Regulatory Affairs Program Manager

Berlin, Germany hybrid model: mix between office and home-office

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elemed

Calling all high flyers! A unique opportunity has arisen in a global company as a Regulatory Affairs Program Manager. If you are ambitious, have software knowledge and are passionate about a product that changes the lives of patients, then read on.

The company

This is a unique role, awarded exclusively to Elemed as sole agency. Our client is a **big player in the treatment of ear, nose and throat conditions**. The products are known around the world, for the huge patient benefit it brings. With an excellent work life balance, low staff turnover, and ideal location in Germany's capital Berlin, this is a very unique role **that will make you want to wake up and go to work everyday.**

You will be responsible for areas of **Regulatory Affairs**, as defined below:

- **Regulatory Strategy**: Define and develop corporate regulatory strategies for the introduction of new medical devices, and significant modifications (i.e CE mark), along with Marketing and Clinical.

- **Company representative**: Manage the company relationship with Notified bodies, Competent authorities and MOH, including invoice sign off, review of CE submissions and management of meetings, especially in Germany, Switzerland and the UK.

- **Regulatory intelligence**: Follow the developments of the MDR and other critical changes. Actively participate in regulatory associations to represent company interests.

Requirements

- 5+ years experience in the medical device industry
- Key understanding of ISO 13485
- Proven knowledge of 510k (FDA) is a must have
- Software (MedTech) experience highly required
- Fluent German and English language skills are mandatory
- Registration knowledge especially in Germany, UK and Switzerland is a great advantage

Interested to explore this further?

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

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