Regulatory Affairs Manager- Product Development

Zug Area, Switzerland

clarisse@elemed.eu

The Company

Are you experienced in product development and want to develop your career? Come and join a privately owned, growing company of 2000+ people in Zug.

Located in the classic natural beauty of Switzerland, the town has great links to the buzzing city of Zurich. As R&D and regulatory affairs manager, you'll be in the company HQ, right at the centre of where all the key decisions are made, and where the development teams sit.

The Opportunity

This position is focussed on new product development for the company's most famous products, known by women all over the world. You will oversee the entire lifecycle from start to finish as well as develop your skills not only in the EU but also the US and International markets like APAC and LATAM.

The broad portfolio gives you the opportunity to work with active & non-active medical devices, consumer devices and even work on their bluetooth connectivity project giving you the chance to learn a lot! This is a great chance to broaden your horizons beyond the classic "medical devices only" box by learning about some new regulations that are also very interesting!

Do you love collaborative work environments? You'll have the chance to join a multicultural regulatory team, where learning from each other, teamwork and "having fun" is at the heart of their culture. You'll have the chance to learn on the job from a great manager with over 10 years experience in this industry.

Your responsibilities

- Manage your own portfolio of products through development and lifecycle management processes globally
- 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 your own portfolio of medical devices
- 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, notified bodies and International competent authorities such as Canada, Japan, China and Brazil
- Be responsible for technical documentation review, and support the creation and continuous improvement of regulatory related processes.
- Create new and maintain existing registrations globally, follow the changes to the MDR and support with testing activities related to the standards relevant for your product.

Your qualifications

- 2+ years experience in regulatory affairs in medical devices
- Experience with new product development projects inclusive of design control and technical file creation
- Previous experience within the US registration process would be a bonus
- Fluent in English

Interested in this role?

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

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