

Senior Regulatory Affairs Manager

Berlin, Germany

Are you an experienced regulatory professional looking to step into leadership?

Do you like working with high-risk, innovative devices?

Is being hands-on where you thrive?

If your answer is yes, we have a fantastic opportunity for you!

We are looking for a Senior Regulatory Affairs Manager to come and join a medium sized company in their Berlin headquarters. They manufacture Class I - III medical devices to treat cancer and are hoping to be the first company in their field with a CE marked product under MDR.

With such an exciting goal and the date of application around the corner, there is a strong focus on the transition to MDR and obtaining CE certification.

As well as dealing with the European markets, you will be exposed to global registrations in emerging markets such as the Middle East and more!

Reporting to the VP Regulatory and Quality, you will have the opportunity to lead an RA specialist as well as coordinate other external consultants; a good opportunity for someone to take a step up into leadership.

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Your responsibilities:

- Work on innovation projects as the person responsible for regulatory affairs
- Build and nurture key relationships with European Authorities, notified bodies and other international competent authorities
- Put the products on European and other markets such as Middle East and US
- Lead a team of 1 regulatory specialist and act as the point of contact for other third parties such as consultants
- Support and consult other cross functional teams such as Quality, R&D on various projects
- Lead the transition from MDD to MDR

Your qualifications:

- 4+ years regulatory affairs experience in the medical device industry
- Bachelor's degree in engineering or any scientific background
- Speak, read and write fluently in both German and English
- Experience successfully CE marking a medical device

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.

Unless otherwise stated we are not able to consider applicants without EU work authorization.

Elemed is an executive search firm, specialized in finding and representing exceptional talent in medtech.

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