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Either Home-based UK, Madrid Spain or Gouda Netherlands

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#### **THE COMPANY**

Join a company with a history of over 100 years in innovation.

This global leader, with extensive resources in people, technology and partners is at the cutting edge of healthcare and medical imaging solutions such as MRI, Ultrasound and CT scanning systems.

With core values that are people oriented and customer centric, sincere and innovative, this company strives to deliver results which improve the lives of patients in more than 65 countries around the world.

This is an opportunity to work for a company that invests in employee development, in the short and the long term. You can expect a highly interesting and diversified role in a motivated and supportive team, the chance to be part of a company wide QMS transformation and really make an impact.

# **THE OPPORTUNITY**

In this brand new role as QARA Specialist you will work closely with the Senior QARA Manager to build a new QMS from the ground up thus defining the future of the Quality department.

As well as building a new QMS, you will support regulatory activities such as transition from MDD to MDR and participate in (maybe eventually lead) internal and external audits.



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# AS QA-RA SPECIALIST YOU WILL...

- Build and implement a brand new QMS across the whole European region from the ground up
- Define and drive change in quality excellence and processes
- Support, where necessary, the legal manufacturers on the transition from MDD to MDR and ensure compliance to all necessary regulations
- Change the quality culture across the European region
- Support and lead internal and 3rd party, notified body/competent authority inspections and audits
- Own and manage Quality System documents and sub systems
- Answer all questions related to QARA from colleagues and/or subsidiaries

# AS QARA SPECIALIST YOU SHOULD HAVE...

- Minimum 3+ years Quality/Regulatory experience in the medical device industry
- Hands-on experience with ISO 13485, 93/42/EEC (MDD), MDR

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• The ability to speak English fluentlyMethodical approach and autonomous

#### **WE'D LOVE TO HEAR FROM YOU!**

#### Please send your CV to kristina@elemed.eu for a confidential career discussion.

Only applicants who meet the requirements above will be considered for the role. Unless otherwise stated we are not able to consider applicants without EU work authorization.

Elemed is an executive search firm, specialized in finding and representing exceptional talent in medtech. To find out more about our Candidate Services visit: https://www.elemed.eu/candidates/



