BSI/UK/1682/TR/1219/EN/GRP

ISO 14971:2019 Risk Management for Medical Devices: Requirements

Training course

STAGE 1 2 3

Essential information about the course

This course is designed to provide you with an understanding of ISO 14971:2019 and the impact it has on the design, development, manufacturing and lifecycle of medical devices.

It will also provide medical device manufacturers with knowledge of how ISO 14971:2019 links with the ISO 13485:2016 standard and the MDR 2017/745.

Practical activities throughout the day will give you the opportunity to apply your skills, implementing risk management activities so that these can be embedded within the organization on completion of the course.

Our course agenda

- Introductions, overview of learning objectives and course structure
- Terms and definitions
- Risk management and regulatory requirements
- Risk management and the Quality Management System (QMS)
- Risk management and the Medical Device Regulation (MDR)/In Vitro Diagnostic Regulation (IVDR)
- ISO 14971:2019: Application of risk management to medical devices
  - General structure
  - Annexes and ISO/TR 24971
  - Scope
  - General requirements for risk management systems
  - Risk management process
  - Risk analysis and risk evaluation
  - Risk control and evaluation of overall residual risk
  - Risk management review
  - Production and post-production activities
- Course summary and review

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

Make sure the course is right for you

Who is this course for?

This course is ideal for you if you're in a QA/Regulatory/Engineering/Manufacturing role involved in medical device design, development and manufacturing.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Define risk management terminology • Explain how risk management relates to the product lifecycle • Outline the stages of the risk management process • Define the key deliverables of the risk management process • Apply risk management principles within your organization • Identify the links between ISO 14971:2019, ISO 13485:2016, MDR 2017/745 and the IVDR 2017/746	This course will help you to: • Identify the key requirements of ISO 14971:2019 • Interpret and communicate the key requirements and expectations of ISO 14971:2019 to your organization • Gain knowledge of how ISO 14971:2019 links to ISO 13485 and the regulations; MDR 2017/745 and IVDR 2017/746 • Apply the fundamental risk management activities for medical devices within your organization

Prerequisites - you are expected to have the following prior knowledge:

You should have experience with, or basic knowledge of, quality management systems for the medical device industry. We recommend you have a basic awareness of medical device development, quality assurance and ISO 13485:2016.

Why invest in training from BSI?

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire the skills that will continue to be of use beyond the course.

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered at your site could be a convenient and cost effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

Next steps with the BSI Academy

Want to learn more? You may be interested in:

Requirements of the Medical Device Regulation (MDR) Training Course, Implementation of the Medical Device Regulation (MDR) for CE Marking Training Course and Medical Device Directive (MDD) to Medical Device Regulation (MDR) Transition Training Course

bsi.

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