

ISO 14971 TRAINING COURSE

Learn the basics of ISO 14971 with working examples, team exercises and our industry knowledge and experience. You get an overview of risk management and assessment techniques, an understanding of how to apply the standard with a detailed insight and examples of risk analysis techniques.

DURATION: 1 Day

LANGUAGE: English or German

COURSE CONTENT:

- Overview of ISO 14971 and responsibilities
- Interdependencies and relationship with other standards
- Risk management planning
- The Risk Management File and responsibilities
- Risk assessment and analysis
- Risk analysis techniques (FMEA, FMECA, FTA, HAZOP and STAMP)
- Software risk management
- AI risk analysis
- Risk control techniques
- Residual risk assessment
- Risk/benefit analysis
- Cybersecurity
- Usability
- Post-market activities

TARGET AUDIENCE:

Regulatory, quality, design, development and manufacturing personnel

PREREQUISITES:

This course is suitable for delegates with no prior knowledge of ISO 14971 or can be customized for a more experienced audience.

FURTHER INFORMATION:

The training takes place either online or live. The duration of the training is 8 hours (including a 30 minute lunch break and 2 shorter breaks).

On request we grant a discount for group bookings.

ISO 14971

RISK MANAGEMENT FOR MEDICAL DEVICES



We are happy to work with your organization to develop **customized and cost-effective training** that meets your requirements in terms of date, timing and content.

PLEASE CONTACT US FOR YOUR BOOKING OR ENQUIRY:

info@lorit-consultancy.com
+43 676 338 8884 or
+44 7708 360023