EXECUTIVE DIRECTOR - INTERNATIONAL REGULATORY AFFAIRS

EMEA, CIS, LATAM + APAC

- Remote in Netherlands, UK, Ireland, Germany, Italy, Spain or France
- Travel 25%
- Contact: elena@elemed.eu

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→ THE COMPANY

Is it time for a **FRESH**, **NEW** challenge in a **FRESH**, **NEW COMPANY**?

This company is starting a new chapter of its story.
And it's a story you will have the chance to shape!

This is an exciting senior leadership position to join a global Healthcare company that's a household name. This company is starting a new chapter of its story. And it's a story you will have the chance to shape!

If you want to go far, go together. This role is for a people oriented leader with diplomacy skills. Someone who takes a genuine interest in different cultures and backgrounds. You'll leading a department of 85+ people and working with partners all across the world.

Elemed loves this role because:

Impact: You'll have the chance to shape the future
Influence: You will sit on the global Regulatory Leadership Team
Broad leadership scope: across EMEA, CIS, APAC and LATAM
Creativity: develop new processes & put your own stamp
Complexity: broad product portfolio of drugs, devices, OTC and more!
Be a change catalyst: by challenging the how, the what and the why
Geo expansion: is on the agenda and you will facilitate it!
Partnership: sit at the cross-section between R&D, the business & the region

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→ OPPORTUNITY

Your role as Executive Director for International Regulatory Affairs:

Are you comfortable challenging the status quo?

In this role, you'll lead the international & commercial side of regulatory affairs.

The Executive Director, International 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, 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 regulatory role focussed technical documentation, this isn't for you.

This role is all about providing direction across different regions where there is regulatory complexity, setting strategic priorities based on business needs, getting the best out of your team, and building the future. Do you have a creative, problem-solving mindset?

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→ 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

→ RESPONSIBILITIES

- Lead interactions with regulatory authorities across the regions in order to negotiate cost effective and timely registration pathways
- 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 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!

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REQUIREMENTS

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

GET IN TOUCH

Interested to explore this further?
Please send your CV to **elena@elemed.eu** to arrange a confidential career discussion.

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/

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