REMOTE, FRANCE

Regulatory Affairs Specialist

MONIA@ELEMED.EU

The company

This is a fantastic opportunity to join a leader of medical devices in their field

They are 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 participate in the registration in the European and international markets and maintain regulatory files with a team of experts in their area

Join a well-established, French start-up company that will change the lives of patients

The opportunity

This opportunity will give you the chance to develop your regulatory knowledge for the European market but not only! Indeed you will be also involved in the US market!

You will get the chance to be surrounded by a top expert in his field! Someone that will share his knowledge to make you the future Regulatory expert in the company!

This is your chance to be part of some very interesting challenges and have an overview from A to Z!

Your responsibilities

- Create and maintain the necessary technical documentation for the CE marking according to EU Regulation 2017/745
- Register medical devices in the EUDAMED database
- Prepare and maintain 510(k) submissions for commercialisation in the United States.
- Prepare registration files for exports (outside the EU and USA) in collaboration with the sales department
- Establish a regulatory strategy for new products and work closely with the R&D department to address normative and regulatory requirements
- Contribute to product risk assessments and maintain the risk management file
- Participate in design reviews

Your responsibilities

- Evaluate modification requests for their impact on CE marking, 510(k) submissions, and product registrations
- Review labelling, product user manuals, and promotional documentation from a regulatory perspective
- Conduct regulatory and normative monitoring related to medical devices and communicate changes within the company
- Assess customer complaints to determine if they need to be reported to authorities as part of vigilance activities and if necessary initiate reporting and follow-up
- Maintain relationships with Materiovigilance correspondents from healthcare institutions

Requirements

- Master's level (Bac+5) in a scientific field
- 5 years in a similar position within the medical industry
- Fluent in English and French

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

MONIA@ELEMED.EU

elemed