WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

The European Medical Device New Regulation 2017/745

Product ID: N180
Duration: 285 mins
SME: Mona Magnuson
First Released On: 01/16/2019

Course Description:
This 11-part course covers all aspects of the EU MDR 2017/745 in a comprehensive manner, providing practical guidance and identifying major differences with the current MDD/AIMD on the following topics:

- Basics and background of EU medical device regulations, including roles and responsibilities of key players (such as notified bodies and competent authorities)
- Structure of the EU MDR and other related regulations
- Definition and classification of medical devices (MEDDEV 2.4/1 Rev 9)
- Conformity assessment procedures and routes
- Quality system requirements
- General safety and performance requirements in Annex I and the use of harmonized standards
- Clinical evaluations, including references to MEDDEV 2.7.1/Rev 4 and clinical investigations
- Technical file and design dossier requirements
- Medical device vigilance
- Designation and oversight of notified bodies by the Medical Device Coordination Group (to be released in Q1 2019)
- UDI-DI requirements in Annex VI (to be released in Q1 2019)

Watch the Course Trailer:

Learning Objectives:
Upon completion of this course, learners will have acquired:

- Comprehension of the European regulatory model according to MDR 2017/745 and how to apply its key principles
- Knowledge of how to use relevant product-specific directives in conjunction with MDR
- Understanding of combination product requirements and how to perform directive-based interactions with medicinal products, animal tissue origin products, and others, as per the demarcation guidance
- Decision-making skills regarding what clinical data is needed for CE-marking and how to safely keep marketed products in compliance with MDR post-market surveillance requirements and related guidance documents
- Application of the requirements for technical files and design dossiers
- Insight into how notified bodies are designated and how they interact with MDCG and expert groups
- Implementation of the UDI-DI requirements outlined in Annex VI

Who Should Enroll:
Regulatory Affairs Associates and Managers; Quality Assurance Associates, Managers, and Engineers; Manufacturing Engineers; Supply and Purchasing Managers; Design and Validation Engineers; Notified Body, Internal, and Lead Auditors; Regulators; Electrical Safety Engineers; Pre-Clinical Study Managers; Clinical Affairs Directors; Clinical Project Managers; Export Managers; and R&D Engineers are welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
Knowledge of basic regulatory principles outlined in the GHTF documents is encouraged. The course does, however, cover MDR basic principles.

Price:

Premium: €631.00.- **Basic:** €841.00.-

Course Format:
All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete

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each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: http://www.adobe.com/products/flashplayer).

Premium Account Holders:
Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.