Regulatory Affairs Specialist

Occitanie, France

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The company

Are you up for a challenge?

Following a recent acquisition, this global Medtech manufacturer and world leader in the MedTech industry is looking for a Regulatory Affairs Specialist for one of its key entities. If you are passionate about regulatory and interested in challenging devices, then this is a great role for you!

Reporting to the Group Regulatory Director in the US and working closely with other team members and departments, you will implement the necessary actions to ensure the site's compliance for the company's development.

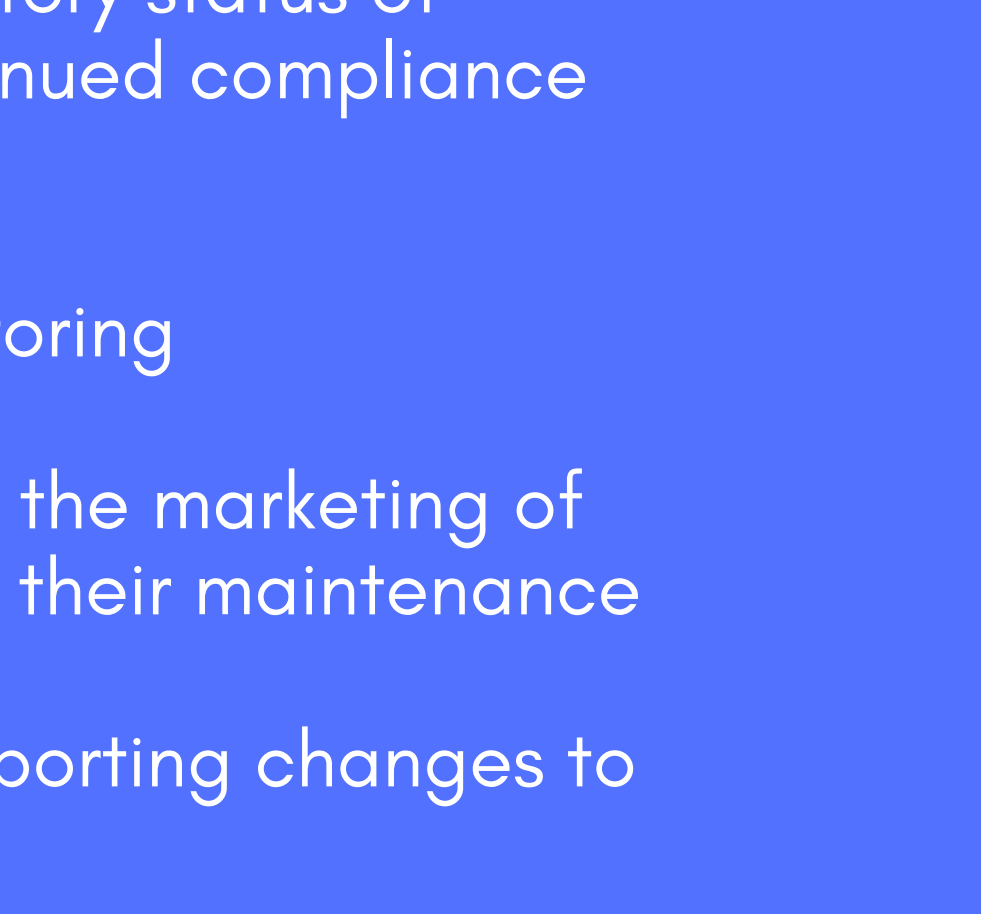
The opportunity

You will be in their innovation center, working with state-of-the-art medical devices, receiving excellent training, and helping to improve the lives of millions of people around the world.

You'll have no worries about the future and stability of this company, which has been performing well in the market for years and growing for the long term! This position will give you the chance to join a collaborative and skilled team where you will work with interesting products and develop your knowledge of the US market!

The responsibilities

- Ensure product compliance with the standards applicable in the markets where the product is sold
- Maintain the technical file for CE marking and the design history file in conjunction with the R&D and production departments
- Manage product registration processes in different countries and ensure their renewal according to commercial needs
- Review proposed product changes to assess their impact on the regulatory status of products and ensure continued compliance with applicable standards
- Organize regulatory monitoring
- Manage the processes for the marketing of devices, registrations, and their maintenance
- Manage the process of reporting changes to the relevant bodies
- Interpret and apply current regulations and standards to company practices and ensure appropriate dissemination of information



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The responsibilities

- Participate in development projects as an RA representative
- Inform the project development teams about the regulations, their evolution, and ensure their application
- Maintain the technical file for CE marking and the design history file in conjunction with the R&D and production departments
- Authorize the release of products if necessary by checking the adequacy between the regulatory status of the products and their destination
- Participate in the marketing/regulatory strategy for the planning of the product launch
- Participate in development projects as an RA representative
- Authorize the release of products if necessary by checking the adequacy between the regulatory status of the products and their destination
- Ensure regular reporting to the Group Regulatory Affairs Director

Qualifications

- Minimum of 3 years experience in a Regulatory Affairs operational function in the medical device industry
- Knowledge of FDA
- Professional written and spoken English and French

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

john@elemed.eu

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