BSI Training Academy
Implementing ISO 14971:2012

Level 1 C 2

The course was developed to provide participants with the knowledge and techniques to implement a Risk Management System associated with Medical Devices in accordance with the requirements of ISO 14971: 2012, verifying their impact on decision-making processes.

The training session provides the skills necessary to develop and implement a risk management system within the quality management system of medical devices ISO 13485: 2012.

By participating in this course, you will learn how the application of ISO 14971 gives presumption of conformity with the Essential Requirements of Directive 93/42 / EEC and subsequent additions / modifications, bringing benefits for your business at the same time.

- Length: **2 days**
- Led by a **BSI expert tutor**
- **Teaching material** are for personal use

This is the course for you if:

- You have a basic understanding of quality management systems for Medical Devices companies and a general familiarity with Medical Devices
- You need to implement or manage an ISO 14971: 2012 management system
- You are part of a team involved or responsible for ISO 14971: 2012
- You need to perform a gap assessment of Risk Management System you have in place

How will I benefit?

- Understand the role of risk management in Medical Devices companies
- Learn the structure and purpose of ISO 14971 and the areas of application of the standard within the organization
- Describe the implementation process in the organization
- Provide a plan for implementing risk management
- Prepare a risk analysis model appropriate to your organizational structure and to the type of medical devices you produce

Certificate

Upon successful completion of your course, you'll receive an **internationally recognized BSI certificate.**

bsi.

...making excellence a habit.™

Your training journey

We understand the challenges of meeting regulatory requirements and maintaining quality management systems. We understand because it's what we do, every day of every week; for you, for your customers, and for your bottom line.

We have dynamic course owners around the world, allowing delivery of training in many local languages. Our course owners are subject matter experts and use practical examples from their experiences to bring each lesson to life.

By working closely with you and fully understanding your requirements, we can create a training solution that meets the needs of your organization, whether you're training on existing standards, regulatory approval, or business improvement. We're one of few certification bodies offering diverse medical device training portfolios consisting of specialized training classes.

In-company

You can have this course delivered to your team on-site so it can be adapted to your learning needs.

Hebrew

All our training courses are delivered in Hebrew.
Training material is in English.

Related courses

Want to learn more?
Discover all training courses on our website.
www.bsigroup.com/en-IL

During the course, you will receive a copy of ISO 14971:2012 **only for consultation**.

Book your place on www.bsigroup.com/en-IL

Agenda

Day 1

- Introduction
- Participant introductions
- Boundaries: Conflict of Interest and Expertise
- Overview of course structure and learning objectives
- Learning Objectives
- Intended Audience
- Risk Management – Terms and definitions
- Regulatory Requirements: MDD, AIMDD, IVDD
- Risk Management and the QMS: Links between EN ISO 13485 and EN ISO 14971
- Requirements of ISO 14971:2012
- Regulatory significance of risk management
- Risk Management Process - Overview

Day 2

- How to do risk management: ISO 14971
- Risk management process: step by step
- Summary of risk analysis methods from Annex G
- Risk Analysis and Risk Evaluation
- Risk Control and Evaluation of Overall Residual Risk
- Risk Management Report
- Production and Post-Production Information
- Medical device vigilance
- Example of a Technical file
- Summary and Course Review
- Final Questions

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