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 14971:2019

Part B – Implementing the Article 120 Transition
  
  - MDD certificates
  - MDR elements
  - The Notified Body
  - Managing the system
  - The EUDAMED delay

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/IVDR
  ▪ Linkage to ISO 14971:2019
  ▪ 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 Postmarket Surveillance System (PMSS)
  • Requirements from the MDR/IVDR
  • Clinical/performance evaluation and updates
  • Postmarket clinical/performance 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 (UDI)
  - The role of UDI
  - The basic UDI-DI
  - 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
• Required 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
Course 2

Day 1

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

8:30 a.m. – 10:30 a.m.  Part A – Overview of the Postmarket Activities

- Identification of the activities
- Role in the quality management system
- Annex IX documentation
- Notified body obligations

Part B – Premarket Activities

- Clinical/performance 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 – Postmarket Surveillance (PMS)

- 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 – Postmarket Clinical Follow-up (PMCF)**

- PMCF/ Postmarket performance follow-up (PMPF) plan
- PMCF/PMPF evaluation report
- Linkage to other activities
- Exercise D1 – Developing Elements of the PMCF/PMPF Plan
- Exercise D2 – Preparing the PMCF/PMPF 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 & 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 14971:2019 risk matrix
- Exercise G1 – Developing the Trend Reporting Plan

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

Course 3

8:00 a.m. – 8:30 a.m.  
**Registration/Continental Breakfast**

8:30 a.m. – 9:30 a.m.  
**Part A – The Internal Quality Audit Program**
- ISO 13485:2016 audit requirements
- Planning internal audits
- Conducting internal audits
- Reporting internal audits
- Resolving audit nonconformances

9:30 a.m. – 10:15 a.m.  
**Part B – EU-MDR/IVDR Conformity Assessment Paths**
- Annex VIII classification
- Options for EU-MDR Devices
- Options for EU-IVDR Devices
- Exercise B1 – Selecting a Conformity Assessment Path

10:15 a.m. – 10:30 a.m.  
**Morning Break**

10:30 a.m. – 11:15 a.m.  
**Part C – EU-MDR/IVDR QMS & RMS Considerations**
- Understanding Article 10
- Understanding CEN/TR 17223:2018
- Understanding ISO 13485:2016
- Understanding ISO 14971:2019
- Developing the Annex II and Annex III documentation
- Exercise C1 – Identify and Resolve Gaps from ISO 13485:2016
11:15 a.m. – 12:00 p.m.  Part D – Preparing the Application to the NB

- EU-MDR applications
- EU-IVDR applications

12:00 p.m. – 1:00 p.m.  Lunch Break

1:00 p.m. – 2:15 p.m.  Part E – The NB Approach

- The NB QMS requirements
- Specific NB audit areas
- Specific NB competence requirements
- EU-MDR Article 106 Expert Panels
- EU-IVDR Article 100 Reference Laboratories
- Exercise E1 – Review Specific NB Audit Areas and Develop Plans

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

2:30 p.m. – 4:00 p.m.  Part F – Mapping the NB Approach to the Audit Program

- Specific audits
- Specific internal auditor competence
- Resolving audit nonconformances
- Management review
- Exercise F1 – Map the NB Audit to the Internal Audit Program
- Exercise F2 – Report to Management Review

4:00 p.m.  Workshop Completed