WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

Internal Auditor Training for Medical Device Manufacturers

Product ID: 209
Duration: 214 mins
SME: Carole Stamp
First Released On: 02/17/2014

Course Description:
This course introduces the theoretical segment of WMDO's internal audit training program and describes how to develop an effective and useful Internal Audit Program (IAP).
The course demonstrates how to perform internal audits for medical device manufacturers or third party quality systems, including related processes. It also takes into account the requirements of ISO 13485, European Medical Device Directives, and the affiliated sections 21CFR820.
This course covers the following topics:
- Definition and background of internal auditing
- Regulatory and statutory frameworks of internal auditing
- The internal auditing process and its function as part of a management system
- A detailed outline of audit planning, preparation, conduct, and follow-up
- Logical links within the quality system according to the GHTF subsystem structure
- An outline of instructions and requirements on how to become an internal auditor, including training and soft skill development
- Practical instructions for maintaining excellence and efficiency throughout activities involving internal auditing

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Comprehend and apply the appropriate statutory and regulatory requirements in the setup, management, and execution of internal auditing systems
- Prepare and implement an efficient IAP
- Perform internal audits within the framework of an organization's internal auditor qualification program

Who Should Enroll:
Professionals involved in internal auditing as quality managers, quality assurance assistants, manufacturing engineers, supply chain managers, and purchasing officers, managers and officers involved in complaint handling and CAPA, and medical device professionals in charge of ensuring compliance and in need of learning all aspects of internal auditing and how it contributes to overall compliance are all welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
A minimum of five years of experience in medical device manufacturing, a basic to advanced knowledge of the regulatory environment for medical devices, and advanced knowledge in quality system environments for medical devices are all required for this course.

Price:

Premium: €489.00.- **Basic:** €652.00.-

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.