Lorit Consultancy

Your partner for functional safety and regulatory compliance

Job Specification

Medical Device Compliance Consultant

Reports to: Managing Director

Location: Scottish Central Belt (candidates must be able and willing to undertake national and international travel)

Home based with regular team meetings in office space within the Central Belt

Salary: Competitive based on experience (Pension, private healthcare, life assurance and flexible working)

Company Overview:

Based in the Scottish central belt, Lorit Consultancy is a forward thinking and successful business specialising in Functional Safety, Regulatory Compliance and Training in safety critical industries, predominantly the Automotive and Medical sectors. From the concept phase through to start of production, we assist companies with the complex exercise of international standards compliance to ensure their projects meet all safety and regulatory requirements.

The company is entering an exciting period of growth and, due to an expanding international client base, we are looking to grow our core team in Scotland and are seeking a seasoned Medical Device Compliance Consultant with extensive experience of medical device compliance to international standards and guidelines.

Role Description:

This is a role requiring detailed knowledge of medical device development and regulatory compliance. Our ideal candidate will likely come from either a quality assurance or a software development background in order to complement our existing extensive hardware skill set. Training and career development will be offered in areas that will benefit both company and candidate.

Responsibilities will include:

- Reviewing products, projects and processes to medical device standards such as IEC 60601-1, ISO 14971 or IEC 62304
- Reviewing quality management procedures and processes in accordance with ISO 13485 or ISO 9001
- Conducting risk analysis/assessments
- Liaison with the customer at all stages of the development
- Generation of all necessary project work products
- Delivering medical device compliance training courses based on different international standards

Essential Skills:

- Thorough working knowledge of standards such as IEC 60601-1, ISO 14971, IEC 62304 and ISO 13485
- A minimum of 5 years industry relevant experience
- Sound knowledge of software development techniques
- Thorough knowledge of risk assessment techniques such as FMEA
- Excellent technical writing skills and proven ability to produce concise, high quality technical reports
- Experience of U.S. Food and Drug Administration procedures
- Strong customer relationship skills
- Presentation and training experience

Desirable Skills:

- Knowledge of usability engineering to IEC 62366-1 or similar standards
- Software metrics and static analysis techniques
- Experience of Fault Tree Analysis and Isograph Reliability Workbench
- Familiarity with requirement capture tools
- Process improvement techniques
- Atlassian tools
- German language skills

Relationships:

Internal: Managing Director; Consultants; Marketing Manager
External: Various clients and potential clients; External consultancies; Notified bodies; IT and PR support

TO APPLY: Please email your CV to our Resourcing Partner at karen@kmpeoplesolutions.co.uk including a short paragraph highlighting your suitability for this post.