Bioprocess Equipment Qualification (IQ, OQ, PQ) 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

Bioprocess Equipment Qualification (IQ, OQ, PQ) Training Course is engineered to provide a deep, practical mastery of Bioprocess Equipment Qualification (EQ) specifically, the three critical pillars of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). In the highly regulated biopharmaceutical industry, ensuring the consistent product quality and patient safety of biologics relies entirely on the validated performance of manufacturing equipment. This program moves beyond theoretical concepts, focusing on a risk-based lifecycle approach to validation, aligning precisely with current FDA and EMA cGMP guidelines. Attendees will learn to design, execute, and document robust qualification protocols for critical systems like bioreactors, chromatography skids, and filtration systems, preparing them to face regulatory audits with confidence and implement effective data integrity strategies.

The curriculum is built around real-world case studies and hands-on exercises using essential documentation like User Requirement Specifications (URS) and Validation Master Plans (VMP). We emphasize the integration of modern quality principles like Quality by Design (QbD) and GAMP 5 methodologies for computerized systems validation (CSV). Mastering IQ/OQ/PQ is not merely a compliance check; it is a fundamental strategy for risk mitigation, operational excellence, and improving equipment reliability. By completing this training, participants will be empowered to drive their organizations toward achieving sustained compliance and ensuring the quality and efficacy of life-saving biotherapeutic products from process development through commercial manufacturing.

Programme Curriculum

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Course Objectives

1. Master the Risk-Based Lifecycle Approach to Validation per ICH Q8, Q9, and Q10 guidelines.
2. Author and Execute Compliant Installation Qualification (IQ) protocols for complex Bioprocess Systems.
3. Perform thorough Operational Qualification (OQ) to verify functional specifications, alarms, and worst-case conditions.
4. Confirm consistent, long-term Performance Qualification (PQ) under simulated production loads to ensure process repeatability.
5. Interpret and Utilize critical Engineering Documents like P&IDs, electrical schematics, and mechanical drawings.
6. Develop and maintain a comprehensive Validation Master Plan (VMP) and User Requirement Specifications (URS).
7. Implement effective Change Control and Requalification procedures to maintain the qualified state.
8. Ensure Data Integrity and 21 CFR Part 11 compliance for all automated and computerized systems.
9. Apply Quality by Design (QbD) principles to define Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).
10. Troubleshoot common qualification Deviations and manage Corrective and Preventive Actions (CAPAs) effectively.
11. Prepare for and Successfully Navigate FDA and EMA Regulatory Audits related to equipment.
12. Apply GAMP 5 guidelines for the Validation of Computerized Systems (CSV) in biomanufacturing.
13. Design and execute qualification strategies for modern Single-Use Systems (SUS) and advanced bioprocess technologies.

Target Audience

1. Validation Engineers and Specialists

2. Quality Assurance (QA) and Quality Control (QC) Personnel
3. Bioprocess/Manufacturing Engineers and Supervisors
4. Automation and Computer System Validation (CSV) Specialists
5. Equipment/Maintenance Technicians and Engineering Managers
6. Regulatory Affairs Professionals
7. Project Managers overseeing new facility or equipment implementation
8. Technical Writers involved in SOP and protocol development

Course Modules

Module 1: Foundations & Regulatory Landscape

- Introduction to the Equipment Qualification Lifecycle (DQ-IQ-OQ-PQ).
- Understanding the role of cGMP and Bioprocess Validation (FDA, EMA).
- Defining User Requirement Specifications (URS) and Design Qualification (DQ).
- Key concepts of Data Integrity and 21 CFR Part 11 in equipment.
- Case Study: Reviewing a GMP observation due to missing or inadequate URS.

Module 2: Risk-Based Validation Strategy

- Introduction to the Risk-Based Approach
- Performing Risk Assessment for bioprocess equipment.
- Using risk to define the scope and intensity of IQ/OQ/PQ activities.
- Developing a Risk Mitigation Strategy.
- Case Study: FMEA application on a critical bioreactor sensor system.

Module 3: Validation Master Planning (VMP)

- Purpose and structure of the Validation Master Plan (VMP).
- Defining Roles, Responsibilities, and Validation Strategy.
- Establishing the qualification schedule and resource allocation.
- Linking URS, DQ, IQ, OQ, and PQ within the VMP.
- Case Study: Creating a project-specific VMP for a new single-use bioprocessing suite.

Module 4: Installation Qualification (IQ) Protocol

- Developing and writing a robust IQ Protocol and Acceptance Criteria.
- Verifying equipment installation against manufacturer and design specs.
- Checking utility connections
- Documenting Component Verification and Calibration Records.
- Case Study: Executing IQ on a chromatography skid, verifying major components and utility drops.

Module 5: IQ Documentation and Review

- Management of Supplier Documentation, manuals, and drawings.
- Reviewing and verifying P&IDs and electrical schematics.
- Handling Installation Deviations and Non-Conformances.
- Formalizing the IQ Completion Report and approval.
- Case Study: Resolving an IQ deviation related to a piping weld or material mismatch.

Module 6: Operational Qualification (OQ) Planning

- Developing the OQ Protocol to challenge functional limits.
- Defining Operational Control Limits
- Identifying and testing Worst-Case Conditions and stress testing.
- Testing of Alarms, Interlocks, and Safety Features.
- Case Study: Designing OQ tests for a High-Performance Liquid Chromatography (HPLC) system to challenge its flow rate and column temperature limits.

Module 7: OQ Execution and Functional Testing

- Execution of Functional Tests for all critical equipment features.
- Verifying the integrity of the Control System and HMI functionality.
- Testing all automatic and manual sequences and recipes.
- Documenting test results and establishing OQ Acceptance Criteria.
- Case Study: Performing OQ on a bioreactor's agitation and temperature control loops at the upper and lower operating ranges.

Module 8: Performance Qualification (PQ) Strategy

- Understanding the transition from OQ to PQ (Process Validation link).
- Developing the PQ Protocol for consistent performance demonstration.
- Defining Critical Quality Attributes (CQAs) and Acceptance Criteria for the product.
- Determining the Number of Successful Batches
- Case Study: Establishing the PQ plan for a Continuous Centrifuge used in cell harvesting, defining acceptable yield and purity ranges.

Module 9: PQ Execution and Process Verification

- Executing PQ runs using actual or simulated production materials/loads.
- Demonstrating Process Capability and long-term Process Repeatability.
- Collecting and analyzing Process Data to ensure consistent performance.
- Verifying Standard Operating Procedures (SOPs) for routine use.
- Case Study: Analyzing data from three consecutive PQ batches to demonstrate consistent protein concentration and product yield.

Module 10: Validation of Computerized Systems (CSV)

- Introduction to GAMP 5 and the System Life Cycle.
- Qualification of Automation and Control Systems
- Software Validation principles and Category definition.
- Ensuring Data Integrity throughout the electronic records lifecycle.
- Case Study: Qualification of the Bioreactor's Supervisory Control System (SCADA) software, focusing on user access and audit trails.

Module 11: Single-Use Systems (SUS) Qualification

- Specific challenges and risk factors of Single-Use equipment.
- Qualification of Extractables and Leachables (E&L) profiles.
- Gamma Irradiation and sterility assurance considerations.
- Developing IQ/OQ/PQ for Single-Use Bioreactors and Mixers.
- Case Study: Developing an IQ for a new single-use bag and tubing assembly, verifying material certificates and component integrity.

Module 12: Change Control and Requalification

- Establishing a Formal Change Control System in a qualified environment.
- Performing Impact Assessment for equipment and process changes.
- Defining criteria for Requalification and verification.
- Managing and documenting minor, major, and like-for-like changes.
- Case Study: Assessing the impact of upgrading a filtration system's pump motor on the overall PQ status.

Module 13: Deviations, CAPA, and Final Reporting

- Process for documenting and investigating Qualification Deviations.
- Implementing effective Corrective and Preventive Actions (CAPAs).
- Writing the comprehensive IQ/OQ/PQ Summary Report.
- Maintaining Validation Status through ongoing Calibration and Maintenance.
- Case Study: Analyzing an OQ test failure, root cause investigation, and implementing a corrective action.

Module 14: Audit Readiness and Inspection Practices

- Preparing documentation and personnel for Regulatory Audits.
- Understanding Auditor Expectations for qualification records.
- Responding to Audit Observations and managing follow-up actions.
- Review of current FDA 483 and Warning Letter trends for validation.
- Case Study: Simulating an FDA inspector interview on the validation status of a key upstream piece of equipment.

Module 15: Advanced Topics in Validation

- Introduction to Process Analytical Technology (PAT) integration.
- Qualification for Continuous Bioprocessing equipment.
- Validation for Advanced Therapy Medicinal Products (ATMPs) equipment.
- Qualification of Utilities interfaces.
- Case Study: Discussing the qualification strategy for an in-line PAT sensor system used for real-time quality monitoring.

Training Methodology

The course employs an Interactive, Blended Learning approach combining:

- Case Study Analysis
- Document Workshops
- Group Discussions
- Lectures & Presentations.

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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