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Course Title:

Preparing Successfully for a US FDA Medical Device Inspection

Product ID: 215
Duration: 109 mins
SME: Maria E. Donawa
First Released On: 07/25/2011

Course Description:
This course reviews the necessary preparations for a successful QSR inspection with the US FDA.
For US companies, effective preparation can lead to shorter inspections and fewer disruptions in company operations. Ineffective preparation can result in multiple quality system regulation (QSR) problems.
For non-US companies, effective preparation can lead to fewer nonconformities or none at all. Ineffective preparation can lead to a US FDA warning letter or even auto-detention (when a product is stopped at the US entry port and is not allowed to be shipped to its destination).
Therefore, it is more important now than ever for medical device manufacturers to effectively prepare for US FDA medical device inspections.

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Comprehend the basic regulatory framework for inspections
- Identify which US FDA regulations and requirements are inspected and which are not limited to QSRs but also include other regulations
- Conduct effective internal audits (this is the single most important task for avoiding problems during US FDA inspections)
- Demonstrate US FDA quality system inspection techniques
- Plan the appropriate actions before, during, and after inspection

Who Should Enroll:
Quality assurance personnel who ensure compliance with US quality system requirements, senior executive management officials who are notified of inspections by the FDA, department heads (warehouse, production, quality control, purchasing, and others) who respond to FDA questions during FDA inspections, medical device personnel who operate during FDA inspections, and human resource personnel responsible for training and personnel qualification documentation are all encouraged to take this course.

Related Resources: Yes

Prerequsite Knowledge
The following course is required:
- Overview of US FDA Quality System Regulation (ID 118)

Price:

Premium: €249.00.- **Basic:** €332.00.-

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.