

## Online Training for Medical Device Professionals

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### Course Title:

## ISO 13485:2016 - Medical Devices Quality Management Systems Requirements for Regulatory Purposes

Product ID: 196

Duration: 183 mins

SME: Maria Cianciotto

First Released On: 04/04/2016

Course Updated On: 04/04/2016

### Course Description:

This course introduces the updated 2016 version of the ISO 13485: "Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes," the international reference standard for quality systems for medical device manufacturers in regulatory systems across the globe.

This course covers the following topics:

- Basic principles of ISO 13485:2016
- A step-by-step guide of ISO 13485:2016 requirements
- Detailed explanations of each requirement and quality system links between the requirements

### Watch the Course Trailer:

### Learning Objectives:

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

- Build a strong foundation of the basic principles of ISO 13485:2016
- Participate in the process of implementing a quality system

### Who Should Enroll:

Quality management staff who are new to medical devices, regulatory staff seeking a refresher in quality system requirements, and management staff not directly in charge of compliance issues but wanting an overview are all encouraged to take this course. In addition, any staff member who has taken the ISO 13485:2003 course should take this updated version with all the new requirements that were included in the ISO 13485:2016 standard published March 1, 2016.

**Related Resources:** Yes

### Prerequisite Knowledge

The following material is required:

- Familiarity with other quality system standards or regulations, such as ISO 9001
- A copy of the ISO 13485:2016 standard

### Price:

**Premium:** €275.00.- **Basic:** €366.00.-

### 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.