Advanced Cell Culture Process Troubleshooting 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

Advanced Cell Culture Process Troubleshooting Training Course provides essential, hands-on expertise in systematically tackling complex challenges within advanced cell culture and biomanufacturing processes. In the rapidly evolving landscape of biopharmaceuticals and cell and gene therapies (CGT), even minor deviations from contamination and cell line instability to media optimization and bioreactor control can lead to costly batch failures and significant regulatory hurdles. This program, rich in real-world case studies and root cause analysis (RCA) methodologies, is engineered to transform professionals into expert troubleshooters. Participants will gain mastery over Critical Process Parameters (CPPs), implement Quality by Design (QbD) principles, and leverage Process Analytical Technology (PAT) to ensure process robustness, product quality, and GMP compliance. By elevating technical competency in upstream processing, this training is a critical investment for maintaining competitive advantage and accelerating the path from process development to successful commercial manufacturing.

The central focus is on proactive and reactive strategies to maintain high cell viability and productivity across various platforms, including 3D culture and perfusion systems. We move beyond fundamental techniques to delve into the nuances of advanced systems, such as solving issues in chemically-defined media, mitigating mycoplasma and viral contamination risks, and managing the complexities of scale-up and technology transfer. Through a blend of theoretical instruction, interactive workshops, and simulated troubleshooting challenges, attendees will build a structured problem-solving framework. This empowers teams to quickly diagnose, effectively resolve, and prevent recurrence of bioprocess issues, directly contributing to operational efficiency, cost reduction, and an unwavering commitment to quality that meets stringent regulatory expectations in the global biopharma industry.

Programme Curriculum

Advanced Cell Culture Process Troubleshooting Training Course

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Course Objectives

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

1. Apply sophisticated RCA and fishbone diagrams to identify the true origins of complex bioprocess failures.
2. Swiftly identify and mitigate bacterial, fungal, viral, and especially insidious Mycoplasma contamination sources.
3. Troubleshoot and control genetic drift and cell line instability that impact product Critical Quality Attributes
4. Analyze and correct issues related to nutrient depletion, metabolite toxicity, and poor performance of chemically-defined media.
5. Pinpoint and resolve Critical Process Parameter (CPP) deviations in upstream bioprocessing
6. Utilize and troubleshoot real-time monitoring and control systems
7. Diagnose and mitigate hydrodynamic stress and mass transfer limitations during scale-up and tech transfer.
8. Apply troubleshooting and deviation management protocols that adhere to strict Good Manufacturing Practice (GMP) standards.
9. Identify and eliminate root causes of sterility breaches in cleanroom and biosafety cabinet operations.

10. Interpret complex bioprocess data and implement statistical process control (SPC) for early deviation detection.
11. Address unique challenges in 3D cell culture, organoids, and spheroids related to viability and heterogeneity.
12. Troubleshoot issues specific to continuous biomanufacturing and perfusion culture
13. Formulate effective Corrective and Preventive Actions (CAPA) to ensure sustained process robustness and quality.

Target Audience

1. Cell Culture Scientists/Engineers
2. Process Development (PD) Specialists
3. Manufacturing/Upstream Bioprocess Technicians
4. Quality Assurance (QA) and Quality Control (QC) Professionals
5. R&D Scientists in Biologics/CGT
6. Technology Transfer Specialists
7. Bioprocess Automation and PAT Engineers
8. Lab/Facility Managers overseeing Bioproduction

Course Modules

1. Fundamentals of Advanced Bioprocess Failure

- Differentiating normal process variability from true deviation.
- Establishing a Structured Troubleshooting Framework
- The role of Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs) in failure analysis.
- Introduction to Root Cause Analysis (RCA) tools.
- Case Study: RCA of a sudden, unexplained product titre drop in a fed-batch bioreactor.

2. Contamination Control and Mitigation Strategies

- Identifying subtle signs of bacterial, fungal, and yeast contamination.
- Advanced techniques for routine and rapid Mycoplasma detection
- Troubleshooting recurring sterility breaches in Biosafety Cabinets and cleanroom environments.
- Aseptic technique audit and remediation plans for personnel and equipment.
- Case Study: A facility-wide investigation into a non-sterile raw material source leading to repeat contamination.

3. Bioreactor Performance Troubleshooting

- Diagnosing off-spec pH and Dissolved Oxygen (DO) probes and control loops.
- Resolving issues with gas sparging, agitation, and hydrodynamic stress management.
- Identifying mechanical failures in pumps, tubing, and single-use bioreactor liners.
- Managing foam control and harvest/sampling port sterility.
- Case Study: Analyzing the impact of unexpected DO spikes on cell viability and protein glycosylation.

4. Media and Feed Optimization Issues

- Troubleshooting poor performance or precipitates in chemically-defined media.
- Diagnosing nutrient depletion and metabolite toxicity
- Correcting issues with media preparation, sterilization, and storage stability.
- Strategies for rapid media component failure investigation

- Case Study: Solving a process crash caused by an improperly sourced or stored single amino acid supplement.

5. Cell Line Stability and Viability Problems

- Detecting and mitigating genetic drift and clone instability.
- Troubleshooting poor thaw recovery and low Post-Thaw Viability (PTV).
- Diagnosing cell growth rate inconsistencies and sudden senescence.
- Best practices for cell banking failure analysis.
- Case Study: Investigation of a CHO cell line exhibiting decreased specific productivity after a high passage number.

6. Process Analytical Technology (PAT) and Monitoring

- Troubleshooting errors and calibration issues with in-line and at-line PAT sensors
- Using PAT data for early warning sign detection.
- Diagnosing soft sensor and bioprocess modeling prediction failures.
- Integrating and validating new PAT tools into a regulated environment.
- Case Study: Resolving a discrepancy between off-line metabolite measurement and in-line Raman spectroscopy data.

7. Scale-Up and Technology Transfer Hurdles

- Identifying and resolving mass transfer limitations at larger scales
- Troubleshooting performance differences between lab-scale and pilot/commercial bioreactors.
- Managing equipment and procedural variations during tech transfer.
- Using dimensionless numbers for predictable scale-up.
- Case Study: A successful scale-up project hampered by inadequate CO2?Çï stripping in a large-scale tank.

8. Aseptic Processing and Cleanroom Control

- Identifying gaps in personnel gowning and material transfer procedures.
- Troubleshooting recurring positive results in Environmental Monitoring (EM).
- Analyzing HEPA filter integrity test failures and air handling system deviations.
- Best practices for sterilizing and maintaining single-use systems.
- Case Study: Tracing an EM failure back to a specific operator's gowning breach during a critical step.

9. Deviation and CAPA Management

- Developing effective, science-based Corrective and Preventive Actions (CAPA).
- Documenting and classifying deviations per GMP.
- Performing Effectiveness Checks (EC) to verify CAPA success.
- The regulatory expectation for thorough investigation and documentation.
- Case Study: Developing a CAPA plan to prevent recurrence of a recurring probe failure leading to multiple batch deviations.

10. Continuous and Perfusion System Issues

- Troubleshooting cell retention device fouling and failure.
- Diagnosing process instability in perfusion culture and continuous biomanufacturing.
- Managing cell density and viability control in steady-state operation.

- Resolving issues with continuous media feeding and spent media removal.
- Case Study: Analyzing the impact of a gradual TFF filter flux decline on long-term continuous culture stability.

11. 3D Culture and Organoid Process Challenges

- Troubleshooting poor spheroid/organoid formation and size heterogeneity.
- Diagnosing nutrient and oxygen gradient issues within 3D structures.
- Resolving issues with scaffold/hydrogel variability and batch-to-batch consistency.
- Analyzing viability and differentiation inconsistencies in regenerative medicine products.
- Case Study: Optimizing culture conditions to reduce necrotic core formation in large-scale therapeutic spheroids.

12. Viral and Adventitious Agent Control

- Strategies for preventing and investigating potential viral contamination events.
- Process steps for effective viral inactivation and removal.
- Risk assessment and mitigation for raw materials
- Regulatory requirements for Adventitious Agent Testing (AAT).
- Case Study: Investigating a suspected PPV (Porcine Parvovirus) contamination event in a final product.

13. Data Integrity and Electronic Records

- Troubleshooting issues with data integrity in electronic Bioprocess Monitoring Systems.
- Ensuring audit trail compliance and secure data archiving.
- Resolving discrepancies between automated and manual data collection.
- The role of Digital Twins and Machine Learning in predictive troubleshooting.
- Case Study: Investigating an unrecorded change to a bioreactor setpoint parameter in an electronic batch record.

14. Advanced Statistical Process Control (SPC)

- Using Control Charts to detect process drifts early.
- Implementing multi-variate statistical analysis for complex parameter interactions.
- Determining process capability for critical steps.
- Application of Design of Experiments (DoE) for robust problem-solving.
- Case Study: Using SPC to identify a subtle, but persistent, upward trend in a key metabolite level.

15. Regulatory Expectations and Audits

- Preparing investigation reports that satisfy regulatory scrutiny
- Understanding and responding to 483s and Warning Letters related to process control.
- Simulating a regulatory audit of a process deviation and its resolution.
- The importance of Quality Risk Management (QRM) in troubleshooting.
- Case Study: Review of a past regulatory audit finding related to incomplete deviation investigation and CAPA failure.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.

- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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

Start Date	End Date	Location	Price
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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