REGULATORY AFFAIRS SPECIALIST

→ UTRECHT, THE NETHERLANDS

→ Contact: monia@elemed.eu

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→ THE OPPORTUNITY

Tired of being a number in your company?

Do you want to be part of a company where you can make a real difference?

I have the company for you! This medical device manufacturer is offering you the opportunity to join its regulatory team to develop products that have a real impact on healthcare professionals and patients.

You will be part of a constantly evolving environment with the advantages of a small structure but also the support of a large group. You will be in direct contact with the different teams and will be able to participate in the development process from A to Z!

→ THE ROLE

The regulatory team is looking for a Regulatory Affairs Officer to join its team to support the Regulatory Director in the various activities. You will be in an environment where every day will be different! You will have the chance to work with interesting and challenging devices.

This position will also give you the opportunity to develop your skills thanks to a team of experts where you will regularly exchange with the different departments (Quality, R&D, Commercial) but also with external stakeholders (distributors, customers, suppliers, notified bodies, competent authorities).

The regulatory affairs manager will also be able to act internationally and have visibility on all projects.

RESPONSIBILITIES

- Ensure regulatory and standards monitoring
- Ensure that the company is in compliance with the regulatory requirements in force
- Drafting and updating of technical files (CE marking, 510k...)
- Support the RAQA team in case of material vigilance
- Participate in the drafting of specifications
- Follow the approval files and the registration processes with the organisations and administrations
- Manage the processes prior to the marketing of devices developed by the company: CE marking (MDR), approval, etc.
- Register devices internationally in accordance with the company's strategy
- Interact with Notified Bodies and Competent Authorities

QUALIFICATIONS

- You have a Master's degree, ideally oriented towards "Regulatory Affairs in the health industries"
- You have a minimum of 2 years of experience as a regulatory affairs officer in the medical device industry
- Speak and write English

→ GET IN TOUCH

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

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