

Sample List of Topics Included in Clinical & Lab Compliance

All Access pass

Below is a sample list of topics. There are more than 150 topics available through all access pass and new topics get added during the course of the year.

Clinical Compliance

- Eliminate the Confusion - New Requirements for Clinical Laboratories to Meet GCP
- Project Management for Auditors - Improving audit productivity for GCP, GMP and GLP
- Requirements for Running Clinical Trials in Pediatrics for the EU
- Hypothesis Testing, P-values and Inference: When Thinking like a Statistician Makes Sense
- Surviving an FDA Sponsor Inspection - Training for Success
- Risk Based Monitoring for GCP Compliance
- FDA Compliance and Clinical Trial Computer System Validation
- Power Analysis for Sample Size Calculations
- How to Manage Your Vendors in Clinical Research
- Use of Wearable Devices in Clinical Trials
- The Impact of ICH E6 R2
- Management of the Data Safety Management Committee for Clinical Trials
- Effective Time Management in Clinical Trials

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Lab Compliance

- Understanding and Implementing USP <1058>: Analytical Instrument Qualification
- Good Laboratory Practice Regulations
- Bioanalytical Methods Validation
- Transfer of Analytical Methods According to the USP Chapter <1224>
- Conducting Effective Investigations of Out of Specification and Atypical Laboratory Results
- Ensuring Integrity and Security of Laboratory Data
- System Suitability Testing (SST) for USP and FDA Compliance
- Laboratory Inspection Readiness - Implementing GMPs for the Pharmaceutical Laboratory
- Selection and Use of (Certified) Reference Material in Analytical Laboratories
- Method Validation under Good Laboratory Practices (GLP)
- QbD Approach to Analytical Method Lifecycle: Design, Development, Validation and Transfer
- Measurement Uncertainty in Microbiology
- Good Laboratory Practices (GLPs) - Comparing and Contrasting with Good Manufacturing Practices (GMPs)
- Practicing Laboratory Safety in the Workplace
- How Medicare's Market-Based Payment System Is Upending the U.S. Clinical Laboratory Market
- Validation of GC / GC-MS Methodologies

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