



Training Topics

These are some of the topics that we have presented in the past. We can provide training on the following topics as well as customize training to your needs:

- 21 CFR, Part 11--Use of Computers in a GMP Environment
- An Evaluation of the SUPAC Guidance
- Annual Product Reviews
- Batch Records--FDA Systemic Inspection Approach
- Batch Records--Dealing with Issues
- CAPA
- Preparing an Investigation Report--Quality Oversight of New or Existing Facility Construction Projects
- Certificate of Suitability
- Change Control
- Cleaning Overview: Potent Compounds
- Computer System Validation
- Conducting an Investigation
- Cross Contamination Prevention
- Discern FDA Expectations of Stability Testing When a Packaging System is Changed
- Drug Master Files
- European Drug Master File
- FDA Systemic Inspection Process
- GLP/GMPs in the Lab
- GMPs for Finished Pharmaceuticals
- IND/NDA/ANDA
- Internal Auditing
- ICH Q7A GMP Guidance for Active Pharmaceutical Ingredients
- Investigating Stability Failures
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- Investigations – the basics
- Laboratory Auditing
- Living with 483s, Warning Letters, and Consent Decrees
- Outliers
- Pharmaceutical Cleaning
- Pharmaceutical Process Validation and What it Means to You--PAT (Process Analytical Technology)
- Preparing for the Audit
- Preventive Maintenance
- Problem Solving Tools
- Quality Plan Development
- Quality System Regulation (QSR)
- Recalls/Adverse Event Reporting
- Road Map to the US Market – Brief Overview of Drug Development
- Root Cause Analysis
- Tamper Evidence
- The Barr Decision
- The Quality Audit--General ICH Guidelines
- The Quality System Overview
- Warehousing
- What Happens when Stability Results Fail???
- Writing SOPs Covering Investigations

Call us at 513-860-3512 to conduct your annual GMP Training or to assist in establishing a program.

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