Head of Regulatory Affairs / Responsable Des Affaires Réglementaires

Valence, France

The company

Are you a Leader? Are you passionate about developing your team? Would you like to be part of a supportive and welcoming company?

This is a fantastic opportunity to join a leader of medical devices in their field. The company has a real international presence, with a number of subsidiaries in different countries as well as strong global exportation. As head of Regulatory Affairs, you will be based in their main site in Valence, which means at the very heart of the decision making and of the company operations.

They are continually expanding their portfolio with a strong investment in R&D projects, so this role is key to helping the R & D department to bring new products to the market.

You will lead the regulatory department to complete registration in the European and international markets and maintain regulatory files. Working at this company, you'll enjoy working across a wide variety of products: the portfolio ranges from class I to class III.

Your responsibilities:

As Head of Regulatory Affairs you will:

- Plan regulatory submissions interact with the notified body to obtain approvals
- Be responsible for distributing tasks across the team of 6, and support them in their regulatory affairs tasks to help them achieve their goals
- Support and provide guidance to the R&D department
- Supervise the files update according to the new regulation and meeting the deadline
- Anticipate regulatory issues that may impact the distribution of the company's products
- Be the regulatory representative on important development projects
- Plan and coordinate the submission of files in collaboration with the export department
- Participate in the preparation of management reviews and audits;
- Lead, train and support your team
- Promote regulatory culture to all staff
- Contribute effectively to regulatory monitoring and global regulatory intelligence

The requirements

Your qualifications:

- 8 years in Regulatory Affairs in the medical devices industry
- Team management experience
- Fluent in French and English

Interested in this role?

If you are interested in this exciting role, please send your application directly to clarisse@elemed.eu

Visit https://www.elemed.eu/vacancies/ for more opportunities