Sample List of Topic types Included in Medical Device 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 for Medical Device Manufacturers - Master IQ, OQ, PQ
- Validation Planning to Meet US FDA and ISO 13485 Requirements

more….

Data Integrity

- FDA Compliance and Enforcement Trends focused on Data Integrity
- Data Integrity Compliance for Computer Systems Regulated by FDA
- Implementing a Robust Data Integrity Program

more….

Sterilization

- Ethylene Oxide (EO) Sterilization Basics for R&D Engineers
- Basics of Testing Associated with Sterilization Validation and Routine Processing
- What Is A Sterilization Dose Audit and How Are They Performed?

more….

Supplier Management

- Supplier Management: Challenges and Opportunities
- Creating a Risk-based Supplier Management program
- Supplier Management with the new MDR EU MDR 745/2017

more….

FDA Inspection

- Regulatory Inspections - How to prepare for a visit from an FDA Auditor
- FDA Inspection Readiness
- FDA Inspections: Understanding the Core Elements – Part I

more……

Documentation

- Avoid Documentation 'Time Bombs'
- GDP for FDA Regulated Industry
- US FDA's Plan for Modernizing the 510(k) Pathway - Meet the New Expectations

more….

Manufacturing

- Risk-based Design Control - The New Paradigm for Medical Device Design
- Process Validation Requirements & Compliance Strategies
- US FDA Medical Device QSR, 21 CFR 820 and QMS

more….

Marketing and Labeling

- Reprocessing Reusable Medical Devices - Cleaning and Labeling Requirements
- Post Market Surveillance with the new MDR EU MDR 745/2017
- eLabeling for Medical Devices: Valuable but not easy

more….

Regulations

- User / Human Factors Engineering Under IEC 62366-1, -2
- Lead Auditor EN ISO 13485:2016 and EU MDR 2017/745 - Regulation
- Supplier Management with the new MDR EU MDR 745/2017
- EU MDR 2017/745 Medical Device Classification

more….

Recall

- Complaint Handling, MDR's & Recalls
- Preventing Product Liability Lawsuits and Recalls - New Product Development
- Medical Device Complaints, MDR's and Recalls

more….

Vendor Management

- Vendor Management for Pharmaceuticals, Biologicals, and Medical Devices
- How to Ensure Your Foreign Vendors are FDA Compliant – Conducting Vendor Audits, Monitoring, and Using Checklists
- How to Buy COTS Software, and Audit and Validate Vendors

more….

Complaint Handling

- Spotlight on Complaint Handling and Medical Device Reporting
- Complaint Handling, MDR's & Recalls

more….

CAPA

- Introduction to Root Cause Investigation for CAPA
- Powerful Closed-loop CAPA - Meeting FDA Expectations
- Mastering CAPA: A Stepwise and Sustainable System

more….

Submission

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

more….