AGENDA

Course 1 – Day 1

8:00 a.m. – 9:30 a.m. Registration and Continental Breakfast

9:30 a.m. – 10:30 a.m. **Part A – Overview of the New Regulation**

- Reasons for Change
- Summary of major changes from the MDD
- Notified Bodies
- Transition Period
- Understanding Standards and Harmonization
- EU Versions of ISO 13485:2016 and ISO 14971:2007

Part B – Obligations of the Manufacturer

- Economic Operators
- Single Registration Number
- QMS, RMS, and PMS
- CE Mark and Declaration of Conformity
- UDI Requirements
- Incidents and Field Safety Corrective Actions
- Person Responsible for Regulatory Compliance
- Product Liability Insurance
- Exercise B1 – Person Responsible for Regulatory Compliance
- Exercise B2 – Economic Operators

10:30 a.m. – 10:45 a.m. Break

10:45 a.m. – 12:00 p.m. **Part C – The Quality Management System (QMS)**

- Requirements from the MDR
- Linkage to ISO 13485:2016
- The role of CEN/TR 17223:2018
- QMS Certificates
- Exercise C1 – Elements of the QMS

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:15 p.m. **Part D – The Risk Management System (RMS)**

- Requirements from the MDR
- Linkage to ISO 14971:2007

- Changes from EN ISO 14971:2012
- Exercise D1 – Elements of the RMS

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 5:00 p.m. **Part E – The Post-market Surveillance System (PMSS)**

- Requirements from the MDR
- Clinical Evaluation and Updates
- Post-Market Clinical Follow-Up
- Linkage to Risk Management
- Vigilance
- Trend Reporting
- Field Safety Corrective Actions
- Exercise E1 – Elements of the PMSS

5:00 p.m. Session Wrap-up End of Day One

Course 1 – Day 2

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

8:30 a.m. – 10:00 a.m. **Part F – Unique Device Identification**

- The Role of UDI
- Application to Devices and Packaging
- UDI and the Declaration of Conformity
- The EU Database for UDI
- Exercise F1 – Unique Device Identification

Part G – Device Classification

- Definitions for the Classification Rules
- Applying the Classification Rules
- Attributes in Addition to the Device Class
- Exercise G1 – Device Classification

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. **Part H – Conformity Assessment**

- Conformity Assessment Methods
- Connecting the Device Class to the Conformity Assessment Paths
- Attributes in Addition to the Device Class
- Understanding Annex IX
- Exercise H1 – Conformity Assessment

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:15 p.m. **Part I – General Safety and Performance Requirements**

- Overview of the Requirements
- Developing a Checklist

- Role of Harmonized Standards
- Role of Common Specifications
- Exercise I1 – General Safety and Performance Requirements

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 4:30 p.m. **Part J – Technical Documentation**

- Understanding the Technical Documentation
- Require Content
- Maintaining the Technical Documentation
- Role of the Person Responsible
- Role of the Authorized Representative
- Exercise J1 – Technical Documentation in Annex II
- Exercise J2 – Technical Documentation in Annex III

Part K – The Notified Body

- Role of the Notified Body
- Declaration of Conformity
- The EU Database
- Exercise K1 – Declaration of Conformity

4:30 p.m. Workshop Completed

Course 2 – Day 3

8:00 a.m. – 8:30 a.m. Registration and Continental Breakfast

8:30 a.m. – 10:30 a.m. **Part A – Overview of the Post-market Activities**

- Identification of the Activities
- Role in the QMS
- Annex IX Documentation
- Notified Body Obligations

Part B – Pre-market Activities

- Clinical Evaluation (Plan and Report)
- Risk Management (Plan and File)
- Benefit-Risk Determination
- Indicators and Thresholds
- Exercise B1 – Indicator and Threshold Analysis

10:30 a.m. – 10:45 a.m. Break

10:45 a.m. – 12:00 p.m. **Part C – Post-market Surveillance**

- PMS Plan
- PMS Report
- Periodic Safety Update Report (PSUR)
- Linkage to Other Activities
- Exercise C1 – Developing Elements of the PMS Plan

- Exercise C2 – Creating and Updating the PSUR

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:15 p.m. **Part D – Post-market Clinical Follow-up (PMCF)**

- PMCF Plan
- PMCF Evaluation Report
- Linkage to Other Activities
- Exercise D1 – Developing Elements of the PMCF Plan
- Exercise D2 – Preparing the PMCF Evaluation Report

Part E – Summary of Safety and Clinical Performance (SSCP)

- Application
- Content
- Distribution
- Exercise E1 – Preparing an SSCP

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 4:30 p.m. **Part F – Vigilance & Trend Analysis**

- Field Safety Corrective Action
- Incident Classification
- Reporting Serious Incidents
- Trend Reporting (Non-serious Incidents)
- Exercise F1 – Classifying Incidents

Part G – Statistically Significant Increase

- The Concept of Statistical Significance
- Trend Reporting Plan
- Calculating a Trend Line
- Using Excel to Test for Statistical Significance
- Using an ISO 14971:2007 Risk Matrix
- Exercise G1 – Developing the Trend Reporting Plan

4:30 p.m. End of the Workshop