NETHERLANDS, UK, IRELAND, FRANCE, BERLIN/MUNICH, MILAN, MADRID

Executive Director - International Regulatory Affairs

EMEA, CIS, LATAM + APAC

ELENA@ELEMED.EU

The company

This is a company going through a transformation.

If your initial reaction to the sentence above was a feeling of dread - this role isn't for you - but Elemed has loads of other great opportunities, so please go back and check out our vacancy page!

If "transformation" evokes curiosity and excitement, read on! This role is a huge opportunity for an executive regulatory leader who's open to a new challenge - not just a new job. It's a chance to inject some excitement back into your professional life, roll up your sleeves, and have some fun along the way.

This is an exciting senior leadership position to join a global Healthcare company that's a household name all over the world. In this role, you'll lead the international & commercial side of regulatory affairs.

If you want to go far, go together. This role is for a people-oriented leader, someone who takes a genuine interest in different cultures and backgrounds, because you'll be leading a department of 85+ people across EMEA, CIS, APAC, and LATAM.

The opportunity

Your role as Executive Director for International Regulatory Affairs:

The Executive Director, Regulatory Affairs, will provide leadership and strategic direction for all commercial regulatory affairs topics in key markets; leading commercial regulatory teams in Europe, Russia, Australia, and India to name a few. This is a multicultural, multilayered role, interfacing heavily with the senior leadership of the Commercial Organisation, Global RA, and Business Unit leadership within the company.

If you’re looking for a technical regulatory role focused on creating technical documentation, this isn’t for you. This role is all about regulatory complexity across different regions, leading culturally diverse teams, and acting as a key strategic partner to the business to support timely registration, regulatory clearance, and regulatory approvals in the regions. Do you have a creative, problem-solving mindset? Brexit, Swisxit, the changing situation in Russia - are all challenges your team will work on.

The responsibilities

This is a position with a high level of visibility within the company, and reports to the Senior VP of Regulatory Affairs. As executive director of regulatory affairs you will be an active member of the global regulatory affairs Leadership team:

- Partner with the Global Regulatory team on the development of strategies for NPI and lifecycle management - to ensure regional and local requirements are taken into consideration during product development activities
- Identify as early as possible, the required documentation and any content, quality, and/or timeline issues. Negotiate the delivery of approved technical source documents in accordance with project timelines.
- Lead an international and cross-cultural department, managing managers in multiple countries
- Develop and manage upcoming leaders to improve overall team performance and capability
- Build a sound working relationship and partner with other senior stakeholders from Commercial, Supply chain, Quality, and Global RA, to set objectives and priorities in line with business goals...

The responsibilities

- Ensures regulatory deliverables are agreed and executed on time and in line with budgets
- Provide leadership to international regulatory teams and drive submission activities to achieve timely regulatory clearance in the company’s key markets
- Regulatory Intelligence: provide guidance on regulatory changes and opportunities in the region to legal manufacturer teams, executive management, and other partners
- Ensures that data are identified, obtained, and effectively presented for successful filing, approval, registration, market launch, maintenance of business, and regulatory compliance
- Support key company-wide initiatives and transformation projects;

We are looking for a strong regulatory leader with a proven track record of managing culturally diverse teams. If you are excited by the prospect of working in a growing company that favours innovation and inclusion, this is the role for you!

Expectations

- Degree in Life Sciences or Engineering
- min. 15+ years of working experience in medical devices
- Multi-layer management experience (managing managers)
- Fluent English
- Regional Regulatory experience
- Track record of managing through change

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

ELENA@ELEMED.EU

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