



Pharmaceutical GMP and Process Validation Training: Cleanrooms, Qualification and CAPA



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Introduction:

Pharmaceutical GMP and process validation training covering cleanrooms, qualification and CAPA is a 10-day course for production, quality assurance, quality control, validation and engineering staff in medicine and related manufacturing plants, ending with a GMP Gap Assessment and Validation Master Plan Outline. Plants receive critical inspection findings when cleanroom grades are misassigned, equipment runs without documented qualification, cleaning limits lack a rationale and deviations close without effective CAPA. Nominees already operate, test, qualify or release product at work and examine a case solid-dose plant through inspection walkthroughs. CoreConcept Training Center delivers this pharmaceutical GMP course.

Course Objectives:

- Apply GMP principles, the ICH Q10 pharmaceutical quality system and ICH Q9 quality risk management to site procedures and risk registers
- Assess premises, cleanroom grades, HVAC zoning, environmental monitoring and purified water systems against contamination control requirements
- Plan and review design, installation, operational and performance qualification protocols for process equipment and utilities
- Define process validation stages and cleaning validation acceptance limits for a product family on shared equipment
- Handle batch record review, deviations, investigations, CAPA, change control, supplier qualification and self-inspection so the validated state is maintained
- Produce a GMP Gap Assessment and Validation Master Plan Outline for a solid-dose plant

Target Audience:

- Production staff who run granulation, compression, encapsulation and packaging operations under batch records
 - Quality assurance staff who approve deviations, change controls and batch disposition decisions
 - Quality control staff who sample starting materials, water and production environments and report results
 - Validation staff who write, execute and report qualification and validation protocols
 - Engineering and maintenance staff who operate HVAC units, water systems and process equipment
 - Warehouse and materials staff who receive, quarantine, sample and issue starting materials
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Course Outline:

Day 1: GMP Principles and the Pharmaceutical Quality System

- GMP Principles Applied to Contamination, Mix-Up and Error Prevention
- ICH Q10 Pharmaceutical Quality System Elements and Management Review
- Quality Unit Responsibilities Separating Production, QC and QA Authority
- Site Master File and Quality Manual Structure
- GMP Documentation Hierarchy From Policies to Batch Records

Day 2: Quality Risk Management, Training and Personnel Hygiene

- ICH Q9 Quality Risk Management Process and Risk Review
- FMEA Scoring of Contamination and Cross-Contamination Hazards
- GMP Training Matrix, Qualification Records and Effectiveness Checks
- Personnel Hygiene, Health Reporting and Gowning Qualification Procedures
- Risk Register Linking Hazards to Facility and Procedural Controls

Day 3: Premises, Cleanroom Grades and Contamination Control

- ISO 14644-1 Cleanroom Classes and Particle Concentration Limits
- GMP Grades A to D at Rest and in Operation
- Personnel, Material and Waste Flow Zoning on Layout Drawings
- Pressure Cascades, Airlocks and Segregation for Potent Products
- Contamination Control Strategy Covering Facility, Process and People

Day 4: HVAC, Environmental Monitoring and Pharmaceutical Water Systems

- HEPA Filtration, Air Change Rates and Unidirectional Airflow Design
- Environmental Monitoring Plan With Particle Counters and Settle Plates
- Alert and Action Limits With Excursion Trending Procedure
- Purified Water Generation, Storage and Distribution Loop Design
- Water System Sampling Plan, Microbial Limits and Sanitisation Cycles

Day 5: Guided Case Study on a Solid-Dose Facility and Utilities

- Case Tablet Plant Layout Review Against Cleanroom Grade Assignments
 - Granulation and Compression Suite Dust Containment Assessment
 - Case HVAC Zoning and Pressure Cascade Drawing Critique
 - Case Purified Water Loop Excursion Data Interpretation
 - Week-One Facility Risk Register Presented for Peer Challenge
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Day 6: Equipment and Utility Qualification From DQ to PQ

- User Requirement Specification Drafting for Process Equipment
- Design Qualification Review Against Requirement Traceability Matrix
- Installation Qualification Protocols, Drawing Verification and Calibration Checks
- Operational Qualification Test Cases for Alarms and Interlocks
- Performance Qualification Under Load and Requalification Triggers

Day 7: Process Validation Lifecycle and Cleaning Validation

- Process Design Stage Linking Critical Parameters to Quality Attributes
- Process Performance Qualification Batches and Sampling Plan Rationale
- Continued Process Verification Using Control Charts and Capability Indices
- Cleaning Validation Acceptance Limits From Dose and Toxicity Criteria
- Swab and Rinse Recovery Studies With Worst-Case Product Grouping

Day 8: Batch Records, Release and Quality Event Handling

- Batch Manufacturing Record Design and Review by Exception
- Batch Disposition Decision and Release Signatory Responsibilities
- Deviation Classification Into Minor, Major and Critical Categories
- Root Cause Investigation With Fishbone and Five Whys Methods
- CAPA Plan Design With Effectiveness Verification Criteria

Day 9: Change Control, Materials, Suppliers and Quality Metrics

- Change Control Impact Assessment on the Validated State
- Starting Material Sampling, Quarantine and Release Status Labelling
- Supplier Qualification Questionnaire, Audit and Approved Supplier List
- Self-Inspection Schedule, Checklists and Finding Severity Grading
- Quality Metrics Dashboard for Deviations, CAPA Ageing and Right-First-Time

Day 10: Inspection Walkthrough Capstone and Validation Master Plan Outline

- Case Solid-Dose Plant Walkthrough Against GMP Gap Checklist
 - Gap Assessment Findings Graded by Patient Risk Severity
 - Validation Master Plan Scope, Responsibilities and Qualification Matrix
 - Mock Inspection Opening Meeting, Document Requests and Back-Room Handling
 - GMP Gap Assessment and Validation Master Plan Outline Completion
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Skills You Will Gain:

- Quality Risk Assessment
- Cleanroom Classification
- Environmental Monitoring Trending
- Purified Water System Control
- Equipment Qualification
- Cleaning Limit Calculation
- Deviation Investigation
- Supplier Qualification

Why Attend This Course:

- Deliver a GMP Gap Assessment and Validation Master Plan Outline to the site quality head and engineering manager as the basis for a remediation and qualification schedule
- Decide whether a deviation, equipment change or cleaning failure affects the validated state and which batches need impact assessment
- Avoid repeat inspection observations, failed qualification runs and batch rejections caused by unclear limits and unclosed CAPA
- Share gowning, monitoring, protocol and investigation templates with operators, analysts and junior validation staff

Conclusion:

Back at the site, the participant hands the quality head and engineering manager a GMP Gap Assessment and Validation Master Plan Outline that ranks facility, utility and procedural gaps by patient risk and sets the qualification and validation scope for the coming period. Management uses it to prioritise remediation spending, schedule equipment requalification and assign CAPA owners before the next external inspection. After the first self-inspection cycle and the first completed qualification, the unit should review which gaps closed, which deviations recurred and whether the plan matched the actual validation workload.

Frequently Asked Questions FAQ:

What should participants know before the pharmaceutical GMP and process validation training?

Participants should already work in a regulated manufacturing, testing, engineering or quality role and be familiar with batch records and standard operating procedures. Bringing a site layout, a recent deviation or a qualification protocol helps them apply the walkthroughs and case exercises to their own plant.

How does this pharmaceutical GMP and process validation training differ from a data integrity or regulatory affairs course?

This course covers the manufacturing floor: facilities, utilities, qualification, validation and quality events. Documentation practice, stability testing and dossier submissions are touched only where they meet manufacturing and are taught in depth by separate specialised courses.

Why does pharmaceutical GMP require process validation as well as finished product testing?

Testing a sample cannot prove every unit in a batch meets its quality attributes. Process validation gives documented evidence across design, qualification and continued verification that the process consistently delivers the required quality, so quality is built in rather than tested in.

What do participants take back from the pharmaceutical GMP and process validation training?

Participants take back a GMP Gap Assessment and Validation Master Plan Outline for a case solid-dose plant, adaptable to their own site, together with checklists for cleanroom reviews, qualification protocols, cleaning limits and deviation investigations.
