Validation and Qualification in Pharma Plants Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The pharmaceutical industry operates within a highly regulated environment where Validation, Qualification, GMP Compliance, Data Integrity, Quality Assurance, Risk Management, Regulatory Excellence, Digital Validation Systems, Process Verification, Sterile Manufacturing, CSV (Computer System Validation), Annex 1 Compliance, and Pharmaceutical Quality Systems (PQS) are essential for ensuring product quality, patient safety, and regulatory approval. Validation and Qualification activities form the backbone of pharmaceutical manufacturing by providing documented evidence that facilities, utilities, equipment, systems, and processes consistently perform according to predetermined specifications and regulatory requirements.

As pharmaceutical manufacturing embraces Industry 4.0, Automation, Digital Transformation, Continuous Manufacturing, AI-driven Quality Systems, PAT (Process Analytical Technology), Quality Risk Management (QRM), Lifecycle Validation, and Global Regulatory Harmonization, organizations require professionals capable of implementing effective validation programs. Validation and Qualification in Pharma Plants Training Course provides participants with advanced knowledge and practical skills in qualification and validation methodologies, covering facility qualification, utility validation, equipment qualification, cleaning validation, process validation, computerized systems validation, and regulatory inspection readiness through practical case studies and industry best practices.

Programme Curriculum

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Course Objectives

By the end of this training course, participants will be able to:

1. Understand pharmaceutical validation and qualification lifecycle principles.
2. Apply current **GMP and Annex 1** requirements in validation activities.
3. Develop effective Validation Master Plans (VMPs).
4. Perform risk-based qualification using Quality Risk Management tools.
5. Execute Installation Qualification (IQ) protocols effectively.
6. Conduct Operational Qualification (OQ) studies and assessments.
7. Implement Performance Qualification (PQ) methodologies.
8. Design and manage process validation programs.
9. Perform cleaning validation and contamination control assessments.
10. Validate pharmaceutical utilities and critical systems.
11. Implement Computerized System Validation (CSV) frameworks.
12. Prepare facilities for regulatory inspections and audits.
13. Improve compliance through continuous verification and lifecycle validation.

Target Audience

1. Validation Engineers
2. Qualification Specialists
3. Pharmaceutical Production Managers
4. Quality Assurance Professionals
5. Quality Control Scientists
6. Engineering and Maintenance Personnel
7. Regulatory Affairs Specialists
8. Pharmaceutical Project Managers

Course Modules

Module 1: Fundamentals of Validation and Qualification

- Validation principles and terminology
- Regulatory expectations and compliance
- Qualification lifecycle approach
- Documentation requirements
- Validation project planning
- **Case Study:** Establishing a validation program for a new pharmaceutical facility.

Module 2: Global Regulatory Requirements

- FDA validation expectations
- EU GMP Annex 15 requirements
- PIC/S guidelines
- WHO validation guidance
- Inspection trends and findings
- **Case Study:** Analysis of regulatory warning letters related to validation failures.

Module 3: Validation Master Planning (VMP)

- Structure of a VMP
- Validation strategy development
- Responsibility matrices
- Resource allocation
- Validation scheduling
- **Case Study:** Developing a Validation Master Plan for a sterile manufacturing plant.

Module 4: Quality Risk Management in Validation

- ICH Q9 principles
- Risk assessment methodologies
- FMEA applications
- Criticality analysis
- Risk mitigation planning
- **Case Study:** Risk-based qualification of a purified water system.

Module 5: Design Qualification (DQ)

- User Requirement Specifications (URS)
- Functional specifications review
- Design review processes
- Compliance verification
- Documentation practices
- **Case Study:** DQ execution for a pharmaceutical HVAC system.

Module 6: Installation Qualification (IQ)

- Equipment installation verification
- Utility connections assessment
- Calibration verification
- Material certification review
- IQ documentation preparation
- **Case Study:** IQ protocol execution for tablet compression equipment.

Module 7: Operational Qualification (OQ)

- Operational testing procedures
- Alarm and control verification
- Challenge testing
- Operating range evaluation
- OQ report generation
- **Case Study:** OQ testing of a clean steam generation system.

Module 8: Performance Qualification (PQ)

- Product performance verification
- Process capability assessment
- Sampling strategies
- Acceptance criteria development
- PQ execution and reporting
- **Case Study:** PQ of an aseptic filling line.

Module 9: Facility and Utility Qualification

- HVAC qualification
- Water system qualification
- Clean steam validation
- Compressed air qualification
- Environmental monitoring integration
- **Case Study:** Qualification of a pharmaceutical cleanroom facility.

Module 10: Process Validation

- Process design stage
- Process qualification stage
- Continued process verification
- Statistical process analysis
- Validation protocol development
- **Case Study:** Process validation for oral solid dosage manufacturing.

Module 11: Cleaning Validation

- Cleaning validation principles
- Residue limit calculations
- Sampling techniques
- Analytical method requirements
- Revalidation criteria
- **Case Study:** Cleaning validation of shared manufacturing equipment.

Module 12: Computerized System Validation (CSV)

- GAMP 5 framework
- Software lifecycle management
- Data integrity requirements
- Electronic records compliance
- Validation testing strategies

- **Case Study:** Validation of a Manufacturing Execution System (MES).

Module 13: Analytical Method Validation

- Method validation parameters
- Accuracy and precision evaluation
- Linearity assessment
- Robustness testing
- Regulatory expectations
- **Case Study:** Validation of an HPLC analytical method.

Module 14: Validation Documentation and Audit Readiness

- Protocol development
- Report writing
- Deviation management
- Change control integration
- Inspection preparation
- **Case Study:** Managing validation observations during a GMP inspection.

Module 15: Lifecycle Validation and Continuous Improvement

- Continued process verification
- Trending and monitoring
- Requalification strategies
- Digital validation tools
- Continuous improvement initiatives
- **Case Study:** Implementing lifecycle validation in a biopharmaceutical facility.

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
28 Sep 2026	09 Oct 2026	Online	$2,000
28 Sep 2026	09 Oct 2026	Physical	$3,000
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0
28 Sep 2026	09 Oct 2026	Physical	$0

Ready to enroll or request a customized program? Book online or contact us:

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