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 – Overview of the New Regulations**

- Reasons for Change
- Summary of major changes from the MDD
- Notified Bodies
- Transition Period
- EU Versions of ISO 13485:2016 and ISO 14971:2007
- Exercise A1 – QMS and RMS Analysis

10:15 a.m. – 10:30 a.m. Break

10:30 a.m. – 12:00 p.m. **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

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:30 p.m. **Part C The Quality Management System (QMS)**

- Requirements from the MDR
- Linkage to ISO 13485:2016
- QMS Certificates
- Exercise C1 – Elements of the QMS

Part D The Risk Management System (PMS)

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

- Exercise D1 – Elements of the RMS

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:30 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

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

Day 2

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

9:00 a.m. – 10:15 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

10:15 a.m. – 10:30 a.m. Break

10:30 a.m. – 12:00 p.m. **Part G – Device Classification**

- Definitions for the Classification Rules
- Applying the Classification Rules
- Exercise G1 – Device Classification

Part H – Conformity Assessment

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

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:30 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

Part J – Technical Documentation

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

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:15 p.m. **Part K – The Notified Body**

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

4:15 p.m. – 4:30 p.m. **Summary, Conclusions, and Lessons Learned**

4:30 p.m. Adjourn Workshop