

Online Training for Medical Device Professionals

Course Title:

Preparing Risk Management File & Which Techniques Apply

Product ID: 83

Duration: 24 mins

SME: Bert Degens

First Released On: 09/02/2010

Course Description:

This course addresses:

- Basic content of the risk management file and how to prepare it.
- Which risk management techniques to use and when to use which technique.

Note that the techniques presented are just a selection of the techniques you may use. This selection contains a number of commonly used techniques.

Learning Objectives:

After completion of this course the learner will be able to successfully understand:

- which elements to include in the risk management file
- which risk management techniques to use and when
- how to use specific risk management techniques.

Who Should Enroll:

- Clinical Professional involved in clinical strategic activities of the medical device life cycle.
- Director clinical investigations
- Regulatory Affairs Coordinator
- Quality Engineer
- Regulatory Affairs Specialist
- Regulatory Affairs Manager
- Quality Assurance Manager
- Product development managers and project leaders
- Design Engineer
- Manufacturing Engineers

Related Resources: Yes

Prerequisite Knowledge

- WMDO course: ISO 14971: 2007 Review (ID 78)
- ISO 14971: 2007 Medical devices –Application of risk management to medical devices

Price:

Premium: €55.00.- **Basic:** €73.00.-

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



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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.