Senior Manager QA/RA

REMOTELY BASED IN FRANCE

THE COMPANY

Are you motivated by innovation in the medtech industry? Are you a people person? This is an amazing chance to join one of the great modern day pioneers in medical technology capital equipment. This is a company enjoying huge success right now, with 20% year on year growth to date.

Due to an expanding presence in Europe, the company has created a new commercial site in the picturesque region of Bordeaux, France, and along with it, a new position for a Senior Manager QA/RA has been opened.
The primary purpose is to be the go-to person for commercial related regulatory and quality matters for the whole of the company's Western Europe region.
With a dotted line to the GM of the region, we are looking for someone who is able to take complex regulatory topics and translate them into clear, simple messages in order for the region to achieve success.

This is not a typical QA/RA position. In this role you'll implement a new strategy, have the chance to create something, rather than to remediate, and to eventually build your own team as the company grows. Furthermore, you will have the responsibilities of EU Authorised Representative.
If you want to truly have an impact and make your mark, this is an opportunity for you!

You'll be the go-to person to provide regulatory and quality input to commercial functions such as sales, marketing and service teams, as well as be the subject matter expert for the QA/RA strategy across Western Europe for Corporate and global teams.

You'll be the face of the company towards regulatory agencies in your region, as well as for local manufacturer organisations such as SNITEM.

To achieve success in this role, you need to be someone who loves working with people of different backgrounds, and have strong influencing skills.

AS SENIOR MANAGER REGULATORY AFFAIRS / QUALITY YOU WILL :

- Represent QA/RA for all commercial related activities for France, Benelux and the Nordics.
- As part of the commercial leadership team for Western Europe, ensure that all activities are in compliance with all relevant regulations
- Take on responsibilities as EU Authorised Representative
- Manage regulatory operations activities and registrations for the region
- Build the relationship between the company and Competent Authorities i.e ANSM, through transparent communication and frequent dialogue.
- Take responsibility for ensuring compliance interpretations by the competent authorities are documented and understood internally.
- Develop advocacy skills by representing the company at local trade association level, and promoting the company's objectives to regulatory bodies.
- Support post market surveillance, complaint handling and adverse event reporting by identifying gaps, developing and implementing processes to ensure compliance.
- Design regulatory strategies to further the company's presence and commercial objectives in the region by bringing new and existing products into those markets.
- Guide and influence decisions relating to commercial activities by being the go-to person for QA/RA.
- Be part of a new Quality Management System (QMS) implementation project for your region, ensuring it is aligned to Corporate QMS, but adapted to the specific needs of the region, and support with QMS activities thereafter (CAPA, documentation, training, audit etc)
- Support with other key projects and activities as needed
- Should the need arise for an AR, you'll act as the Authorised Representative under EU MDR and EU MDD, developing a strong relationship with ANSM as the main Competent Authority for the EU rep.

Are you interested in joining **a collaborative** working environment?

Would you like to join a company where the **culture is transparent** and there is no red tape?

Do you find the idea of **building** something appealing? **Then we'd love to hear from you!**

EXPECTATIONS

- 8+ years experience in a regulatory or quality position in the medical device industry
- Previous experience contributing to the development of a QMS
- Regulatory experience working with SNITEM or ANSM
- Medical device industry experience
- Proven leadership experience OR strong potential to become a team manager
- Fluent English & French speaker
- Knowledge of relevant regulations: ISO 13485:2016, EU MDD 93/42/EEC, EU MDR 2017/745/EU, US FDA CFR 21

INTERESTED TO EXPLORE THIS FURTHER?

Please send your CV to **elena@elemed.eu** to arrange a confidential career discussion.

Please note!!! Elemed has exclusive agency rights and a written mandate to recruit this role. Be wary of applying to false adverts or other agencies advertising this role as it may lead to your application being withdrawn.