

## 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:

- ISO 14971 overview
- Risk management planning
- The risk management file and responsibilities
- Interdependencies and relationship to other standards
- Risk assessing hazards and intended safety
- Risk analysis techniques (FMEA, FMECA, FTA, HAZOP and STAMP)
- Risk analysis for software, hardware and usability
- Risk control techniques
- Risk benefit analysis
- 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 customised 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.

**Your partner for functional safety  
and regulatory compliance.**

# ISO 14971

## RISK MANAGEMENT FOR MEDICAL DEVICES



**TRAINER:**  
Verena Wieser



**TRAINER:**  
Dijaz Maric

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

### PLEASE CONTACT US FOR YOUR BOOKING OR ENQUIRY:

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