



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Clinical Audits: Sponsor/Third Party Audits of Clinical Investigation sites

Product ID: 218

Level: CMDP

Duration: 66 mins

SME: Alodia Ruiz

First Released On: 08/02/2011

Course Description:

This course reviews the steps to prepare, conduct, and close out effective investigation site audits.

The content of this course is based on:

- ISO 14155: 2011: Good Clinical Practice for Medical Devices
- ICH-E6: Good Clinical Practice for Pharmaceutical Products
- 21CFR 50 Protection of Human Subjects
- 21CFR 54 Financial Disclosure by Clinical Investigators
- 21CFR 56 Institutional Review Boards
- 21CFR 812 Investigational Device Exemptions
- 93/43/EEC Medical Device Directive
- 90/385/EEC Active Implantable Medical Device Directive

Watch the Course Trailer:

Learning Objectives:

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

- Determine when an investigation site audit is required
- Prepare an investigation site audit
- Identify the relevant areas of facility, staff, clinical investigation conduct, and documentation to include in the audit
- Write effective audit reports
- Establish corrective and preventive actions where needed
- Conduct closing activities, including close-out meetings

Who Should Enroll:

Clinical project managers, clinical research auditors, and quality assurance and regulatory managers interested in establishing an auditing system for clinical investigations or in preparing clinical investigation audits are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following material is required:

- Extensive experience with medical device good clinical practice activities
- A minimum of five years (preferably) in an active CRA or project management position in the medical device field
- Clinical Audits: Fundamentals of Auditing Medical Device Clinical Evaluations (ID 217)

Price:

Premium: €151.00.- **Basic:** €201.00.-

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



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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.