IPI Academy

MANAGEMENT forum

Presented by
Management Forum

An introduction to Risk Management ISO 14971:2019

11 March 2025
+ 11 July 2025, 11 November 2025

Dive into the core principles of risk management using ISO14971:2019. Learn to assess, analyse, and mitigate risks effectively, ensuring compliance with international standards and enhancing decision-making in various industries.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Course overview

Understand the use of risk management in the medical device industry and how to review and construct risk management documentation to meet both quality and regulatory requirements.

The global regulation of medical devices is increasingly taking the risk based approach, whether that be when building a quality management system or building technical documentation for registrational submissions. ISO 14971:2019 is the international standard which supports the assessment of risks and construction of compliant risk management documentation to support these areas.

Linda Garrod of IVDeology has constructed the Introduction to Risk Management ISO14971 course to provide participants with foundational knowledge and practical skills related to the application of ISO14971:2019, an international standard for medical device risk management.

Key topics to be addressed:

- Overview of ISO14971:2019
- Risk management framework
- Risk management planning
- Risk analysis techniques
- Risk evaluation and acceptability
- Risk control measures
- Documentation and record keeping
- Risk management throughout the product lifecycle
- Compliance with regulatory requirements

Benefits of attending

- **Understand** the use of a risk-based approach and how ISO14971 supports this
- **Gain** a clear understanding of ISO14971 content and the use of key terminology
- **Review** each step In the risk management pathway to fully understand expected analysis and content
- **Be able to** identify the content expected for each type of risk management record
- **Understand** the use of well constructed risk management documentation to support post market device analysis and complaint handling

Who should attend?

Risk Management is a function that is best served by a cross department team to ensure all aspects have been identified and unacceptable risks mitigated. This course is particularly important for those working in the medical device industry, including:

- Medical device managers who must sign off on risk management files
- Regulatory professionals
- Quality specialists
- Research and development scientists
- Manufacturers
- Clinical support team members

Programme

What is risk management?

ISO 14971 standard and risk management planning

- Intro to the ISO standard and its significance in the medical device industry Basic Principles of Risk Management
- Understanding the fundamental principles of risk management as outlines in ISO
- Identification of key terms, definitions and concepts related to risk.
- Guidelines for developing a risk management plan in accordance with the ISO.
- Determining the scope of risk management activities and establishing objectives
- Clarification of roles and responsibilities within the context of risk management.
- Discussion on the involvement of different stakeholders in the risk management process.
- Guidance on how the ISO aligns with regulatory requirements for medical devices.
- Ensuring that risk management practices comply with applicable international regulations.

Risk assessment

- Criteria for evaluating and assessing risks.
- Determining acceptable risk levels and making risk acceptability decisions

Risk controls

- Strategies for implementing risk control measures to reduce or eliminate identified risks.
- Integration of risk controls into the design and development process

Benefit-risk analysis

- Intro to various risk analysis techniques prescribed by the ISO.
- Practical application of risk analysis methods, such as hazard analysis, fault tree analysis and failure mode and effects analysis

Risk management report & post-production activities

- Requirements for documenting and maintaining records of the risk management process.
- Best practices for creating comprehensive documentation that meets regulatory standards.
- Understanding the application of risk management at various stages of the medical device lifecycle
- Incorporating risk management into design, manufacturing, post-market surveillance and other phases

Presenter

Linda Garrod

Linda Garrod is a Quality Specialist at IVDeology Ltd, based in Kent, UK. She brings her exceptional quality experience from 20 years within the medical device industry, to support manufacturers in the creation and continual improvement of Quality Management Systems, compliant with the demands of ISO 13485, MDSAP and CE IVDR.

Course dates

11 March 2025	**Live online** 09:30-13:00 **UK (London)** (UTC+00) *Course code 15420*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 04 Feb**
11 July 2025	**Live online** 09:30-13:00 **UK (London)** (UTC+01) *Course code 15421*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 06 Jun**
11 November 2025	**Live online** 09:30-13:00 **UK (London)** (UTC+00) *Course code 15422*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 07 Oct**

How to book

Online:
ipi.academy/2780

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy