Sample List of Topic types Included in Life Science 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

- Process Validation - Overview of Why and How
- Validation Sampling Plans
- Validation Planning to Meet US FDA and ISO 13485 Requirements

more….

Data Integrity

- Implementation and Management of GMP Data Integrity
- Data Integrity Compliance for Computer Systems Regulated by FDA
- Implementing a Robust Data Integrity Program

more….

Sterilization

- Steam Sterilization Microbiology and Autoclave Performance Qualification
- Sterilization of Pharmaceutical Products and Medical Devices
- What Is A Sterilization Dose Audit and How Are They Performed?

more….

Supplier Management

- Establishing a Robust Supplier Management Program
- Assess Impact For Supplier Change Notices
- How to Conduct Successful Supplier Audits

more….

FDA Inspection

- The FDA Inspection Process: From SOP to 483
- How to Prepare for an FDA Inspections?
- The FDA Inspection: Best Practices for Preparation, Management, and Follow-Up

more….

Documentation

- GDP and Record Keeping Regulations (FDA & EMA)
- Good Documentation Practice (GDocP) for FDA Regulated Industry
- GxP/GMP Requirements and its Consequences for Documentation and Information Technology Systems

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

- Reprocessing Reusable Medical Devices - Cleaning and Labeling Requirements
- Packaging and Labeling for Commercial and Clinical Products
- Labeling, Advertising and Promotion in the Regulated Environment
- Promoting and Advertising Dietary Supplements in Compliance with FDA and FTC Regulations

more….

Regulations

- Quality Risk Management Overview for Pharma, Biopharma and Combination Products - ICH Q9/ISO 14971
- ICH Stability Requirements and Challenges
- FDA Regulations for Environmental Monitoring (EM) Program

more….

Recall

- Complaint Handling, MDR's & Recalls
- Complaint Handling Requirements (US); Interrelationship with CAPA, Change Control, Adverse Event Reporting, Recalls and Life Cycle Process Activities
- Effective Line Clearance - Prevent Product Holds and Recalls the Easy Way

more….

Vendor Management

- Building a Vendor Qualification Program for FDA Regulated Industries
- How to Ensure Your Foreign Vendors are FDA Compliant: Conducting Vendor Audits, Monitoring, and Using Checklists
- Vendor Management for Pharmaceuticals, Biologicals, and Medical Devices

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….

CAPA

- How FDA trains its investigators to review CAPA and what should you do to prepare
- Powerful Closed-loop CAPA - Meeting FDA Expectations
- Introduction to Root Cause Investigation for CAPA

more….

Submission

- ANDA Submission and GDUFA Guidance
- How to prepare a 510(k) FDA Submission
- Pre-Market Submission Implications of FDA’s Human Factors Guidance and Device Priority List

more….