

## **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
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- Guidance 018 - Equipment Cleaning Validation For Active Pharmaceutical Ingredients
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- Guidance 020 - Equivalency Comparison of Drug Product Validation Batch Data to Reference Batches
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- Guidance 022 - Evaluating Non-Cleaned Equipment Hold Times for Cleaning Validation of APIs & Drug Products

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**GMP Quality Guidance**

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