Advanced Cell Line Development and Engineering 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 rapidly expanding, with an ever-increasing global demand for biologics, including monoclonal antibodies (mAbs) and advanced therapies like cell and gene therapies (CGT). At the heart of this manufacturing process lies Cell Line Development (CLD), a foundational and critical step that determines the speed, quality, and cost-efficiency of drug production. Advanced CLD and Engineering is no longer a traditional, labor-intensive workflow; it has transformed into a high-throughput, data-driven discipline leveraging cutting-edge tools. Advanced Cell Line Development and Engineering Training Course is designed to equip bioprocessing professionals with the next-generation skills necessary to engineer stable, high-titer and manufacturable cell lines that meet stringent regulatory compliance standards. We will dive deep into genome editing, vector optimization, high-throughput screening (HTS), and the integration of automation and data analytics to significantly accelerate the transition from gene to Master Cell Bank (MCB).

This intensive program emphasizes practical application and Quality by Design (QbD) principles across the entire CLD lifecycle, ensuring participants can strategically de-risk their development timelines. Trainees will gain proficiency in selecting and engineering superior host cell systems, such as Chinese Hamster Ovary (CHO) cells, for optimal expression and product quality. A core focus will be on implementing sophisticated techniques for monoclonality assurance and process intensification, which are crucial for enhancing manufacturing efficiency and securing successful IND/BLA submissions. By mastering these advanced bioprocess concepts and technologies, participants will be positioned as leaders capable of driving innovation and resolving complex challenges in the production of life-saving biotherapeutics, ultimately contributing to a faster market entry.

Programme Curriculum

Advanced Cell Line Development and Engineering Training Course

Introduction

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Course Duration

10 days

Course Objectives

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

1. Master the principles of mammalian cell line development and genetic engineering for bioproduction.
2. Implement CRISPR-Cas9 and other genome editing tools for precise and high-efficiency cell line modification.
3. Design and optimize high-performance expression vectors for enhanced recombinant protein and mAb production.
4. Apply high-throughput screening (HTS) and automated single-cell sorting techniques for lead clone selection.
5. Develop robust strategies for ensuring and documenting monoclonality for regulatory submissions.
6. Integrate Quality by Design (QbD) and Process Analytical Technology (PAT) into the CLD workflow.
7. Evaluate and select appropriate host cell systems based on product and process needs.
8. Utilize automation and digitalization to streamline workflows and manage large datasets
9. Characterize cell lines for long-term stability and optimal Critical Quality Attributes (CQAs), like glycosylation.
10. Understand and ensure compliance with cGMP and global regulatory guidelines for cell lines and MCB creation.
11. Troubleshoot common challenges in cell culture, bioreactor scale-up, and process intensification.
12. Apply advanced omics technologies for rational cell line engineering and process understanding.

13. Explore the fundamentals of CLD for emerging modalities, including Cell and Gene Therapies (CGT).

Target Audience

1. Cell Line Development Scientists/Associates
2. Bioprocess/Upstream Process Development Scientists
3. Molecular and Cell Biologists
4. Research & Development (R&D) Scientists in Biologics
5. Quality Control (QC) and Quality Assurance (QA) Personnel supporting CLD
6. Bioengineers and Automation Specialists in biomanufacturing
7. Project Managers
8. Academic researchers transitioning to industry or focused on biomanufacturing innovation

Course Modules

Module 1: Foundations of Mammalian Cell Line Development

- Overview of the CLD workflow: from gene to Master Cell Bank (MCB).
- Selection criteria for industrial host cells
- Fundamentals of recombinant protein expression and gene copy number.
- Regulatory considerations in host cell line selection.
- Case Study: Comparing CHO-K1 vs. CHO-GS systems for mAb productivity.

Module 2: Advanced Vector Design and Optimization

- Components of high-performance expression vectors
- Strategies for maximizing expression.
- Engineering vectors for multi-chain proteins
- Stable versus transient transfection methods and their use in screening.
- Case Study: Designing an optimized vector to improve a fusion protein's expression titer by 50%.

Module 3: CRISPR-Cas9 and Genome Engineering

- Principles and practical application of **CRISPR-Cas9** for precise genome modification.
- Strategies for knock-in (KI) and knock-out (KO) to enhance cell line attributes.
- Utilizing CRISPR to engineer metabolic pathways and improve product quality
- Off-target effects analysis and mitigation strategies.
- Case Study: Engineering a host cell line to abolish a protease gene to improve product stability.

Module 4: High-Throughput Screening (HTS) Techniques

- Overview of HTS platforms.
- Miniaturization and automation of the screening process
- Primary and secondary screening assays for productivity and product quality.
- Strategies for rapid and early identification of top-performing clones.
- Case Study: Implementing an automated 96-well HTS workflow to reduce screening time by 4 weeks.

Module 5: Monoclonality Assurance and Documentation

- Regulatory requirements for demonstrating **monoclonality**.
- Single-cell deposition techniques and limiting dilution methods.
- Documentation and software solutions for clone tracking and lineage tracing.

- The role of imaging systems in providing evidence of single-cell origin.
- Case Study: Generating a regulatory-compliant Monoclonality Report for an IND submission.

Module 6: Clone Selection and Lead Optimization

- Criteria for selecting a development-ready lead clone (VCD, viability, titer, CQAs).
- Clone stability testing protocols and stress-testing.
- Integrating data from molecular, biological, and bioprocess assays for selection.
- The process of selecting clones for a Research Cell Bank (RCB).
- Case Study: Selection of a lead clone based on a multi-parameter decision matrix and risk assessment.

Module 7: Bioprocess Intensification and Fed-Batch Optimization

- Fundamentals of fed-batch, perfusion, and intensified culture strategies.
- Advanced media and feed design for high-density, high-titer cultures.
- Use of small-scale models for process optimization.
- Monitoring and control of critical process parameters (CPPs).
- Case Study: Optimizing a fed-batch process to achieve a 10 g/L protein titer.

Module 8: Quality by Design (QbD) in CLD

- Defining the Quality Target Product Profile (QTPP) and Critical Quality Attributes
- Implementing Design of Experiments (DoE) for robust process understanding.
- Risk-based approaches (FMEA) to identify and mitigate CLD risks.
- Establishing the Design Space for the upstream process.
- Case Study: Using DoE to optimize transfection conditions for maximum stable pool yield.

Module 9: Data Analytics and Digitalization in CLD

- Leveraging Machine Learning (ML) and AI for predictive clone selection.
- Data management, integrity, and creation of centralized data lakes.
- Statistical analysis of HTS and stability data.
- Integration of automation systems with data capture and visualization tools.
- Case Study: Utilizing multivariate data analysis (MVDA) to identify key predictors of high-titer clones.

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

- Application of PAT tools for real-time monitoring.
- In-line, at-line, and off-line analytical techniques.
- Using real-time data to inform feeding strategies and maintain process control.
- Benefits of real-time monitoring for quality and consistency.
- Case Study: Implementing a glucose feedback control loop using an at-line analyzer to minimize lactate production.

Module 11: Characterization of Critical Quality Attributes (CQAs)

- Analytical techniques for characterizing recombinant protein.
- Detailed analysis of glycosylation patterns and charge variants.
- Monitoring aggregation, fragmentation, and other product-related impurities.
- The relationship between cell culture conditions and product quality.
- Case Study: Investigating a shift in mAb glycosylation profile during scale-up and corrective actions.

Module 12: Cell Bank Preparation and Management (MCB/WCB)

- Protocols for creating and testing the Master Cell Bank and Working Cell Bank
- cGMP requirements for cell bank manufacturing and storage.
- QC testing for identity, sterility, mycoplasma, and viral safety.
- Cryopreservation techniques and stability testing of cell banks.
- Case Study: Developing a comprehensive QC release panel and documentation for a cGMP-compliant MCB.

Module 13: Regulatory Compliance and Audits

- Global regulatory landscape for cell lines in biomanufacturing
- Essential documentation for IND/BLA submissions
- Risk assessment and management for regulatory compliance.
- Preparing for and successfully navigating a mock regulatory audit of a CLD lab.
- Case Study: Responding to a common regulatory query regarding evidence of monoclonality.

Module 14: Omics Technologies and Rational CLD

- Integrating Genomics, Proteomics, and Metabolomics into CLD.
- Using single-cell omics to profile and select superior clones.
- Metabolic engineering strategies for increased productivity and robustness.
- Systems biology approaches for predicting cellular behavior.
- Case Study: Using scRNA-Seq to identify gene expression profiles correlating with high product quality.

Module 15: CLD for Next-Generation Modalities

- CLD challenges and strategies for Cell and Gene Therapies (CGT).
- Engineering viral vector producer cell lines
- Induced pluripotent stem cells and their application in drug discovery.
- Future trends: Synthetic biology and in silico CLD.
- Case Study: Developing a stable HEK293 producer line for high-titer AAV manufacturing.

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
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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