Medical Devices | Requirements of ISO 14971:2019

International Training

Number of days 1

Key information about the course

This one-day intensive course helps medical device manufacturers understand the benefits and impact of ISO 14971:2019. It's ideal for anyone in a quality assurance, regulatory, engineering or manufacturing role. We also recommend a basic knowledge of medical device development, quality assurance and ISO 13485:2016.

Through a mix of practical activities, classroom learning and group discussion, you will learn risk management terminology and the stages of the risk management process. You'll also be able to identify links between ISO 149721:2019, ISO 13485:2016, MDR 2017/745 and IVDR 2017/746.

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Agenda

- Benefits to you, welcome and introductions
- Course aims, objectives and structure
- Risk management: 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 final questions

Once you have completed the training, you will receive a BSI training certificate.

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Pedagogical objectives

- Understand, interpret and explain key requirements of ISO 14971:2019
- In-depth knowledge of how ISO 14971:2019 links to ISO 13485 and the regulations; MDR 2017/745 and IVDR 2017/746
- Carry out risk management for medical devices within your organization
- Gain an internationally recognized BSI training certificate from your partner in learning

Skills to be acquired

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 IVDR 2017/746

Targeted audience

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

Pedagogical, technical and framing means

Course materials including:

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed

Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included ?

- Course materials, provided electronically
- Letter of attestation
- Official certificate

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Prerequisites: 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.

These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

Each delegate receives a training convention after the enrolment.

Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrolment. For the in-house sessions, the deadline would be of two weeks prior to the start of the course.

Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

You can contact us on **training.france@bsigroup.com** or **01 89 79 00 40**

Contact us:

Phone: **+33 (0)1 89 79 00 40**

Email : **training.france@bsigroup.com**

Website : **bsigroup.fr/nos-services-formation**