WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Suite Title:

Auditing Medical Device Clinical Investigations

Suite ID: 216
Duration: 160 mins
SME: Alodia Ruiz
First Released On: 10/20/2011

Suite Description:
Course Description
Bringing a medical device to the global market requires more and more clinical data that need to be generated in strict compliance with the applicable regulations. The industry must be prepared for answering critical questions from the regulators and medical community both prior to or after placing a device on the market.

Whether required by regulators or not, audits will allow the sponsor to gain additional confidence in the data that have been generated during clinical investigations and provide essential preparation of both the sponsor team and investigators prior to a regulatory inspection, which are bound to occur more and more. Auditing requires specific techniques and knowledge of the area that is subject to the audit.

The 3 course suite “Auditing Medical Device Clinical Investigations” provides a comprehensive overview that will prepare professionals to effectively conduct a clinical investigation audit which needs to not only reflect an accurate picture of the status of the clinical data, but also contribute significantly to improving the overall clinical investigation system both at the sponsor, CRO and investigation site.

“Auditing Medical Device Clinical Investigations” 3 course suite:
Course 1: Fundamentals of Auditing Medical Device Clinical Investigations
Course 2: Sponsor/Third Party Audits of Clinical Investigation Sites
Course 3: Auditing the Clinical Research Organization and the Sponsor

This Suite Includes:
Course1: Clinical Audits: Fundamentals of Auditing Medical Device Clinical Investigations
Course2: Clinical Audits: Sponsor/Third Party Audits of Clinical Investigation sites
Course3: Clinical Audits: Auditing the Clinical Research Organisation and the Sponsor

Learning Objectives:
Upon completion of this course, trainees will be able to correctly and successfully:

·Identify when a clinical investigation of a medical device should be audited

·Identify the areas/departments/teams/facilities that should be covered by the clinical audit program

·Comprehend the basic elements of an effective audit from planning to closure

·Recognize the applicable regulatory standards and decide which ones to apply for the audit plan

·Distinguish the reasons that require an Investigation Site and CRO audit

·Illustrate how to prepare for conducting an Investigation Site and CRO audit

·Characterize the relevant areas of the facility, staff, clinical investigation conduct and documentation that are to be included in the audit

·Write effective audit reports

·Identify corrective and preventive actions where needed

·Conduct closing activities, including a closing meeting

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Related Resources: Yes

Who Should Enroll:
Clinical project managers, clinical research auditors, quality assurance managers and regulatory managers, interested in establishing a quality audit system for clinical investigations and/or prepare for clinical investigation audits.

Prerequsite Knowledge
Extensive experience with medical device GCP activities, preferably a minimum of 10 years of active CRA position in the medical device area or project manager position in the medical device area. Professionals that come from the pharmaceutical industry should ensure they master perfectly the regulatory requirements of medical devices as outlined in the course description.
The three courses are tied together in a logical learning process. We strongly recommend learners take the courses in the order starting with Course 1.

Price:

Premium: €336.00.- **Basic:** €449.00.-

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.