Advanced Quality Control for Cell and Gene Therapy Products 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 rapidly expanding field of Cell and Gene Therapy (CGT) represents a paradigm shift in medicine, offering curative potential for previously intractable diseases. However, these Advanced Therapy Medicinal Products (ATMPs) introduce unprecedented Quality Control (QC) complexities due to their biological nature, short shelf-life, and patient-specific autologous and allogeneic manufacturing workflows. A robust and sophisticated QC strategy is paramount for ensuring patient safety, product efficacy, and adherence to stringent global regulations. Advanced Quality Control for Cell and Gene Therapy Products Training Course is designed to empower quality professionals with the advanced analytical methods, risk-based strategies, and cutting-edge technologies required to master the QC challenges inherent in this innovative sector, moving beyond conventional biologics testing to embrace the future of personalized medicine and real-time release testing.

This intensive training delves into the critical requirements for establishing and maintaining a GxP-compliant Quality Management System (QMS) specific to the CGT lifecycle. Participants will gain practical expertise in analytical method validation for key Critical Quality Attributes (CQAs), including identity, purity, potency, and safety testing. A strong focus is placed on the integration of modern tools like AI-driven bioprocessing, high-throughput assays, and digital data integrity solutions to optimize workflows and accelerate therapeutic development. Ultimately, successful completion of this course will equip trainees to lead their organizations in achieving regulatory compliance and operational excellence, directly contributing to the commercialization and timely delivery of life-saving therapies.

Programme Curriculum

Advanced Quality Control for Cell and Gene Therapy Products Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the principles of Quality-by-Design (QbD) for developing a robust, risk-based QC strategy across the entire CGT product lifecycle.
2. Analyze and Evaluate the Critical Quality Attributes specific to Autologous and Allogeneic cell and gene therapy modalities.
3. Implement and Validate advanced analytical methods for testing Identity, Purity, and Safety
4. Design and execute Potency Assay strategies that accurately reflect the Mechanism of Action (MOA) and support product release.
5. Interpret and Apply the latest Global Regulatory Guidelines for Advanced Therapy Medicinal Products, focusing on CMC and QC submission requirements.
6. Develop effective strategies for Supply Chain Integrity and Chain of Identity (CoI) / Chain of Custody (CoC) management for patient-specific therapies.
7. Optimize QC workflows using principles of Lean QC and the application of Automation and High-Throughput Technologies.
8. Evaluate the use of Next-Generation Sequencing (NGS) and ddPCR as advanced tools for genetic stability and Vector Copy Number (VCN) analysis.
9. Establish rigorous Stability Testing programs to determine product shelf-life and appropriate handling/storage conditions
10. Ensure adherence to Data Integrity principles and 21 CFR Part 11 compliance for electronic QC records and laboratory systems (LIMS).
11. Conduct thorough Root Cause Analysis (RCA) and implement effective Corrective and Preventive Actions (CAPA) for critical QC deviations and Out-of-Specification (OOS) results.
12. Integrate AI and Machine Learning into QC monitoring for enhanced Process Analytical Technology (PAT) and predictive trending.

13. Justify and Execute strategies for In-Process Controls (IPCs) and enabling Real-Time Release Testing (RTRT) to expedite commercial manufacturing.

Target Audience

1. QC/QA Scientists and Analysts.
2. QC/QA Managers and Directors.
3. Process Development (PD) Scientists.
4. Regulatory Affairs Professionals.
5. Manufacturing and Operations Personnel.
6. Internal Auditors and Compliance Specialists.
7. Laboratory Informatics Specialists.
8. CDMO/CRO Personnel.

Course Modules

Module 1: Foundations of CGT Quality & Regulatory Landscape

- Defining Cell and Gene Therapy Products and their unique Quality challenges
- Overview of GxP in a CGT context and the Quality Management System.
- FDA/CBER, EMA, and ICH guidelines for ATMPs.
- Establishing Critical Quality Attributes and linking them to Critical Process Parameters via QbD.
- Case Study: Analysis of a FDA Warning Letter to a CGT facility due to QMS deficiencies in aseptic processing control.

Module 2: Raw Material and Critical Reagent Control

- Risk-based classification, qualification, and acceptance testing of Critical Raw Materials
- Managing the supply chain for materials that directly contact the product, focusing on Animal-Origin Free status.
- Establishing material specifications and vendor qualification/audit programs.
- Controlling and testing Ancillary Products and final formulation components.
- Case Study: Implementing a risk-mitigation strategy for a critical, single-source viral vector raw material using enhanced incoming QC and stability monitoring.

Module 3: Chain of Identity and Custody for Autologous Therapies

- Principles of Chain of Identity and Chain of Custody for patient-specific products.
- Design and implementation of secure, bidirectional Traceability systems from patient to batch and back.
- The role of advanced LIMS/MES systems and electronic batch records in maintaining CoI/CoC integrity.
- Mitigating the risk of cross-contamination and mislabeling in multi-product facilities.
- Case Study: Review of a regulatory finding related to a CoC break during cryopreservation and its implications for product release.

Module 4: Advanced Analytical Method Validation for CGT

- Harmonizing validation strategies according to ICH Q2 and specific ATMP guidance.
- Defining validation parameters.
- Strategies for validating assays with limited sample volume and high variability
- Method qualification for early-phase clinical trials vs. full validation for commercialization.
- Case Study: Validation and comparability study for a qPCR-based residual plasmid assay across multiple manufacturing sites.

Module 5: Identity and Purity Testing

- Testing for Residual Host Cell DNA (HCD) and Host Cell Proteins using sensitive, quantitative assays
- Confirmation of product Identity using Flow Cytometry and immunophenotyping.
- Methods for Cell Viability and Cell Count and their importance as quality indicators.
- Analysis of aggregation and physical attributes in final product formulation.
- Case Study: Troubleshooting an assay failure in an ELISA for HCPs due to matrix interference from the final product formulation buffer.

Module 6: Potency Assay Design and Development

- Defining Potency as a Critical Quality Attribute and correlating it to the product's Mechanism of Action.
- Development of Cell-based Functional Assays
- The use of Reporter Gene Assays and surrogate assays for release testing.
- Strategies for establishing Acceptance Criteria and managing assay variability.
- Case Study: Transitioning a complex, low-throughput in vitro T-cell killing assay to a multiplexed, high-throughput flow-cytometry-based platform.

Module 7: Safety and Sterility Assurance

- Rapid and conventional Sterility Testing methods and the challenges of short product half-life.
- Detection and risk mitigation for Mycoplasma, Endotoxin, and Adventitious Agents.
- Testing for Replication-Competent Viral vectors and related biosafety concerns.
- Establishing robust Environmental Monitoring programs in Grade A/B Aseptic facilities.
- Case Study: Investigation of a false-positive Mycoplasma result and the subsequent CAPA involving raw material and equipment control.

Module 8: Viral Vector Quality Control

- Specific QC challenges for Gene Therapy vectors
- Assaying for Vector Integrity using AUC or Chromatography.
- Testing for Vector Copy Number and integration site analysis using ddPCR and NGS.
- Assessing residual Helper Virus and Packaging Cell components.
- Case Study: Demonstrating comparability of AAV vector purity using different purification trains and subsequent impact on in vivo efficacy.

Module 9: Stability Testing and Shelf-Life Determination

- Design of Accelerated and Real-Time Stability programs for cryogenic and liquid formulations.
- Defining and monitoring stability-indicating parameters
- Managing shipping and transport validation for temperature-sensitive CGT products.
- Extending product shelf-life through robust stability data and re-test interval justification.
- Case Study: Using Genetic Stability data from NGS to justify a shelf-life extension for a cryopreserved CAR-T product.

Module 10: In-Process Controls and Real-Time Release Testing

- The strategic role of In-Process Controls in monitoring and assuring process consistency.
- Principles of Process Analytical Technology and the use of At-Line/In-Line monitoring tools.
- Developing a regulatory-acceptable framework for Real-Time Release Testing.
- Statistical Process Control (SPC) for continuous process verification.

- Case Study: Implementing an RTRT scheme for final product sterility based on a validated Rapid Microbial Method (RMM) and process controls.

Module 11: Data Integrity and Electronic Records

- Core principles of Data Integrity:
- Compliance with FDA 21 CFR Part 11 and EMA Annex 11 for electronic records and signatures.
- Auditing electronic systems to ensure system validation and security.
- Best practices for audit trails, data backup, and long-term archival.
- Case Study: Review of an audit finding involving a lack of control over electronic raw data and the implementation of a validated SDMS to address the gap.

Module 12: Laboratory Automation and High-Throughput QC

- Evaluating and implementing automated liquid handling and robotic systems for QC assays.
- Transitioning manual assays to High-Throughput Screening platforms for increased efficiency.
- Validation and qualification of automated systems and associated software.
- The role of automation in supporting In-Process Testing and rapid turnaround times.
- Case Study: Qualification of a fully automated ddPCR platform for VCN analysis to replace a semi-manual method.

Module 13: Deviations, OOS, and CAPA Management

- Structured investigation process for Out-of-Specification and Out-of-Trend results in a QC setting.
- Techniques for effective Root Cause Analysis tailored to biological variability.
- Developing and implementing robust Corrective and Preventive Actions.
- Evaluating the impact of deviations on batch release and regulatory reporting.
- Case Study: Performing an RCA on a repeated OOT observation in a Potency Assay and developing a CAPA to optimize cell culture conditions.

Module 14: Quality Risk Management in QC

- Applying ICH Q9 principles to identify, assess, and control risks in the QC laboratory.
- Conducting Failure Mode and Effects Analysis for analytical methods and QC processes.
- Risk-based decision-making for batch release and deviation management.
- Integrating QRM into method validation and instrument qualification.
- Case Study: Use of FMEA to redesign the workflow for a complex Flow Cytometry panel to reduce human error and critical failure points.

Module 15: Emerging Technologies and Future Trends in CGT QC

- The role of Artificial Intelligence and Machine Learning in predictive QC and trend analysis.
- Advanced sequencing technologies for deeper product characterization.
- The move towards Platform Technology and assay harmonization across different CGT modalities.
- Regulatory perspectives on accepting novel, Non-Compendial QC methods.
- Case Study: Exploration of an organization implementing an AI-driven image analysis tool to automate cell counting and morphology assessment.

Training Methodology

The course employs a highly interactive and practical training methodology, structured to blend theoretical regulatory knowledge with real-world application.

- Expert-Led Lectures.
- Case Study Analysis
- Hands-on Workshops.
- Group Discussions.
- Interactive Q&A.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

Start Date	End Date	Location	Price
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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