SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Medical Device Risk Management and ISO 14971:2019

LS033

Medical Device Risk Management and ISO 14971:2019

Our fully interactive Risk Management course provides attendees with all the knowledge and skills they need to comply with ISO 14971:2019 and Medical Device Regulations, such as the EU MDR and IVDR. The course is fully tutor led and focuses on the practical implementation of Risk Management from the standpoint of; design, manufacture, distribution, and use, right through to post-market feedback. The course involves practical exercises and group working with comprehensive feedback by the course tutor throughout.

Duration & Price

Duration: 2 days
Public Virtual Training: €695
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
21 - 22 Oct 2025	Virtual	Book Date

In-Company Training

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

What's covered?

- ISO 14971: 2019 – the Risk Management process and analysis of the requirements of the standard.
- How to use EN ISO 14971:2019&A11:2021 (European Amendment Z Annexes) to comply with the EU MDR and IVDR.
- ISO TR 24971:2020 and its relationship to ISO 14971: 2019 and the MDR/IVDR.
- Understanding the difference between AFAP and ALARP.
- Characterizing Medical Devices.
- Identifying possible hazards.
- Estimating the associated risk – removing subjectivity.
- Risk Review and Risk Reduction.
- Risk Management Techniques.
- Practical Exercises on;
  ? Preliminary Hazard Analysis (PHA)
  ? FMECA
  ? HAZOP
  ? Fault Tree Analysis (FTA)
- Application of Risk Management to Software Risks.
- Using ISO 14971 to comply with the following standards;
  ? IEC 62304 (Software Development)
  ? IEC 62366 (Usability)
  ? ISO 10993 (Biocompatibility)
- The Practical Implementation of ISO 14971.
- Benefit-Risk analysis.
- Risk Management Reporting.
- Production and Post Production Information.
- How to Determine the State-of-the-Art.
- Disclosure of Residual Risk.
- How to apply Risk Management to the Product Lifecycle.
- End of Course Assessment

Who should participate?

Anyone involved in the implementation of Risk Management for medical devices or anyone wishing to get a good practical grounding in the application of ISO 14971:2019 will greatly benefit from attending this course. This may include;

- Quality / Engineering / Technical / Production personnel
- R&D Managers and Engineers
- Regulatory and Clinical personnel
- Quality Auditors

What will I learn?

Participants in this course will be able to apply Risk Management techniques in compliance with ISO 14971:2019 and regulations such as the EU MDR and IVDR. Participants will gain the knowledge and skills necessary to document risk assessment outcomes in an audit-ready fashion.

How do we train and support you?

In-House Courses

For In-House courses the tutor will contact you in advance to discuss the course programme in more detail in order to tailor it specifically for your organisation.

Course Manual

Delegates will receive a very comprehensive course manual.

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

QQI AWARD | IEMA APPROVED | CompEx Part of the JTL Group | FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE | CQI IRCA APPROVED TRAINING PARTNER | Chartered Institute of Environmental Health

SQT Training Ltd. | T: +353 61 339040 | E: info@sqt-training.com
W: sqt-training.com

Please follow us on social media for relevant news, events and updates