Senior Regulatory Affairs Specialist

Zug, Switzerland (with home office flexibility)

clarisse@elemed.eu

The Company

Are you passionate about innovation and groundbreaking development? Do you want to join an organisation where you can really make an impact? Have you got Regulatory Affairs experience for medical devices?
If yes, we have a fantastic opportunity for you!

This is a chance to join an extremely well funded, early commercialisation stage company with over 1000 patents - a huge innovation portfolio. Right now they are developing and bringing to market not one, but FOUR Class III active and (non active) implantable medical devices that are about to totally change the status quo.

With the continuous growth and development, the company is looking for a strong RA professional to support the portfolio of products from cradle to grave and register them in key countries in and outside of Europe. This is an opportunity to step into a brand new position, no old shoes to fill here and really make an impact on the Regulatory and Quality processes in the company, working with some of the most innovative and life-changing products.

Your responsibilities:

- Manage, review and support the creation of technical documentation and the submission process on an international scale
- Support the management of the products portfolio through development and lifecycle management processes globally
- Work on innovation projects as a regulatory representative, supporting input regarding risk management, standards and guidance documents
- Work closely with the RA team to create and maintain regulatory and quality processes
- Closely collaborate in 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 and International competent authorities

Your qualifications:

- 5+ years regulatory affairs experience in the medical device industry
- Fluent speaking, reading and writing in English

Interested in this role?

Interested in further conversation? Please send your CV to clarisse@elemed.eu to arrange a confidential career discussion.

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