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

- QMS and RMS standards
- Transition time lines for standards and certificates
- Transition timelines for the EU-MDR and EU-IVDR
- FDA warning letters — Learning from others

Part B – Overview of Connections

- Definitions of Complaints
- Linkage to Servicing
- Linkage to Risk Management
- Linkage to Corrective Action
- Linkage to Adverse Event Reports
- Linkage to Field Action
- Linkage to Design Changes
- Linkage to Regulatory Submissions

Exercise B1 — Preliminary Analysis of Complaint Implications

10:15 a.m. – 10:30 a.m. 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 ISO 13485:2016 complaint management system

Exercise D1 — Complaint Classification

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:30 p.m. Part E – Complaint Metrics and Reporting

- Analysis of complaints in QSR
- Analysis of complaints in ISO 13485:2016
- Using complaint analysis to update the risk management file
- Trend analysis and reporting in the EU-MDD
- Trend analysis and reporting in the EU-MDR

Exercise E1 — Complaint Process 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
- Implementing the US system
- Implementing the Canadian system
- Implementing the EU system under the MDD
- Implementing the EU system under the MDR

Exercise F1 — Adverse Event Reportability

10:15 a.m. – 10:30 a.m. 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)
- Understanding CA&PA interrelationships in the QMS
- 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 additional elements
  - Production change
  - UDI changes
  - Updated submissions
  - Risk management

    - Field actions
- Developing the design change process in QSR
- Developing the design change process in ISO 13485:2016
- Design changes driven from CA from a complaint

Exercise H1 — Complaints Requiring Design Changes

Part I – Field Action

- Understand the role of field action in the QMS
- Implementing the US system
- Implementing the Canadian system
- Implementing the EU system under the MDD
- Implementing the EU system under the MDR

Exercise I1 — Field Action Determination

2:30 p.m. – 2:45 p.m. Break

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

- Understanding the role of regulatory submissions in the QMS
- Implementing the US system for 510(k) devices
- Implementing the Canadian system
- Implementing the EU system under the MDD
- Implementing the EU system under the MDR

Exercise J1 —Determining the Need for a Regulatory Submission

4:30 p.m. Adjourn Workshop