Risk Management (ISO 14971:2019)

This 2 day ISO 14971:2019 Risk Management course focuses on the application of various risk management tools to meet the requirements of the harmonised standard ISO 14971:2019.

ISO 13485:2016 requires medical device manufactures to implement a Quality Management System (QMS) that has a greater emphasis on risk.

This course for medical device manufactures has been developed to meet this more rigorous focus on risk management.

Our expert tutors will provide you with an in-depth understanding of ISO 14971:2019 and compare ISO 14971:2019 with the requirements of the EU Medical Device Regulation (MDR) 2017/745.

"Highly recommend this course to those in the medical device industry! Rod was competent in all aspects of the course, I now have a clear understanding of risk management application!"

Course Content

- Introduction to ISO 14971:2019
- Regulation and the Z-Annexes
- The procedure and plan
- FMEAs and fault trees
- Application to ISO 13485

The relationship with other standards:

- The 60601/61010 series
- Usability (EN 62366)
- Biocompatibility (ISO 10993)

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining a QMS.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

Find out more:
info@meddevsolutions.co.uk
www.meddevsolutions.co.uk/training

Available as
In-House • Public • Virtual

Bespoke
Our experts can customise this course purely for your business needs.