REGULATORY AFFAIRS SPECIALIST

TUTTLINGEN AREA, GERMANY

elemed

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

We are looking for a Regulatory Affairs Expert to join this team and build on their existing skills as well as developing new ones! 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.

THE ACTIVITIES

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

- Work cross functionally across the business on European and international 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
- Work on conformity assessments, risk management, create STEDs and also maintain the documentation
- Analyse and evaluate regulatory guidelines and developments in the market

THE REQUIREMENTS

Applicants must meet the following:

- 1+ years of experience in Regulatory Affairs in the medical device industry
- Business level communication, written and reading skills in both English and German
- Knowledge of risk management and/or technical documentation

INTERESTED IN THIS *position?*

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