Agenda

Day 1

8:00 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 10:15 a.m. **Part A – The Regulatory Framework**

- Quality management systems (QMS) and research management systems (RMS) standards
- Transition timelines for the EU Medical Device Regulations (EU-MDR) and EU In Vitro Diagnostics Regulation (EU-IVDR)
- Records and reports
- Distinguishing pre-market from postmarket activities
- FDA warning letters – learning from others

Part B – Overview of the Postmarket Elements

- The main flow
- Servicing
- Complaint management
- Adverse event report
- Risk management
- Corrective action
- Field action
- Design changes
- Regulatory submissions

Exercise B1 – Preliminary Analysis of Complaint Implications

10:15 a.m. – 10:30 a.m. **Morning Break**

10:30 a.m. – 12:00 p.m. **Part C – Servicing: A Common Source of Complaints**

- Understanding servicing – no clear definitions
- Servicing as an element of the QMS

- Service records and complaints
- Warranty, servicing, and complaints
- Service record analysis – complaint identification

Exercise C1 – Service Record Analysis to Detect Complaints

12:00 p.m. – 1:00 p.m. **Lunch Break**

1:00 p.m. – 2:30 p.m. **Part D – Complaint Management**

- Definitions of a complaint
- Identifying regulatory complaints
- Complaint classification systems
- Implementing a QSR complaint management system
- Implementing an International Standards Organization (ISO) 13485:2016 complaint management system

Exercise D1 – Complaint Classification

2:30 p.m. – 2:45 p.m. **Afternoon Break**

2:45 p.m. – 4:30 p.m. **Part E – Risk Management**

- Life cycle approach
- The risk management plan
- Hazard analysis
- Risk reduction
- Post-production Information

Exercise E1 – Post-Production Data Analysis

4:30 p.m. **Session Wrap-up, End of Day One**

Day 2

8:00 a.m. – 8:30 a.m. **Continental Breakfast**

8:30 a.m. – 10:15 a.m. **Part F – Adverse Event Reporting**

- The concept of an adverse event
- Reportability requirements
- Reportability forms and information
- Compare and contrast the US, EU, and Canadian systems

Exercise F1 – Adverse Event Reportability

10:15 a.m. – 10:30 a.m. **Morning Break**

10:30 a.m. – 12:00 p.m. **Part G – Corrective Action and Preventive Action (CA&PA)**

- The difference between corrective action (CA) and preventive action (PA)
- Implementing CA&PA in QSR
- Implementing CA&PA in ISO 13485:2016
- Applying CA to complaints

Exercise G1 – Complaints Requiring Corrective Action

12:00 p.m. – 1:00 p.m. **Lunch Break**

1:00 p.m. – 2:30 p.m. **Part H – Design Changes**

- Understand the role of design changes in the QMS
- Design change processes in Quality Systems Regulation (QSR)
- Design change process in ISO 13485:2016
- Design changes driven from CA from a complaint
- Compare and contrast the US, EU, and Canadian systems

Exercise H1 – Complaints Requiring Design Changes

Part I – Field Action

- The concept of a field action
- Reportability requirements
- Reportability Forms and Information
- Compare and contrast the US, EU, and Canadian systems

Exercise I1 – Field Action Determination

2:30 p.m. – 2:45 p.m. **Afternoon Break**

2:45 p.m. – 4:30 p.m. **Part J – Regulatory Submission**

- The Concept of a Regulatory Submission
- Submissions Driven by Problem Resolution
- Compare and contrast the US, EU, and Canadian systems

Exercise J1 – Determining the Need for a Regulatory Submission

4:30 p.m. **Adjourn Workshop**