



Medical Devices: Risk Management

REF. GR02 - INTRA/INTER

MANAGING RISKS

COURSE DESCRIPTION

This training will allow you to update or acquire practical knowledge to identify and manage risks related to the use of medical devices in accordance with the recommendations set out in ISO 14971:2019

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the terms and vocabulary
- Identify what is new in the 2019 version compared to the 2012 version
- Become familiar with the risk management methodology described in the standard
- Raise the awareness of all parties involved to ensure effective risk management

TARGET TRAINEES

- MD manufacturers, and more particularly:
- Quality/Regulatory Affairs Manager
 - R&D team
 - Manufacturing Manager
 - Product Leader
 - Sales Representative
 - Technical Director

PREREQUISITES

- General knowledge of the regulatory framework for MDs and/or IVDMDs
- Some knowledge of risk management (EN ISO 14971 version 2012)
- Some knowledge of CE marking requirements in terms of Technical Documentation

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Tailored examples - group exercises
- Reference to Regulation (UE) 2017/745 and EN ISO 14971
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Presentation of the course objectives and method to ensure that they are achieved

1. Regulatory requirements: a review
2. ISO 14971:2012 compared to ISO 14971:2019
 - a. General risk management principles according to EN ISO 14971
 - b. Scope
 - c. Definitions
 - d. Risk management process
 - e. Personnel skills
 - f. Risk management plan
 - g. Risk analysis - Evaluation - Control
 - h. Overall residual risk
 - i. "Production and Post-Production" activities
3. Summary/Q&A
4. Course evaluation and conclusion

Virtual classroom training: the course can be divided into two half-days

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program (*success criteria* $\geq 75\%$).



Do you have a question? Contact us!

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