Senior Manager

Quality/ Regulatory, Medical Devices

Home Based - Europe

Hello@elemed.eu

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 the chance to work at the future of healthcare.

When you join this company, you can be sure that you're more than just a number. You'll have the chance to work for a company that invests in employee development, on 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 transformation and the chance to really make an impact.

>>> Swipe to read about responsibilities

In this brand new role as senior Manager Quality and Regulatory, you will:

- Be the top person responsible for all Quality system (70%) and Regulatory activities (30%) for the whole of the EU region
- Redesign, build and drive change in quality excellence and processes
- Lead a small team of 5 Quality/Regulatory experts, upskill, coach and support their development, to ensure compliance with the companies business codes and other relevant laws/standards: ISO 13485, COCIR, MDR, etc.
- Lead a European wide transformational project, to harmonize all local QMS systems into one - this is a strategic ambition of the company; to build a region with one voice, and harmonized business processes.
- Drive a culture of continuous improvement across all legal entities across Europe
- Lead audits across the European organisations, to ensure compliance and implementation of quality processes, following up with any counter measures necessary.
- Train and deliver workshops to local entities on quality system processes and upcoming quality/regulatory changes
- Host 3rd party, notified body/competent authority inspections and audits
- Support, where necessary, the legal manufacturers with the transition to MDR.

Requirements:

1.Experienced with ISO 13485, and managing a Quality management system in the Medical Device industry?

2.Passionate about change management and continuous improvement?

3.Open minded, to travel within Europe for approximtely 50% of your time?

4. Able to manage and motivate a remote team

TO APPLY
SEND YOUR CV
TO HELLO@ELEMED.EU