Sample List of Topic types Included in Pharmaceutical 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.

Validation

- Validation Sampling Plans
- Best Practices for an Effective Cleaning Validation Program
- Issues in Calibrations and Accuracy in Method Validation

more….

Data Integrity

- Pharmaceutical Data Integrity
- Advanced Auditing for Data Integrity
- Implementation and Management of GMP Data Integrity

more….

Sterilization

- Sterile Filtration of Pharmaceutical Products - Validation and Regulatory Requirements
- Steam Sterilization Microbiology and Autoclave Performance Qualification
- Sterilization of Pharmaceutical Products and Medical Devices

more….

Supplier Management

- How to Conduct Successful Supplier Audits
- FDA’s Expectations from Supplier Management for GMP: Quality Agreements and More
- CMO Supplier Quality Agreements - How to Comply with New FDA and EU Guidelines for Contract Drug Manufacturers

more….

FDA Inspection

- How to Prepare for an FDA Inspections?
- 21 CFR Part 111 - FDA Inspections for Dietary Supplements - How to Prepare
- FDA Inspections: Understanding the Core Elements

more….

Documentation

- How to write SOP's that Avoid Human Error
- Good Documentation Guideline (Chapter <1029> USP)
- Good Documentation Practice and Record Keeping Regulations (FDA & EMA)

more….

Manufacturing

- Human Error Reduction in GMP Manufacturing
- Drug Manufacturing Inspection Part III
- Quality Assurance for Continuous Manufacturing of Small Molecule, Oral Dosage Products

more….

Marketing and Labeling

- Dietary Supplements - Regulatory Compliance Requirements, Product Claims, Labeling Issues and FDA Updates
- The Importance of Packaging and Labeling in Pharmaceutical Product Development
- FDA Regulations for Marketing OTC Drugs in the U.S.
- FDA Regulations and New Legislation for Marketing Cosmetics in the U.S

more….

Project Management

- Project Management for FDA-Regulated Companies
- Project Management for Computer Systems Validation
- Project Management for Auditors - Improving audit productivity for GCP, GMP and GLP

more….

Vendor Management

- Auditing and Qualifying Suppliers and Vendors - An Effective Risk Based Approach
- Vendor Management for Pharmaceuticals, Biologicals, and Medical Devices
- Building a Vendor Qualification Program for FDA Regulated Industries
- How to Manage Your Vendors in Clinical Research

more….

Complaint Handling

- FDA Internal Complaint Handling
- Complaint Management: Best Practices to Assure Regulatory Compliance and Customer Retention
- Complaint Handling Requirements (US); Interrelationship with CAPA, Change Control, Adverse Event Reporting, Recalls and Life Cycle Process Activities

more….

Drug Product Development

- Biomarkers in Drug Development
- Reviewing Drug Product Batch Records
- Setting specifications for drug substances and drug products

more….