Regulatory Affairs Specialist

Bern Area, Switzerland

Contact: tamanna@elemed.eu

Are you looking for a role that will kick start your career within regulatory affairs?

Are you looking for a medical device company where you will grow globally?

Then this is the role for you...

The company

With over 30 years experience, this company is producing innovative and world recognised products. Thus allowing you to be part of an organisation that really appreciates the global platform.

As a result of their investment into new product development projects, they are looking for experienced regulatory professionals to join their growing team. You will be registering devices worldwide with a focus on EU and US markets as well as supporting new product development products from a regulatory perspective. A great opportunity to work develop your career with the FDA and work alongside some of the top experts in this field.

This company also appreciates a strong employee development programme. As an employee you will be enrolled in the flexible working scheme; which will allow you to gain flexibility to have up to two days working from home. You will also be put on a strong career progression path, which will give you the opportunity to develop your career into people management in the future.

If working with cutting-edge technology, in an international environment, at the company's headquarters is what you are looking for, look no further!

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The role

As Regulatory Affairs Specialist you will:

- Collaborate on new product development projects from a regulatory aspect
- Assist and develop key technical documentation for class I-IIb devices
- Prepare regulatory documents and register medical devices for US markets and EU
- Communicate, liaise and drive relationships with authorities such as Notified Bodies and Competent Authorities
- Support various quality activities such as audits, creating quality documents, participate in training and more

Requirements

As Regulatory Affairs Manager you should have:

- 1+ years regulatory experience in the medical technology industry. We will also consider applicants from a pharma background looking to develop their career into medical devices
- Minimum of a Bachelor degree
- Experience of working with the FDA and EU markets would be a bonus
- Understanding of ISO 13485 would be a bonus
- Strong English language skills, where at least conversational level German is required
- Strong motivation and eagerness to learn and develop

Interested in further **CONVERSATION?**

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

tamanna@elemed.eu

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