REGULATORY AFFAIRS MANAGER

Germany, Remote

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contact

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Very interesting opportunity as Regulatory Affairs Manager within an international operating enterprise. If you like innovative products that improve the lives of others, enjoy the flexibility of working remotely - if you like to - and are ambitious, this is for you.

THE COMPANY

This is a unique role, awarded exclusively to Elemed as the sole agency. Our client is a big player in the AIMD, high-risk device field. The device is known around the world, for the huge patient benefit it brings. With an excellent work-life balance and low staff turnover, this is a very unique role that will make you want to wake up and work every day - remotely anywhere you want in Germany!

You will oversee one person and 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
- Regulatory intelligence: Follow the developments of the MDR and other critical changes. Actively participate
- in regulatory associations i.e RAPS, EUCOMED to represent company interests
- Post-market activities: As safety officer, ensure Vigilance and supervise reporting and implementation of FSCA

REQUIREMENTS

- 5+ years experience in the medical device industry
- Proven RA experience: Minimum successful CE marking
- Ability to influence
- BVMED network (or willing to be part of it)
- Battery knowledge (non-medical) is a great plus
- Fluent German language skills (written and verbally)

INTERESTED?

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

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