# 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.

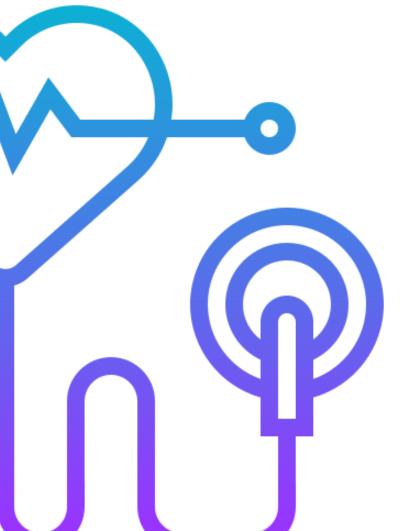
## AS SENIOR DIRECTOR REGULATORY AFFAIRS / QUALITY YOU WILL:

- 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.