

# Introducing your new functional safety and regulatory compliance partner - **Lorit Consultancy**

## **The compliance challenge facing you**

Medical device manufacturers face major challenges in bringing devices to market. They must both identify and mitigate safety risks and ensure that each device complies with a host of safety requirements laid out in standards including IEC 60601, ISO 14971, IEC 62366 and IEC 62304.

This challenge will only get harder as planned regulatory changes for the medical device sector from Europe and international standardisation bodies come into force in the near future, creating further time consuming and complex obligations for more and more companies.

## **Why you need to prioritise functional safety**

Functional safety focuses on the ability of a product to respond correctly to inputs and function safely, reliably and consistently every time. Covering the hardware, software and user interface, it employs design techniques such as self-testing, redundancy and diversity and uses testing to identify potential problems, whether random or systematic. Formal methods can provide proof of safety. Risk analysis identifies unacceptable risks, which must then be mitigated.

In a sector where even a single functional failure can both cause serious harm or worse and produce enormous potential legal liabilities for the manufacturer, it's vital to minimise risk to acceptable levels. Yet with a huge range of relevant standards to master and regulatory change on the horizon, this isn't something to leave to non-specialist in-house risk and quality personnel.

A functional safety expert can provide you with vital help in many ways. They can offer:

- ▶ Guidance through the standards maze, highlighting geographical variations
- ▶ Performance of functional safety assessments
- ▶ Provision of requirements definition and system requirements analysis
- ▶ Performance of:
  - *Hardware reviews*
  - *Failure Modes and Effects Analysis (FMEA)*
  - *Fault Tree Analysis (FTA)*
  - *Embedded software reviews, including architecture, tool selection and metric compliance*
- ▶ Execution of:
  - *Documentation management*
  - *Configuration and change management*
  - *Project management*
- ▶ Delivery of training programmes for your staff.



## Why you should work with Lorit Consultancy

By working with one of the foremost specialist advisory firms in the field, with extensive multi-sector experience, in-depth market knowledge, over 20 years of development experience in safety relevant industries and ability to bring this knowledge to bear when assessing your medical devices, you can minimise your risk to acceptable levels while protecting your corporate reputation and valuation.

You'll save both time and money on re-engineering products, carrying out corrective action in the field or, worse still, product recalls and reputational damage with potentially high legal liabilities. Your staff will be free to focus on their core responsibilities, which will improve your efficiency. You will also gain competitive advantage from remaining up to date and ahead of the field in this important area. By using a multi-sector specialist, you'll additionally benefit from the latest 'best practice' functional safety thinking in other critical areas such as automotive and aviation.

## Meet Lorit Consultancy

Lorit Consultancy was founded in 2014 by Alastair Walker. The Edinburgh based company offers highly focused and personal consultancy and support in functional safety related projects in both English and German. Alastair is a TÜV Rheinland FS Engineer (Automotive 6223/13), and has many years of both hardware and software development experience. Lorit Consultancy has worked on a diverse range of safety related products, including ECG recorders, aviation transponders and electric motorbikes.

Previous healthcare experience include Spacelabs Healthcare, Inside Biometrics and Plexus.

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LORIT CONSULTANCY GAVE US EXCELLENT SUPPORT IN DEFINING THE REQUIREMENTS AND IMPLEMENTING THE BS EN 62304 DOCUMENT STRUCTURE FOR OUR FIRST PRODUCT.  
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Selly Saini – CEO  
*Inside Biometrics*

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LORIT CONSULTANCY PROVIDED A PROFESSIONAL AND EFFICIENT SERVICE IN DEFINING REGULATORY REQUIREMENTS FOR BOTH NEW DEVELOPMENTS AND LEGACY PRODUCTS.  
"**

Alastair Mutch –  
VP Research and Development,  
*Diagnostic Cardiology*

*Spacelabs Healthcare*

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PLEXUS HAS USED THE SERVICES OF LORIT CONSULTANCY IN RELATION TO A NEW HEALTHCARE PROJECT WHERE INSIGHTS INTO ISO 14971 AND IEC 60601-1 INTERNATIONAL STANDARDS WAS NEEDED. WE HAVE BEEN VERY IMPRESSED WITH THE QUALITY OF KNOWLEDGE WITHIN LORIT AND THE QUALITY OF DOCUMENTATION AND DELIVERABLE AND WE LOOK FORWARD TO WORKING WITH CONTINUING PARTNERING WITH LORIT IN THE FUTURE.  
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John Simpson –  
Senior Manager, Engineering *Plexus*

► For more information about how Lorit Consultancy can help you with functional safety and the compliance challenge please contact:

### Lorit Consultancy Ltd

21/4 Comely Bank Avenue  
Edinburgh  
Scotland, UK  
EH4 1EW

Tel (UK): +44 7708 360023  
Tel (DE): +49 3056 795165  
[info@lorit-consultancy.com](mailto:info@lorit-consultancy.com)