

GMP Validation Guidance

Method Validation

- Guidance 001 - Analytical Test Method Validation - General Guidance
- Guidance 002 - Analytical Test Method Validation - Risk Assessment and Prioritization
- Guidance 003 - Analytical Test Method Validation - System Suitability
- Guidance 004 - Analytical Test Method Validation - Precision and Accuracy
- Guidance 005 - Analytical Test Method Validation - Quantitation and Detection Limit
- Guidance 006 - Analytical Test Method Validation - Linearity, Range and Specificity
- Guidance 007 - Analytical Test Method Validation - Robustness

Cleaning Validation

- Guidance 008 - Calculations of Residue Limits For Drug Products for Equipment Cleaning
- Guidance 009 - Guidance for Swab Sampling and Visual Inspection Locations for API Equipment
- Guidance 010 - Product and Equipment Grouping and Worst - Case Product Selection
- Guidance 011 - Rinsate and Swab Sample, Test Method Development and Validation
- Guidance 012 - Visual Inspection and Quantitation
- Guidance 013 - Investigating Unknown Peaks in Chromatography
- Guidance 014 - Cleaning Evaluation Documentation and Instruction - Records for Cleaning Activities

Other Validation

- Guidance 015 - Critical Process Parameters for Drug Product
- Guidance 016 - Identification of the Critical Steps for Drug Product Process
- Guidance 017 - Process Validation for Drug Products and Medical Devices
- Guidance 018 - Equipment Cleaning Validation For Active Pharmaceutical Ingredients
- Guidance 019 - Equivalence Criteria of Impurities for API Process Validation
- Guidance 020 - Equivalency Comparison of Drug Product Validation Batch Data to Reference Batches
- Guidance 021 - Establishing and Extending Clean Equipment Hold Times
- Guidance 022 - Evaluating Non-Cleaned Equipment Hold Times for Cleaning Validation of APIs & Drug Products

Guidance 023 - Evaluation of Changes for Potential Impact on Process Validation

Guidance 024 - General Guidance for Process Validation Sampling

Guidance 025 - Guidance for Swab & Visual Inspection Sampling Locations for Drug Products Equipment

Guidance 026 - In-Process and Bulk Drug Product Holding Times

Guidance 027 - Demonstration of Active Pharmaceutical Ingredient (API) Batch Homogeneity

Guidance 028 - Documentation Example for Continuous Quality Verification

Guidance 029 - Documentation to Support Continuous Quality Verification

Guidance 030 - Guidance on Selection Criteria of Dose & Toxicity Data for Use in Cleaning Limit Calculation

Guidance 031 - Inspection Attributes in Packaging Validation of Non-Sterile Drug Products

Guidance 032 - Laboratory Equipment Qualification

Guidance 033 - Matrices and Bracketing in Process Validation

Guidance 034 - Considerations for Selecting Packaging Lot Sizes during Packaging Validation

Guidance 035 - Non-Sterile API Manufacturing Area Environmental Control

Guidance 036 - Packaging Validation - Potential Critical Process Parameters and Validation Practices

Guidance 037 - Process Validation Sampling for Non-Sterile Liquid Semi Solid Drug Products

Guidance 038 - Process Validation Sampling for Non-Sterile Solid Dose Drug Products

Guidance 039 - Performance Qualification versus Process Validation

Guidance 040 - Periodic Review of Processes and Systems

Guidance 041 - Release For Sale of Drug Product and API Pre-Validation & Validation Batches

Guidance 042 - Selection of Critical Process Parameters for Validation

Guidance 043 - Semi-Solid Dosage Forms-Critical Process Parameters

Guidance 044 - Solid Oral Dosage Forms-Potential Critical Process Parameters

Guidance 045 - Solvent Recovery Validation Example
Guidance 046 - Test Deviations during Validation
Guidance 047 - Validation Activities during Technology Transfers
Guidance 048 - Validation Considerations for Re-work and Re-process of API
Guidance 049 - Validation Documentation
Guidance 050 - Shipping Validation for Biopharmaceutical Materials Derived from Biotech Processes

Guidance 050 - Shipping Validation for Biopharmaceutical Materials Derived from Biotech Processes

GMP Quality Guidance

Guidance 060 - Product Quality Complaint Handling
Guidance 061 - Application of Quality Risk Management to Periodic Review of SOPs
Guidance 062 - Statistical Rationale for Raw Material Sampling
Guidance 063 - Quality Risk Management Application Critical Instrument Calibration
Guidance 064 - Structured On-the-Job Training System

Guidance 065 - Training system for Aseptic and Preparation for Aseptic Operators and Support Staff

Guidance 066 - Disposal of Rejected and Waste Materials
Guidance 067 - Quality Assurance Self-Appraisals
Guidance 068 - Material Status Indication
Guidance 069 - Annual Product Records Review
Guidance 070 - Receipt, Approval and Use of Labels and Labeling
Guidance 071 - Weighing and Measuring Practices In Manufacturing Operations
Guidance 072 - Material Supplier Approval

Guidance 073 - Storage & Distribution of Drug Products, Medical Devices and Related Materials

Guidance 074 - Control of Manufacturing and Packaging Defects Non Sterile
Guidance 075 - Pest Control
Guidance 076 - Raw Materials and Packaging Materials Receipt
Guidance 077 - Sampling of Production Materials and Finished Goods

Guidance 078 - Water Purification, Storage and Distribution for Pharmaceutical Production

Guidance 079 - Use of a Risk-Based Approach to Establish External Quality Assurance Audit Frequency

www.gmpqualityup.com

Guidance 080 - Reduced Testing Program

Guidance 081 - GMP Training System

Guidance 082 - Stability Testing

Guidance 083 - Quality Risk Management Application to Identify Deviations vs. Events

Guidance 084 - Implementation of Real Time Release

Guidance 085 - Preventive Maintenance

Guidance 086 - Calibration

Guidance 087 - Evaluation Process Supporting Elimination of Defined Shipment Temperature Range

Guidance 088 - Determining Testing Patterns and Acceptance Criteria for Analytical Method Transfers

Guidance 089 - Quality Risk Management to Establishment of Weighing Device Performance Testing Intervals

Guidance 090 - Analytical Laboratory Management

Guidance 091 - Microbiology Laboratory Management

Guidance 092 - Transfer of Analytical Methods

Guidance 093 - Quality Agreements