

Head of Regulatory Affairs

Tuttlingen, Deutschland

The Company

Come and join a globally renowned company with a history expanding across 125 years! Present in over 140 countries worldwide they are dedicated to advancing patient treatment all around the world. With a broad and extensive portfolio you can guarantee to continually develop old and build new skills, taking your regulatory knowledge to the next level. Their dedication and investment into innovation means they have set new benchmarks in their field and continue to develop further into new areas.

In this family-owned company, you will count as more than just a number! You will have the opportunity to have a close relationship with the CEO and work cross functionally across the whole business. If you want to work in a close-knit team in the beautiful German countryside, this is the place for you!

The Opportunity

This is an exciting opportunity for someone to take a step into leadership OR for someone who is an experienced leader looking for a new challenge. You will lead a team of 11 RA specialists who are very dynamic and have the ability to shape the structure of the team. This is an opportunity not only to experience a broad portfolio of devices, but also a chance to cover a wide range of regulatory activities from new product development to lifecycle management to international registrations. A few years of experience within quality assurance for medical devices.

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

- Lead, coach and develop a team of 11 regulatory affairs specialists
- Work cross functionally across to business and liaise with key stakeholders on global registrations
- Cover the whole product lifecycle from new product development to registrations and manage the lifecycle of a broad portfolio of medical devices
- Arrange technical documentation for and support the implementation of the MDR
- Build and nurture key relationships with European Authorities and notified bodies

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Requirements

Applicants must meet the following:

- 7+ 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
- 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.

