

Online Training for Medical Device Professionals

Course Title:

Supplier Qualification

Product ID: N145

Duration: 47 mins

SME: Philippe Etter

Course Description:

This course proposes methods for managing and controlling suppliers based on the requirements of the MDD, AIMDD, IVDD, ISO 13485, 21 CFR 820 and guidance from the GHTF (IMDRF). The relevant definitions are clarified while placing the importance of supplier qualification within the regulatory framework, and going further into detail about the identification of critical suppliers, the development of contractual aspects, the control of supplier activities and the handling of non-conformities, before concluding with a list of critical inputs for supplier audit plans.

Learning Objectives:

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

- Set up a supplier qualification system
- Implement methods for effective supplier control within the quality system
- Develop critical tools for supplier audits.

Who Should Enroll:

Supply chain and purchasing managers, quality managers, regulatory affairs managers, production managers, design and development managers, and clinical quality managers involved in defining, selecting and qualifying and overseeing suppliers.

Related Resources: Yes

Prerequisite Knowledge

In order to fully benefit from this course, we recommend familiarity with "SG3/N17:2008 Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers" and knowledge of the subjects discussed in the following WMDO courses:

- ISO 13485: Foundation and Basic Principles (ID 196)
- Overview of US FDA Quality System Regulation (ID 118)
- Risk Management for Medical Devices in the EU and US (ID 77)
- The Design, Development and Industrialization of Medical Devices (ID 183)
- For clinical professionals, understanding resource management as discussed in clinical project manager (ID 100) is a critical combination to improve skills

Peer Reviewer:

Philippe Etter

Peer Reviewer Date

Price:

Premium: €141.00.- **Basic:** €188.00.-

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.