SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











Medical Device Risk Management and ISO 14971:2019

LS033

Medical Device Risk Management and ISO 14971:2019

This two-day highly interactive training programme equips learners with a comprehensive understanding of ISO 14971:2019 and associated medical device regulations and practical skills for the application of risk management throughout the entire medical device lifecycle.

The course is delivered by our expert tutors and focuses on the implementation of Risk Management from the standpoint of; design, manufacture, distribution and use, right through to post-market feedback. The course covers compliance with the risk management requirements of EU MDR/IVDR and 21 CFR Part 820. The course involves practical exercises and group working with comprehensive feedback by the course tutor throughout.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 2 days
Public Virtual Training: €745
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
13 - 14 Apr 2027	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

This course blends theoretical knowledge with hands-on exercises to help learners implement risk management systems in line with ISO 14971:2019. It includes guidance on the application of related standards and practical tools for assessing and controlling risk.

Key topics include:

- The ISO 14971:2019 risk management process
- EN ISO 14971:2019 & A11:2021 (European Amendment Z Annexes) for MDR/IVDR compliance
- Application of ISO/TR 24971:2020 guidance on ISO 14971
- AFAP vs ALARP methodologies
- Hazard identification and risk characterisation
- Risk estimation – removing subjectivity
- Risk reduction and risk control
- Practical exercises in:
- Failure Modes, Effects and Criticality Analysis (FMECA)
- Preliminary Hazard Analysis (PHA)
- Hazard and Operability Studies (HAZOP)
- Fault Tree Analysis (FTA)
- Risk management for software (IEC 62304), usability (IEC 62366) and biocompatibility (ISO 10993)
- Determination of risk acceptability and application of the principle of State-of-the-Art
- Benefit-Risk analysis and disclosure of residual risk
- Collection, analysis and use of post-production data

The training involves practical exercises covering all relevant topics, with learners encouraged to work on examples from their own workplace as part of these practical exercises. If required, content may be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This course is ideal for anyone involved in the development, regulation, or quality assurance of medical devices. It supports those responsible for ensuring compliance with ISO 14971:2019 and, US or EU regulations.

This includes:

- Quality, Engineering, Technical and Production personnel
- R&D Managers and Engineers
- Regulatory Affairs and Clinical professionals
- Quality Auditors

Learners from across the medical device sector will benefit from practical examples and shared best practices.

A good standard of written and spoken English is important to engage effectively with this programme.

What will I learn?

On successful completion of this course, learners will be able to:

- Interpret and apply the ISO 14971:2019 standard within their organisation
- Identify and assess medical device hazards using a range of risk analysis tools
- Conduct risk analyses using FMECA, PHA, HAZOP and FTA methodologies.
- Document risk assessments in an audit-ready format
- Integrate risk management throughout the device lifecycle including post-production feedback
- Align risk management practices with the EU MDR, IVDR and supporting standards
- Communicate benefit-risk decisions and residual risk levels
- Apply risk management techniques to software, usability and biocompatibility standards

These outcomes ensure learners return with practical skills and knowledge necessary to meet regulatory requirements and auditors' expectations.

How will I be assessed?

To consolidate learning and reinforce key concepts, learners complete a **post-course** assessment.

The assessment;

- Checks understanding of the course content and practical scenarios
- Assesses practical understanding and application
- Is completed within one week of course completion

Successful learners will receive a Certificate of Achievement, in addition to their Certificate of Attendance

How do we train and support you?

Our training methodology is highly interactive, combining theory with application to build confidence and capability. Learners participate in structured discussions, case studies and applied activities throughout the programme.

Our support includes:

- Emphasis on hands-on application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation
- Pre-training consultation for In-Company courses to tailor content to organisational needs
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Flexible delivery options to suit different needs:
- Onsite or live virtual sessions tailored for teams
- Scheduled virtual public courses for individual learners
- Real-time support from expert Tutors

Class sizes are generally limited to 12-15 to support personalized learning and individual support.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- Pharmaceutical Quality Risk Management and ICH Q9
- Process and Equipment Validation
- Software Validation
- MDSAP Internal Quality Auditor
- Technical Writing Skills

Tutors



Gerry Burke
View Profile



John Lafferty
View Profile



Kevina O’Donoghue
View Profile

What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.

Click Here

SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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