SENIOR REGULATORY AFFAIRS SPECIALIST

Paris, France

THE COMPANY

Come and join a global leader in cardiovascular medical devices as their new Senior Regulatory Affairs Specialist! Why is this a great opportunity? Keep reading to find out!

This is an opportunity to join a stable company with mature processes and structure but the pace and agility of a start-up. With 16,000 employees worldwide and a strong company brand perception, they are known globally and are really at the forefront of the most cutting edge technology in the cardiovascular field. But it doesn't stop there...This company is continuing to invest in its people and R&D and has plans to grow even further over the next 5 years. With that growth comes your opportunity to evolve, develop and advance your professional career alongside some of the best professionals in the industry. You can grow and thrive in this role.

As a global leader in patient-focused medical innovations, you will get the chance to work with exciting challenges in a truly international, dynamic and friendly working environment.

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THE OPPORTUNITY

This is a high-visibility, advisory position as Senior Regulatory Affairs Manager, reporting to the Regulatory Affairs Director. You will sit at the table of directors, interface with commercial VPs, and really have the opportunity to make an impact within the business.

You will navigate complex regulatory challenges such as MDR and French regulations for the three business units and advise the key stakeholders on strategy and technical elements building trust internally and externally.

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THE RESPONSIBILITIES

- Develop regulatory strategy
- Create complex regulatory submissions/playbook, exercising judgment to protect proprietary information for finalization and submission
- Act as a Member of the French Country Leadership Team
- Identify and develop complex Regulatory Affairs process improvement initiatives
- Execute all RA activities to ensure compliant product distribution
- Lead portions of projects to identify trends, assess impact, analyze alternatives and recommend action plans
- Represent the regulatory function on manufacturing and product development teams to provide input on regulatory requirements

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THE RESPONSIBILITIES

- Prepare documents for submissions, including assuring the appropriate forms for all appropriate regulatory bodies
- Provide guidance and feedback to stakeholders on regulatory activities
- Review and approve materials
- Build and maintain relationships with local regulatory authorities and national trade associations; act as a point of contact for regulatory authorities
- Requests for clinical trial authorizations in the relevant location and monitoring their progress, report serious adverse events
- Local implementation of corrective actions
- Tasks linked to the first marketing of a new medical device
- Provide training and knowledge transfer to team members

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YOUR QUALIFICATIONS

- Minimum of 4 years experience in Regulatory Affairs within the Medical Devices industry
- Knowledge of French regularities regarding RA
- Advanced English speaking and writing ability

INTERESTED TO EXPLORE THIS FURTHER?

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