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 timelines 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