Agenda

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 – Implementing the Article 120 Transition

- MDD certificates
- MDR elements
- The Notified Body
- Managing the system

Part C – 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 C1 – Person Responsible for Regulatory Compliance
- Exercise C2 – Economic Operators

10:30 a.m. – 10:45 a.m. **Morning Break**

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

- Requirements from the MDR
- Linkage to ISO 13485:2016
- The role of CEN/TR 17223:2018
- QMS certificates
- Exercise D1 – Elements of the QMS

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

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

- Requirements from the MDR
- Linkage to ISO 14971:2007
- Changes from EN ISO 14971:2012
- Exercise E1 – Elements of the RMS

2:15 p.m. – 2:30 p.m. **Afternoon Break**

2:30 p.m. – 5:00 p.m. **Part F – 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 F1 – Elements of the PMSS

5:00 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. – 10:00 a.m. **Part G – Unique Device Identification**

- The role of UDI
- Application to devices and packaging
- UDI and the Declaration of Conformity
- The EU database for UDI
- Exercise G1 – Unique Device Identification

Part H – Device Classification

- Definitions for the classification rules
- Applying the classification rules
- Attributes in addition to the device class
- Exercise H1 – Device Classification

10:00 a.m. – 10:15 a.m. **Morning Break**

10:15 a.m. – 12:00 p.m. **Part I – 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 I1 – Conformity Assessment

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

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

- Overview of the requirements
- Developing a checklist
- Role of harmonized standards
- Role of common specifications
- Exercise J1 – General Safety and Performance Requirements

2:15 p.m. – 2:30 p.m. **Afternoon Break**

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

- Understanding the technical documentation
- Require content
- Maintaining the technical documentation
- Role of the person responsible
- Role of the authorized representative
- Exercise K1 – Technical Documentation in Annex II
- Exercise K2 – Technical Documentation in Annex III

Part L – The Notified Body

- Role of the notified body
- Declaration of conformity
- The EU database
- Exercise L1 – Declaration of Conformity

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

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. **Morning 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. **Afternoon Break**

2:30 p.m. – 4:30 p.m. **Part F – Vigilance and 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**