QUALITY AND REGULATORY AFFAIRS MANAGER- MDR

MUNICH, GERMANY (UP TO THREE DAYS FROM HOME OFFICE)

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The company

Are you a quality and/or regulatory professional looking to expand your career within a globally leading MedTech company?

Do you have experience within MDR projects and now looking to expand your knowledge in this key area within our industry?

Come and join a privately owned, growing company of 2000+ people in Munich, Germany. Located in the cluster hub of the MedTech world, you will be joining a company that puts innovation and employee development at their forefront of their vision. If you are looking for a company that will value you and provide you with a great platform to develop into management, then this is the role for you!

The opportunity

As the QA/RA manager you will be the key representative for the MDR projects and changes across Europe, a great responsibility for someone looking to take on that role.

This position is focussed the full life cycle of tasks across both QA/RA- with more of a focus on QA tasks. You will work closely with the directors in the HQ who drive and develop both QA/RA strategy with a key focus on MDR and international projects. A great role if you like ot be part of strategic decisions.

The broad portfolio gives you the opportunity to work with active & non-active medical devices, consumer devices and even work on their bluetooth connectivity project giving you the chance to learn a lot! This is a great chance to broaden your horizons beyond the classic "medical devices only" box by learning about some new regulations that are also very interesting!

Do you love collaborative work environments? You'll have the chance to join a multicultural regulatory and quality team, where learning from each other, teamwork and "having fun" is at the heart of their culture. You'll have the chance to learn on the job from a great director with over 10 years experience in this industry.

Responsibilities

- Support the company EU representative for all matters and projects related to the MDR transition
- Ensure the QMS is set up successfully across all subsidiaries
- Provide key support and drive forward the technical documentation process of products in both the EU and internationally
- Support regulatory intelligence across the EU
- Be part of the full life cycle for QA tasks, from QMS to CAPA and NCR management
- Close alignment with PRRC at the HQ
- Provide key strategy on RA and QA tasks to the directors within the RA/QA department at the HQ

Your qualifications

- 5+ years experience within either RA or QA, or a blend of both (If you are coming from a pure RA background, you must be motivated to drive forward QA tasks)
- Key expert within medical device products
- Experience within MDR projects
- Key knowledge wtihin the EU registration process
- Fluent in English, fluency in German would be a bonus

Get in touch

If you are interested in this exciting role, please send your application directly to **tamanna@elemed.eu**

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