SENIOR DIRECTOR REGULATORY AFFAIRS AND QUALITY ASSURANCE

Cork, Ireland (relocation offered to EU nationals)

THE COMPANY

This is an exciting position to join a world leader at the forefront of healthcare innovation. With over 40,000 employees worldwide, the Regulatory/Quality Senior Director will be THE leader for all EMEA regulatory and quality matters for the company, and part of the extended leadership team for the EU President. This is a multi-site, multi-region and multi-layered responsibility. The team size is approx. 60 people covering various areas in regulatory affairs and quality including;

- Local Country registrations across the EMEA region for the whole portfolio across all business units of the company (class I-III)
- Post Market strategy
- Regional QMS strategy

Your direct reports will be senior managers and associate directors. This is a position with a high level of exposure and influence within the company, and reports directly into the regional president.

AS SENIOR DIRECTOR REGULATORY AFFAIRS / QUALITY YOU WILL:

- Formulate the regulatory strategy for the region, developing departmental budgets, and representing the EMEA RA department in corporate company projects
- Develop the strategy and budget for the department to achieve and optimize key objectives
- Lead a department of approx. 60 regulatory staff in multiple countries across EMEA. Develop and manage upcoming leaders to improve overall performance
- Provide guidance on regulatory changes and opportunities to legal teams and executive management
- Establish RA policy and best practices and ensure compliance to them
- Assess the changing social, political and economic regulatory environment for your region, and develop regulatory strategies for the maintenance and new product introduction of medical devices into these markets
- Oversee communication with regulatory agencies
- Your internal partners will be regional and business unit leaders
- Your role will be to foster strong collaborative relationships with these partners in order to achieve business objectives
- Establish best practices for EU regulatory activities and ensure consistent application across all product lines
- Support new product development by reviewing regulatory launch strategies and advising on any potential issues for registration in the EMEA market
- Act as company RA/QA representative during audits and inspections
- Leading the team responsible for PMS and taking responsibility for recalls, product withdrawals and other associated events.
- Developing the QMS strategy for EMEA and taking responsibility for supplier management and onboarding

We are looking for successful regulatory professionals with a proven track record. If you are excited by the prospect of working in a multifaceted matrix environment and able to build successful working relationships with both internal and external partners, this could be a great career step for you!

EXPECTATIONS

- Degree in Life sciences or Engineering
- 10 years working experience in medical devices
- Strong working experience of regulatory/quality activities in the EMEA region
- Multi layer management experience (managing managers)
- Fluent English
- Strong working knowledge of ISO 13485, QSR, MDR, MDDAbility to build relationships with other areas of the organisation and influence

Interested to explore this further?

Please send your CV to elena@elemed.eu to arrange a confidential career discussion.