WCG FDANEWS PRESENTS THE

Multi-attendee discounts are available!

# 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 MDRIVDR
- 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**


# Agenda

## 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

**Day 1**

**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**