Regulatory Affairs Manager

Be one of the driving forces behind exciting FDA projects

Zurich region, Switzerland (hybrid)

tamanna@elemed.eu

The company

Join a well-established, growing company designing, developing, and producing a Class III active implantable medical device that changes the lives of patients.

To further support the growth of their Regulatory and Quality division, this company are looking to provide a unique opportunity to an experienced RA specialist to continue their career in exciting global markets including the FDA.

This is a great opportunity to join a close-knit team with one vision, surrounded by other senior experts in their field. You will work with some of the top RA/QA experts, allowing you to develop your skills and further develop your career, with specific attention to 510K and PMA projects.

You can be sure that no two days will be the same! You'll enjoy a wide variety of responsibilities covering various elements within Regulatory on an international scale.

Responsibilities

As the Regulatory Affairs Manager your responsibilities will include but not be limited to:

- Management of technical documentation on an international scale
- Support risk management activities
- Key execution of PMA premarket submissions
- Support the development and formulation of 510K applications
- Management in the submission process to key notified bodies internationally
- Work closely in supporting the VP RA/QA and Head of RA/QA with all maintenance activities for regulatory affairs, with specific attention to the FDA
- Support DHF activities for the US

Requirements

- 4+ years of experience in regulatory affairs within medical devices, ideally active medical devices
- Good working experience of the 510K process or PMA process
- Good working experience of working directly with the FDA
- Have worked on products that have been registered in the US
- Excellent communication skills in English – German would be a bonus

Get in touch

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

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