Team Leader Regulatory Affairs

Lubeck, Germany

The Company

Come and join an international leader in medical technology with a history of over 100 years! This company has been crucial in the fight against COVID-19 and has patients' lives at the heart of everything they do. As a family owned company for 5 generations, they value people and understand the importance of work-life balance, collaboration and a positive work environment. You will have the opportunity to have a close relationship with senior stakeholders and work cross functionally across the whole business. If you want to work in a close-knit team with an open and friendly atmosphere, this is the place for you!

The Opportunity

This position is based in the top growing business unit and is currently the focus within the company. It is an exciting opportunity for those who are looking to take a step into leadership OR for those who are experienced leaders looking for a new challenge. Leading a team of 6 RA specialists who are young and dynamic, you will have the ability to shape the team in your image and really put your stamp on the business unit. In this position you will also be able to perform hands-on core regulatory activities; registrations in challenging markets such as US and China, participating in cross-functional strategic meetings, so

As **Team Leader Regulatory Affairs** you will (this is a non-exhaustive list of activities):

- Lead, advise and develop a team of 6 regulatory affairs specialists
- Work cross functionally across the business and liaise with key stakeholders on regulatory strategy
- Develop approval strategy and oversee the global registrations of a broad range of medical devices Class I - IIb
- Arrange technical documentation for and support the implementation of the MDR
- Design efficient processes and methodologies for the regulatory team
- Build and nurture key relationships with European Authorities and notified bodies
- Be hands-on with additional activities such as risk management, biocompatibility etc.

Requirements

Applicants must meet the following:

- 5+ years of experience in Regulatory Affairs in the medical device industry
- Minimum Class IIa medical device experience
- Previous experience leading projects OR leading a team
- Minimum Bachelor's degree with a technical or scientific focus
- Business level communication, written and reading skills in both English and German

Interested in further conversation?

Please send your CV to kristina@elemed.eu to arrange a confidential career discussion.