Regulatory Affairs Manager

Amsterdam or Brussels or Paris
or Lyon

The company

Come and join this leading medtech company. With a brand known globally, innovative devices from Class I-III and a care for quality, they have been recognised as one of the top employers in the industry.

Due to continued growth and investment in product development we are looking for an experienced leader who enjoys implementing process, developing people and managing a team of regulatory professionals working with Class III devices.
The position is representing the division of EMEA and interacting at the VP level.
This is the chance to have a leadership role in a division that has been overperforming in the last few years. They provide great future prospects !

The role

Responsible for leading regulatory team and activities in order to secure timely approvals, renewals and maintain market clearance with a primary focus on EMEA (Europe/Middle East/Africa), other regions as assigned.

The missions

Mentors teams and others on a regular basis, enhancing career development while advancing talent in accordance to business and department needs and upcoming opportunities.
Analyzes existing systems and procedures, recommends solutions/improvements
Prepares and delivers training programs to the department and other functional groups to ensure compliance.
Fully support the Quality Policy by building quality into all aspects of the incumbent's work and by maintaining compliance to all quality requirements
Develops and executes global regulatory strategies for assigned regions.

Provides input on and reviews on regulatory strategies to drive product introductions and support approval/license maintenance, protocols and reports for: design verification, design validation, shelf life, pre-clinical studies, and clinical studies.
Monitors, researches and obtains information clearances/approvals of competitors

Prepares complex submissions to gain approvals for commercial distribution, clinical research and export

Qualifications/Work Experience Required

- Minimum of 6 years experience of Regulatory Affairs, with Medical Devices industry
- Strong leadership skills
- Knowledge and application of regulatory requirements, including EU Medical Devices Directive, EU Medical Device Regulations, ISO 13485 post market surveillance requirements
- Knowledge of clinical trial strategy and study design to support product approvals
- Management of international regulatory submissions activities
- Good understanding of global regulations.

We'd love to hear from you!

Contact Monia at monia@elemed.eu for a confidential career discussion.