

IEC 62304 INTRODUCTORY COURSE

Learn the basics of IEC 62304 with working examples, team exercises and our industry knowledge and experience. This course guides you through the full V model from requirements management to verification and validation, covering the risk management aspects defined by ISO 14971 and, for ME Equipment, the relationship to IEC 60601. It looks at tools and metrics, such as static analysis, cyclomatic complexity, control flow and configuration management, concluding with cybersecurity and IEC 82304 for standalone software.

DURATION: 1 Day

LANGUAGE: English or German

COURSE CONTENT:

- Overview of the V Model according to IEC 62304
- Requirements management
- Software development plan
- Change management according to IEC 62304
- Software development processes, including tools and methodologies
- Consideration of agile techniques
- Software integration and verification
- System integration – relationship to IEC 60601
- Configuration management
- Problem resolution
- Software maintenance
- Risk management
- IEC 82304
- Cybersecurity
- Artificial Intelligence in medical devices
- FDA documentation level
- Requirements for legacy software

TARGET AUDIENCE:

Product safety engineers, compliance engineers, product designers, regulatory approval staff, production support engineers, quality assurance staff.

PREREQUISITES:

This course is suitable for delegates with no prior knowledge of IEC 62304 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.**

IEC 62304 HEALTH SOFTWARE: Software Lifecycle Processes



TRAINER:
Verena Wieser

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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