
# Agenda

**Day 1**

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

**9:00 a.m. – 10:30 a.m.** **Part A – Overview of the Regulations**

- Introductions
- Reasons for Change
- Structure of the Regulations
- Notified Bodies
- Transition Timelines
- Understanding Standards and Harmonization
- EU version of ISO 13485:2016 and ISO 14971:2007

**Part B – MDR Article 120 Transition**

- Status of the EU-MDR Implementation
- Article 120 Transitional Provisions
- Article 120
- ISO 13485:2016 & CEN/TR 17223:2018
- ISO 14971:2019
- Status of NBs
- Harmonized Standards & Common Specifications
- Status of Eudamed
- Manufacturer's Potential Hurdles
- Questions

**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 Operator

**10:30 a.m. – 10:45 a.m.** **Break**

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

- ISO 13485:2016 & CEN/TR 17223:2018
- QMS Requirements
- 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
- Description of Changes for ISO 14971:2019
- The Process Flow in ISO 14971:2019
- Annex I(3) The Risk Management System
- Annex I(4) Risk Control Measures
- Annex I(5) Use Error

**2:15 p.m. – 2:30 p.m.** **Break**

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

- Risk Management
- Benefit-Risk Determination (BRD)
- Clinical Evaluation (CE)
- Post-market Clinical Follow-up (PMCF)
- Post-Market Surveillance
- Post-market Surveillance Report (PMSR)

- Periodic Safety Update Report (PSUR)
- Summary of Safety and Clinical Performance (SSCP)
- Incident Reporting
- Exercise F1 – Elements of the PMSS

**5:00 p.m.** **And much more!**

**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
- Basic UDI-DI
- Application to Devices and Packaging
- UDI and the Declaration of Conformity
- The EU Database for UDI
- Application Dates
- ISO 13485:2016
- Exercise G1 – UDI

**Part H – Device Classification**

- Classification Rules
- Applying the Classification Rules
- Exercise H1 – Device Classification

**10:00 a.m. – 10:15 a.m.** **Break**

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

- MDR Conformity Assessment Methods
- IVDR Conformity Assessment Methods
- 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 the Harmonized Standards
- Role of the Common Specifications
- Exercise J1 – General Safety and Performance Requirements

**2:15 p.m. – 2:30 p.m.** **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 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
- MDR Conformity Assessment
- IVDR Conformity Assessment
- Declaration of Conformity
- The EU Database
- Exercise L1 – Declaration of Conformity

**Summary, Conclusions, and Lessons Learned**

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

**Day 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 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**