REGULATORY AFFAIRS MANAGER

→ SOLOTHURN, SWITZERLAND

→ Contact: tamanna@elemed.eu

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THE COMPANY

Join a well-established, growing company which designs, develops, and produces a Class III active implantable medical device that changes the lives of patients.

To further support the growth of their Regulatory and Quality division, our client has released an exciting newly created position as Regulatory Affairs Manager.

This is an excellent 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 career.

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

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→ RESPONSIBILITIES

- Management of technical documentation on an international scale
- Support risk management activities
- 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
- The key communicator between external test labs with regard to electrical safety
- Management of design control meetings and activities
- Mentor junior RA staff members

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→ REQUIREMENTS

- 5+ years of experience within regulatory affairs
- Expertise within the field of medical devices, with specific expertise within active medical devices
- A key understanding of IEC 60601-1 and software IEC 62304
- Expertise in the creation and maintenance of technical files for active medical devices
- Excellent communication skills in English. German would be a bonus

→ GET IN TOUCH

Interested to explore this further? Please send your CV to **tamanna@elemed.eu** to arrange a confidential career discussion.

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/

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