

# EU-MEDICAL DEVICE REGULATION COMPLIANCE WORKSHOPS

MARCH 17-20, 2020  
DOUBLETREE BY HILTON HOTEL  
PHILADELPHIA CENTER CITY  
PHILADELPHIA, PA

INTERACTIVE WORKSHOP TRAINING FROM FdANEWS AND OMBU ENTERPRISES

## 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**

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### 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**

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### 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**