in Tech Transfer.
- Case Study: Utilizing a Raman probe and multivariable control to maintain optimal glucose and DO in a fed-batch culture, improving consistency.

Module 11: Process Validation and Regulatory Compliance

- Overview of Process Validation stages
- Defining and executing the PPQ protocol
- Preparing regulatory documentation for BLA/MAA submissions and agency audits.
- Managing post-approval changes and CPV for the life cycle of the product.
- Case Study: Writing the PPQ batch records and generating the summary report for a new viral vector manufacturing process.

Module 12: Troubleshooting and Risk Management in Scale-Up

- Common scale-up failures.
- Root Cause Analysis (RCA) methodologies
- Applying Failure Mode and Effects Analysis (FMEA) to assess and prioritize scale-up risks.
- Mitigation strategies for CO2?Çï stripping, nutrient gradients, and high pCO2?Çï in large vessels.
- Case Study: Analyzing a sudden VCD drop during a 5,000L run traced back to inadequate CO2?Çï removal and scaling parameter miscalculation.

Module 13: Continuous Bioprocessing and Next-Gen Scale-Up

- Introduction to Perfusion Culture and Continuous Capture principles.
- Differences in scale-up for continuous versus fed-batch operations.
- Strategies for implementing smaller-scale, high-intensity bioreactors.
- Integration of Industry 4.0 concepts.
- Case Study: Evaluating the economic and technical benefits of transitioning a legacy fed-batch process to a high-density, perfusion system.

Module 14: Downstream Process (DSP) Scale-Up Implications

- The impact of upstream titer and impurity profile on DSP capacity.
- Scaling chromatography and filtration operations
- Managing buffer preparation and hold times at the large scale.
- Equipment differences in DSP between development and manufacturing
- Case Study: Analyzing a bottleneck in a capture chromatography step due to unexpected high cell debris loading from a high-titer upstream scale-up.

Module 15: Documentation, Communication, and Knowledge Transfer

- Standardizing batch records and ensuring cGMP documentation adherence.
- Creating a robust knowledge transfer plan and training curriculum for the receiving team.
- The role of the Tech Transfer team: establishing clear roles, responsibilities, and communication pathways.
- Finalizing the Tech Transfer Report and process sign-off.
- Case Study: Developing a comprehensive TTD package for a viral vector drug substance, including SOPs and KPP justifications.

Training Methodology

The course employs an Active Learning approach to ensure practical mastery and deep understanding.

- Interactive Lectures.
- Industry Case Studies
- Workshops & Simulations.
- Group Problem-Solving.

- Expert Q&A Sessions.

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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