SENIOR REGULATORY AFFAIRS SPECIALIST - EUROPE

Home-based in Europe

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Do you have experience working on CE marking projects or new product development projects from an RA perspective? Are you interested in being at the forefront of the future of healthcare? Are you ready to wake up to a brighter world? If you answered yes to even just one of these questions, take a look at this fantastic opportunity!

THE COMPANY

Having been on the market for more than 15 years, this company is present in over 50 countries globally and has experienced 40% growth in the last 2-3 years alone. Currently at 85 people, this is a great time to be joining the business to help set the tone, inject creativity, and have a huge contribution to the organisation as a whole. This company has a goal to improve people's health by advancing sleep diagnostics, simplifying sleep studies, and improving sleep therapy. With a range of devices and a high percentage of spending in R&D, you can guarantee that you'll have a range of activities across a diverse portfolio of products to keep yourself learning and developing.

THE OPPORTUNITY

As this company continues to see success and invest in new product development, it is time to grow the Regulatory Affairs team and they are looking for passionate experts like you!

If you want to work in a business that recognises the importance of Regulatory Affairs, is passionate about what they do, and is sitting at the forefront of innovation in software and AI, this is the place for you. You will have the opportunity to oversee the full lifecycle of the products from cradle to grave, work on exciting development projects, and navigate complex regulatory landscapes all in a supportive and collaborative environment.

THE RESPONSIBILITIES

As Senior Regulatory Affairs Specialist you will (not an exhaustive list):

- Manage your portfolio of products through development and lifecycle management processes globally
- Strategic planning of RA activities and programs
- Compile technical documentation and prepare the regulatory documentation for submission
- Be responsible for technical documentation review, and support the creation and continuous improvement of regulatory related processes

THE RESPONSIBILITIES

- Work on Innovation projects as the regulatory representative, providing input regarding risk management, standards, and guidance documents
- Support other partners from the company as the subject matter expert for the portfolio of medical devices
- Closely collaborate with multi-disciplinary teams from Regulatory, Quality, Technical, Marketing & R&D on new product development projects and international product launches
- Support key relationships with European Authorities, notified bodies, and International competent authorities
- Develop, implement, and maintain internal procedures ensuring ongoing compliance with national and international regulations, legislations, standards, and guidance
- Create new and maintain existing registrations globally, follow the changes to the MDR, and support with testing activities related to the standards relevant to your product
- Support audits conducted by Notified Body/Conformity Assessment Bodies and Regulatory Authorities

YOUR QUALIFICATIONS

- Minimum 3 years of regulatory affairs experience with active medical devices or software (embedded/SaMD)
- CE marking experience and/or new product development experience

INTERESTED TO EXPLORE THIS FURTHER?

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

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