

Online Training for Medical Device Professionals

Course Title:

Directive 93/42/EEC and update 2007/47/EC: A review for clinical professionals (rev 1.2)

Product ID: 60

Level: CMDP

Duration: 60 mins

SME: Danielle Giroud

First Released On: 10/19/2009

Course Description:

This course lays out the principal sections of MDD 93/42/EEC and its subsequent updates (2007/47/EC) concerning clinical professionals. It offers practical guidance on how to safely and confidently implement MDD requirements to all clinical processes and also includes a section on optimizing cross-functional collaboration between regulatory, quality assurance, and other fields within an organization.

This course details the Directive's clinical evaluation requirements and highlights the parts that specifically pertain to clinical professionals, such as Article 15 and Annexes 1, 8, and 10.

Watch the Course Trailer:

Learning Objectives:

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

- Recognize the Directive's requirements and definitions of clinical data
- Interpret the requirements concerning clinical investigations
- Comprehend and define the Directive's structure and overall regulatory objectives
- Identify the details that clinical professionals must know about Directive 93/42/EEC and its subsequent updates through 2007/47/EC

Who Should Enroll:

Clinical research associate (monitors), clinical study coordinators, clinical trial assistants, clinical project and compliance managers, clinical quality managers and associates, clinical investigators, clinical affairs directors, and clinical professionals wanting to learn more about the MDD 93/42/EEC and 2007/47/EC update are all welcome to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

The following course is required:

- The European Union Regulatory System for Medical Devices (ID 145)

Price:

Premium: €137.00.- **Basic:** €183.00.-

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



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updates for 1 full year.