

## Online Training for Medical Device Professionals

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### Course Title:

## ISO 14155:2019 - Scope

Product ID: N158

Duration: 40 mins

SME: Danielle Giroud

First Released On: 06/06/2019

### Course Description:

This course covers the background of the ISO 14155 standard and how it applies in conjunction with international regulatory documents. It outlines the scope of the ISO 14155 and how its requirements apply to the different types of medical clinical investigations.

The course provides a summary of GCP principles as outlined in the standard and provides a list of documents referenced in the standard.

This course also explores other mandatory standards needed to conduct clinical investigations such as ISO 14971.

## Watch the Course Trailer:

### Learning Objectives:

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

- Know when to apply ISO 14155 requirements
- Use ISO 14155 in conjunction with other international regulatory documents
- Decide whether or not to exempt certain requirements from ISO 14155 for post-market clinical investigations
- Use other standard requirements and guidance documents together with ISO 14155
- Understand the general GCP requirements as further elaborated throughout the ISO 14155.

### Who Should Enroll:

Clinical research associates (monitors), clinical study coordinators, assistant senior clinical research associates, clinical project and data managers, data entry personnel, ethics committee and institutional review board members, regulators, and notified body personnel involved in auditing clinical evaluations are all welcome to participate in this course.

### Related Resources: Yes

### Prerequisite Knowledge

The following courses are required:

For Investigation site personnel

- Medical Device GCP for Investigators (series; IDs 193, 200, 212, 202, 204, 206)

For Sponsor personnel

- History of Good Clinical Practice (GCP) (ID 41)
- Introduction to Good Clinical Practice (ID 42)
- Introduction to Medical Device and Clinical Investigation Planning (ID 43)

### Price:

**Premium:** €91.00.- **Basic:** €122.00.-

### 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>).



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**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.