IPI Academy

MANAGEMENT forum



Presented by
Management Forum

An introduction to Risk Management ISO 14971:2019

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:
Bespoke training

CPD:
3 hours for your records (depending on your requirements)

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 developed the 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

Reviews

★★★★☆

I was hoping to achieve a better understanding of the risk management process so that I could effectively apply it within my role. Through this experience, I have gained greater insight into how risks are identified, assessed, and controlled. I feel confident that I have achieved this goal and can now incorporate risk management principles into my day-to-day work more effectively.

Jasmin Crouch
Bedfont Scientific Limited
Apr 27 2026

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:



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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.

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