Current Good Manufacturing Practice (cGMP) in Biologics 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

Current Good Manufacturing Practice (cGMP) in Biologics Training Course provides a critical, in-depth understanding of Current Good Manufacturing Practices specifically tailored for the Biologics and Biopharmaceutical industry. The course focuses on navigating the complex regulatory landscape established by global authorities like the FDA (21 CFR Parts 210/211/600) and EU GMP Guidelines. Participants will master the Quality System elements essential for producing safe, pure, and potent large molecule drug products, including cutting-edge modalities like Cell and Gene Therapy and Viral Vectors. This knowledge is the foundation for achieving Regulatory Compliance and building a robust Quality Culture from early-stage Clinical Manufacturing through to Commercial Production.

The training bridges theory and practical application by emphasizing risk-based quality management (ICH Q9), data integrity, and the crucial principles of validation and qualification (IQ, OQ, PQ). By focusing on the unique challenges in sterile and aseptic processing for biologicals, including contamination control and environmental monitoring, this course empowers professionals to proactively manage quality. Graduates will be equipped to implement effective corrective and preventive actions (CAPA), handle deviations and investigations, and successfully prepare for and navigate regulatory inspections and audits, ultimately protecting patient safety and ensuring product consistency in the rapidly evolving global biomanufacturing environment.

Programme Curriculum

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Course Objectives

1. Interpret and Apply the foundational FDA Biologics Regulations and Global GMP requirements
2. Master Aseptic Processing and Sterile Manufacturing principles, including best practices for Gowning and Cleanroom Operations.
3. Develop and implement a robust Contamination Control Strategy to prevent microbial, viral, and cross-contamination risks in bioproduction.
4. Effectively apply Quality Risk Management (QRM) principles (ICH Q9) to biomanufacturing processes and critical quality decisions.
5. Understand the requirements for Process Validation and Cleaning Validation specific to large molecule drug substance and drug product manufacturing.
6. Ensure Data Integrity and Good Documentation Practices (GDP) across all phases of the biopharmaceutical product lifecycle.
7. Differentiate and manage the specialized Facility and Equipment Qualification (IQ/OQ/PQ) requirements for bioreactors and purification systems.
8. Implement a comprehensive Quality Management System (QMS) that drives continuous improvement and regulatory compliance.
9. Conduct thorough Root Cause Analysis and develop Corrective and Preventive Actions (CAPA) for complex manufacturing deviations.
10. Analyze the regulatory expectations for Analytical Method Validation and Quality Control Testing of biological products
11. Gain competence in managing Change Control and Deviation Investigations for both drug substance and drug product operations.
12. Prepare for and successfully manage Regulatory Inspections and internal/external quality audits.
13. Discuss the cGMP implications and requirements for emerging therapies, such as Cell and Gene Therapy and Viral Vector Production.

Target Audience

1. Quality Assurance (QA) Professionals.
2. Quality Control (QC) Personnel.
3. Manufacturing/Operations Staff.
4. Regulatory Affairs (RA) Specialists
5. Validation Engineers.
6. R&D Scientists Transitioning to GMP.
7. Facility and Engineering Staff.
8. Contract Development and Manufacturing Organization (CDMO) Personnel.

Course Modules

Module 1: The cGMP Regulatory Framework for Biologics

- Overview of the FDA cGMP regulations and CFR 600-680 for Biological Products.
- Introduction to ICH Quality Guidelines and their application to biomanufacturing.
- Defining Purity, Safety, and Potency for biologics and the Biologics License Application process.
- Understanding the differences between cGMP and Good Tissue Practice.
- Case Study: Analyzing a recent FDA Warning Letter citing failures to comply with 21 CFR Part 600 general biological product standards.

Module 2: Quality Management System (QMS) Essentials

- Core components of an effective QMS.
- Management responsibilities and the role of the Quality Unit in cGMP compliance.
- Establishing a Quality Culture and promoting employee engagement in quality.
- Regulatory expectations for Internal Audits and Self-Inspections.
- Case Study: Review of a company recall due to a QMS failure where the Quality Unit lacked authority over production.

Module 3: Personnel and Training

- cGMP requirements for Personnel Qualifications and defined job roles/responsibilities.
- Developing effective, job-specific cGMP Training Programs and SOP training.
- Mandatory Aseptic Gowning and hygiene requirements for cleanroom personnel.
- Managing temporary staff and contractors in a cGMP environment.
- Case Study: Examination of a media fill contamination incident directly linked to a failure in personnel gowning and aseptic technique training.

Module 4: Documentation and Data Integrity

- The principles of Good Documentation Practices
- Requirements for Batch Records, Logbooks, and Standard Operating Procedures
- Electronic Records and Signatures compliance and validation.
- Implementing systems to prevent and detect Data Manipulation or Falsification.
- Case Study: A disciplinary action or regulatory citation resulting from back-dating laboratory records or incomplete batch record entries.

Module 5: Facilities and Utilities

- Design and construction requirements for Biologics Manufacturing Facilities
- Cleanroom Classification and environmental control.
- Qualification of Critical Utility Systems

- Facility maintenance, cleaning, and sanitization programs.
- Case Study: A citation for poor facility design leading to non-segregation between a cleaning area and a product filling line, resulting in cross-contamination risk.

Module 6: Equipment Qualification and Maintenance

- The difference between Commissioning, Qualification, and Validation.
- Executing Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for bioprocess equipment
- Calibration, Preventive Maintenance, and Change Parts control.
- Cleaning and sterilization of reusable equipment in biomanufacturing.
- Case Study: A situation where a critical pressure gauge was found out-of-calibration, invalidating product release testing results.

Module 7: Materials Management and Control

- Control of Raw Materials, Components, and Containers/Closures
- Supplier Qualification and Auditing for critical bioproduction materials
- Quarantine, sampling, storage, and release/rejection procedures.
- Management of Excursion Materials and proper material traceability.
- Case Study: A manufacturing failure traced back to an unqualified vendor supplying contaminated raw material, causing a batch loss.

Module 8: Bioprocess Production Controls

- Key controls for Cell Banking and cell line characterization.
- Controls for Upstream Processing
- Controls for Downstream Processing
- Batch-to-Batch Consistency and critical process parameters
- Case Study: Troubleshooting a low-yield batch due to uncontrolled CO2?Çï levels in a bioreactor, highlighting the need for tight process control.

Module 9: Sterile and Aseptic Processing

- Principles of Sterile Filtration and membrane integrity testing.
- Requirements for Aseptic Filling and container-closure integrity.
- Execution and evaluation of Media Fill Simulations to validate the aseptic process.
- Managing Interventions and procedural controls in a Grade A/B environment.
- Case Study: An example of a non-sterile product recall following a failed media fill and inadequate root cause investigation.

Module 10: Process and Cleaning Validation

- Process Design, Process Qualification, Continued Process Verification
- Regulatory guidance on Viral Clearance Study validation for purification steps.
- Principles of Cleaning Validation for multi-product facilities
- Validation for complex processes like Chromatography and Tangential Flow Filtration
- Case Study: A failure to perform a robust PPQ resulting in product variability and inconsistent quality over time.

Module 11: Laboratory Controls and QC Testing

- cGMP for the Quality Control Laboratory.
- Requirements for Analytical Method Validation
- Testing for biological products.
- Reference Standard Management and out-of-specification investigation process.
- Case Study: An OOS investigation where the QC analyst failed to rule out laboratory error and incorrectly invalidated a retest, leading to a regulatory finding.

Module 12: Deviations, CAPA, and Change Control

- Developing a compliant system for Deviation Management and SOP violations.
- Conducting effective Root Cause Analysis using tools like Fishbone or 5 Whys.
- Implementing and verifying the effectiveness of Corrective and Preventive Actions
- The Change Control Process.
- Case Study: Analyzing a company's failure to close a high-priority CAPA in a timely manner, resulting in a repeat deviation and a regulatory citation.

Module 13: Packaging, Labeling, and Distribution

- cGMP controls for Labeling Operations.
- Requirements for Storage and Distribution
- Compliance with Unique Device Identification and serialization regulations
- Handling of returned, salvaged, and reprocessed drug products.
- Case Study: A product recall due to a labeling error where the wrong strength information was applied to the final product containers.

Module 14: Quality Risk Management (QRM) in Biologics

- Introduction to ICH Q9 principles and the Risk Management Process.
- Applying QRM to prioritize CAPAs and define validation scope.
- Using tools like Failure Mode and Effects Analysis to assess manufacturing risks.
- Risk-based approach to Contamination Control and environmental monitoring.
- Case Study: Workshop where participants perform an FMEA on a critical purification step in bioproduction.

Module 15: Regulatory Inspections and Future Trends

- Preparation strategies for FDA Inspections and hosting regulatory auditors.
- Responding effectively to a Form 483 and drafting a comprehensive Warning Letter Response.
- Cell and Gene Therapy GMP and Advanced Therapy Medicinal Products
- The role of Quality by Design and Process Analytical Technology in modern biologics cGMP.
- Case Study: Review of a successful regulatory inspection and the key factors that contributed to its positive outcome.

Training Methodology

The course employs a highly interactive and practical learning model, blending theory with real-world application.

- Expert-Led Lectures.
- Case Studies and Debates.
- Interactive Workshops.
- Q&A Sessions.

- Gowning/Aseptic Technique Simulation

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
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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21 Sep 2026	02 Oct 2026	Physical	$0

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