Director Regulatory Affairs EMEA

Zurich, Switzerland

This is an exciting position to join a world leader at the forefront of healthcare innovation. With over 15,000 employees worldwide, the Regulatory Affairs Director EMEA will be THE leader for all EMEA regulatory 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. 100 people covering various areas in regulatory affairs including;

- MDR
- Product regulatory submissions across 3 sites (mainly class III devices, accessories and biomaterials)
- Middle East, North Africa & CIS region
- Local EU Country registrations 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 to the Global VP of Regulatory
- 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 to the Global VP of Regulatory

As Director Regulatory Affairs EMEA 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
- Oversee the development of regulatory submissions (including FDA regulatory submissions and global submissions), evaluation of labelling, marketing, advertising and promotional material
- Lead a department of approx. 100 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
- Oversee communication with regulatory agencies
- Manage the regulatory affairs workstream for MDR (the MDR transition project is well underway with a dedicated budget and internal resources)
- Your internal partners will be regional and business unit leaders. As Director RA EMEA, your role will be to foster strong collaborative relationships with these partners in order to achieve business objectives
- Represent the organisation in industry associations such as Medtech Europe and AdvaMed
- Establish best practices for EU regulatory activities and ensure consistent application across all product lines

>>> Swipe up

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 Lifesciences or Engineering
- 10 years working experience in medical devices (invasive or implantable)
- Strong working experience of the CE marking process and regulatory affairs
- Multi layer management experience (managing managers)
- Fluent English
- Strong working knowledge of ISO 13485, QSR, MDR, MDD
- Ability to build relationships with other areas of the organisation and influence

We'd love to hear from you!
Please send your CV to elena@elemed.eu to arrange a confidential career discussion.