

Lorit Consultancy offer consultancy and support in functional safety related projects in the Medical, Automotive and Aviation sectors. From the concept phase through to start of production, we can assist you with the complex exercise of international standards compliance.

With extensive experience in safety related products and industries, we assist you through our in-depth knowledge and understanding of the normative standards.

## Why choose Lorit Consultancy?

As a team of distributed consultants, we're well equipped to help you reach your goals. Here's why.

- › More than 40 years' experience in safety relevant design
- › Expertise in the sector specific normative standards
- › A network of associates across Europe
- › Detailed knowledge of safety relevant architecture
- › In-depth knowledge of hardware and software metrics in safety relevant design
- › Comprehensive knowledge of cybersecurity and usability
- › Bespoke safety and compliance training courses

### Functional Safety Consultancy Services

- › Requirement definition
- › System requirements analysis
- › Hardware reviews
- › Failure Modes and Effects Analysis (FMEA)
- › Failure Modes, Effects and Diagnostic Analysis (FMEDA)
- › Fault Tree Analysis (FTA)
- › Embedded software reviews, including architecture, tool selection and metric compliance
- › Documentation management
- › Configuration and change management
- › System and Software Process Improvement
- › Project management

### Regulatory Compliance Consultancy Services

- › Implementation of projects to standards for compliance with CE Marking and FDA audits
- › Safety
- › Risk Management
- › Usability / Human Factors
- › Software
- › Quality Management
- › Cybersecurity
- › EU Medical Device Directives

#### Medical

ISO 14971, IEC 60601-1, IEC 62304, IEC 62366-1, ISO 10993, AAMI TIR 57, CFR 21 Part 820, ISO 13485



#### Automotive

ISO 26262, IATF 16949, IEC 61508  
Automotive SPICE®, SAE J3061



#### Aviation

DO-178-C, DO-254



#### General

ISO 15504, ISO 9001

## Our Network of Associates

We collaborate with a network of business partners across Europe to further underpin the extensive knowledge and expertise we offer our clients.

### Automotive Sector Expertise



- Functional Safety Reviews
- ISO 26262
- IEC 61508
- Hardware Reviews & Metrics
- Automotive SPICE®
- J3061 Cybersecurity
- IATF 16949

#### Associate 1

- Safety Concept Generation
- Cybersecurity Assessments
- Systems Architecture
- ISO 26262
- ISO 15504 & Automotive SPICE®
- ECQA Certified Training

#### Associate 2

- Software Design
- Software Review & Support
- Software Architecture
- Software Integration
- Software Verification & QA

### Medical Sector Expertise



- Functional Safety Reviews
- IEC 60601-1 Safety
- ISO 14971 Risk Management
- IEC 62304 Software
- IEC 62366-1 Usability
- AAMI TIR57 Cybersecurity
- ISO 13485 & 21 CFR 820

#### Associate 3

- Project Management
- Product Design
- Hardware Design & Development
- Prototyping
- Hardware Verification
- Computational Analysis
- Manufacturing Strategy

#### Associate 2

- Software Design
- Software Review & Support
- Software Architecture
- Software Integration
- Software Verification & QA

## Training

We offer bespoke training in the following areas:

- › Medical Functional Safety
- › Medical Device Regulatory Compliance
- › Automotive Functional Safety
- › Safety Relevant Architecture
- › System and Software Process Improvement

We can also adapt and tailor training packages to an organisation's specific needs.



## Want to know more?

For more information about how Lorit Consultancy can help your business with the functional safety and compliance challenge, contact us and let us show you how we can ensure you meet appropriate safety and quality requirements on every project.

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