SENIOR MANAGER RAQA

Lund, Sweden with hybrid possibilities

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Are you an experienced leader in Regulatory Affairs and Quality? Do you have an aptitude for thinking strategically? Are you interested in being at the forefront of the future of healthcare? If you answered yes, take a look at this fantastic opportunity!

THE COMPANY

Rated as one of the best employers in medical devices, this company proudly boasts one of the highest rates of employee happiness in the world. With a vast portfolio of medical devices up to class III that the company sells in all markets worldwide, it really is a global player.

Collaboration is at the core of what this company does both externally with its customers and internally with its employees. You can expect lead a team that thrives on working together driving towards the same common goal to make healthcare better whilst also being investing in your own growth and development.

THE OPPORUNITY

This company is looking for a passionate RAQA leader like you!

This is a great chance for an established and experienced leader to spearhead the RAQACL team in Sweden responsible for a key life-saving product amongst others. If you want to work in a business that is collaborative, invests in its people and is passionate about what they do, this is the place for you. You will have the opportunity to be responsible for the Quality and Regulatory strategy for global markets and oversee an experienced team of 5 including a team manager.

THE RESPONSIBILITIES

As Senior Manager RAQA you will (not an exhaustive list):

- Interpret and identify the applicable regulations and guidelines for compliance and registration globally and advise other teams accordingly
- Oversee a team of experts and team managers to deliver the business strategies for the Lund portfolio
- Strategic planning of RA activities and programs
- Be responsible for technical documentation review, and support the creation and continuous improvement of regulatory-related processes
- Monitor and analyse medical device regulations to ensure submission requirements and design output compliance
- Maintain and implement an efficient and effective QMS in compliance with the standards and regulations
- Supervise and/or lead management review meetings and report to the senior leadership team on improvement topics etc
- Act as PRRC
- Ensure NPD projects meet the regulatory requirements and quality expectations
- Resource and implement the clinical evidence portfolio to support global market access
- Navigate and build key relationships with global regulatory authorities and consultants
- Support audits conducted by Notified Body/Conformity Assessment Bodies and Regulatory Authorities

YOUR QUALIFICATIONS:

- Minimum 8 years of regulatory affairs and quality experience with medical devices
- Previous experience managing teams
- Speak English and Swedish

INTERESTED TO EXPLORE THIS FURTHER?

If you are interested in this exciting role, please send your application directly to

KRISTINA@ELEMED.EU

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/

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