Regulatory Affairs & Quality Manager- MDR

Thurgau, Switzerland OR Vienna, Austria
With home office opportunities

tamanna@elemed.eu

The Company

Are you a quality and/or regulatory professional looking to expand your career with a company that will truly value your goals and nurture your career?

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 close-knit business where employees' voices and goals are at the forefront of the business owners' plans. This company specialise in exciting Class IIa products that are currently being developed across Europe. You will report to the business owner where you will play a key role in the development and strategy of the RA/QA department; while also having a great hands-on role.

If you are looking for a role where you will be empowered to make decisions and develop a business's RA/QA department then this is the role for you!

The opportunity

As the RA/QA 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. You will report to the business owners advising them on regulatory and quality activities.

This position is focused on the full life cycle of tasks across both regulatory affairs and quality assurance- with more of a focus on RA tasks. You will work closely with the directors and business owners who drive and develop both QA/RA strategy with a key focus on MDR and international projects. This is a great role if you like to be part of strategic decisions.

The innovative product portfolio gives you the opportunity to work with interesting medical devices, 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, in line with the new MDR regulations.

Do you love collaborative work environments? You’ll have the chance to work with experts in different fields, 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 supportive business owners who will have your career goals and training and the heart of their decisions.

The responsibilities

- Support the company's EU representative for all matters and projects related to the MDR transition
- Ensure the QMS is set up successfully across the business according to ISO 13485
- Provide key support and drive forward the technical documentation process of products in the EU
- Support regulatory intelligence across the EU
- Be part of the full life cycle for QA tasks, from QMS to CAPA and NCR management
- Provide key strategy on RA and QA tasks to the directors within the RA/QA department

The requirements

- 3+ 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 within the EU registration process
- Fluent in English, fluency in German would be a bonus

Interested in this role?

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

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