

Regulatory Affairs Specialist

Berlin, Germany

Come and join a leading medical device manufacturer with a long history of over 170 years!

Present in over 50 countries around the world, this company continues to grow in new and exciting markets such as China, Japan and more!

With an extensive and innovative portfolio you can guarantee to continually develop old and build new skills taking your regulatory knowledge to the next level.

You will have the opportunity to work with some of their most well-known Class IIb and Class III devices.

Due to some organisational changes internally, we are looking for a regulatory affairs specialist who has experience with Chinese submissions to help them enter the highly regulated and fast growing market.

You will be liaising with various international governing bodies to bring the products to market and be responsible for understanding and implementing the required regulations.

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Your responsibilities:

- Support other cross functional departments on regulatory submissions outside of Europe
- Lead the strategy to register products in China, Japan, Russia and other international regions
- Liaise with competent authorities, notified bodies and other governing bodies internationally
- Prepare technical documentation to comply with regulatory requirements

Your qualifications:

- Minimum 1 year experience registering medical devices in China
- Experience with implantable medical devices
- Bachelor's degree or equivalent in engineering or any other scientific background

We'd love to hear from you! Please send your CV to kristina@elemed.eu for a confidential career discussion. Only applicants who meet the requirements above will be considered for the role.

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