

Online Training for Medical Device Professionals

Course Title:

Implications of EN ISO 14971:2012

Product ID: N189

Duration: 28 mins

SME: Danielle Giroud

First Released On: 10/11/2013

Course Description:

This course focuses on Annexes Z of ISO 14971, which document the 2012 version of the standard's changes in approach on how to apply the standard under the European Regulatory System. The course provides a general overview of the changes and outlines what they mean for both existing and future medical devices.

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, learners will be able to:

- Apply the approach explained in Annexes Z of ISO 14971: 2012 to current products and those within the same pipeline

Who Should Enroll:

Clinical affairs directors, clinical compliance, quality, and safety managers, clinical project managers, regulatory affairs coordinators and managers, quality assurance engineers and managers, manufacturing and R&D engineers, regulators, validation, design, and electrical safety engineers, internal, lead, and notified body auditors, CEOs, COOs, pre-clinical study managers, quality management, regulatory, and clinical research professionals, and professionals involved in the design, manufacturing, and validation of medical devices are all encouraged to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

Learners should have a basic knowledge of risk management.

The following courses are required:

- ISO 14971: 2007 Review (ID 78)
- Preparing Risk Management Files & Which Techniques Apply (ID 83)
- Integrating Risk Management into Your Quality Management System (ID 94)

Peer Reviewer:

Danielle Giroud

Peer Reviewer Date

Price:

Premium: €64.00.- **Basic:** €85.00.-

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 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.



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

Online Training for Medical Device Professionals
