

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 60601-1. 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

- › Risk management
- › Overview of the V Model according to IEC 62304
- › Requirements management
- › Software development plan
- › 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
- › Cybersecurity
- › IEC 82304

### Who Should Attend?

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.

### Training Schedule

Training typically runs for 8 hours each day, including a one hour lunch break and two shorter breaks in the morning and afternoon. This can be adapted as required to meet specific business requirements.

**Price:** £500 per person per day for a minimum of 2 and up to 7 participants. Thereafter a fixed rate will be charged for the training session.



### To Book:

For a convenient and cost effective training solution, we can work with your organisation to develop bespoke training to meet your exact requirements.

To book this course or discuss customised training, please email us at [info@lorit-consultancy.com](mailto:info@lorit-consultancy.com) or call us on +44 7708 360023.

[www.lorit-consultancy.com](http://www.lorit-consultancy.com)