WMDO
WORLD MEDICAL DEVICE ORGANIZATION

WMDO SA
Route de Denges 28C
1027 Lonay
Switzerland
Tel. +41 21 349 96 36
Fax +41 21 349 96 37
contact@wmdo.org

WMDO USA
3565 IDS Center 80
South 8th Street, Minneapolis
MN 55402,USA

Course Title:

The European Union Regulatory System for Medical Devices

Product ID: 145
Duration: 175 mins
SME: Danielle Giroud

Course Description:
This course provides a clear and comprehensive understanding of the EU regulatory model. It focuses on key principles essential to both ensuring the safety of medical devices and bringing them to market efficiently.
This course covers the following topics:
- EU directives
- Key players, definitions, and classifications within the EU Regulatory System
- Conformity assessment procedures
- Quality system requirements and evaluations using ISO 14155 (including directives 93/42, 90/385, and subsequent updates)
- Related product-specific directives
- Combination product requirements
- Interactions with directives for pharmaceutical products
- Tissue engineering products
- Additional products taken from the demarcation guide

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Comprehend and define the working fundamentals of the European Regulatory System for Medical Devices, which includes:
- Basics of EU medical device directives, including roles and responsibilities of key players such as notified bodies and competent authorities
- Structure of the MDD and other directives
- Definitions and classifications of medical devices
- Conformity assessment procedures
- Quality system requirements
- Essential requirements found in Annex 1 and the use of harmonized standards
- Clinical data and evaluations using ISO 14155
- Technical File and Design Dossier requirements
- Medical device vigilance
- Demarcation with other directives
- Role of notified bodies (MEDDEV 2.7.1 Rev 3, NBOG requirements)

Who Should Enroll:
Regulatory Affairs Associate, Regulatory Affairs Manager, Quality Assurance Associate, Quality Assurance Manager, Quality Assurance Engineer, Manufacturing Engineer, Supply Manager, Purchasing Manager, Design Engineer, Validation Engineer, Notified Body Auditor, Regulator, Electrical Safety Engineer, Internal Auditor, Lead Auditor, Pre-Clinical Study Manager, Clinical Affairs Director, Clinical Project Manager, Export Manager, and R&D Engineer are welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

Price:

Premium: €388.00.- **Basic:** €517.00.-

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

WMDO SA
Route de Denges 28C
1027 Lonay
Switzerland
Tel. +41 21 349 96 36
Fax +41 21 349 96 37
contact@wmdo.org

WMDO USA
3565 IDS Center 80
South 8th Street, Minneapolis
MN 55402,USA

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.