DIRECTOR REGULATORY AFFAIRS

Paris, France

Language requirements:

English and French

Do you have the following experience?

Essential requirements

1. 10+ years of experience in regulatory affairs
2. Medical devices OR IVD
3. Strong leadership/team management experience

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The company

Tired of working for the same big slow moving corporation where the key decisions are made far away of Europe? Are you looking for a role that will allow you more autonomy and the chance to lead a regulatory affairs team?

Located in the cosmopolitan city of Paris, is Elemed's newest client; a fast growing, IVD manufacturer. Small in terms of people, but not small in terms of presence. This is **not** an opportunity in a mono-product, mono-franco environment. This company has a significant product portfolio covering reagents, instruments AND software. The company designs, develops, manufactures and sells their products for the global market: EMEA, N.AMERICA, LATAM & APAC.

In this role you'll be at the heart of the company's operations as legal manufacturer, overseeing a broad range of activities covering both premarket and postmarket Regulatory affairs activities, as well as leading a growing and dynamic team. This is a great role for an ambitious Regulatory professional, wanting a chance to step up to director level.

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The role

In this role as Director Regulatory affairs, your responsibilities will centre on the following goals:

Leadership: Manage the Regulatory affairs team organising their work and priorities, supporting them to achieve their objectives and ensuring the continuous skills-development of the group. This role will also act as the deputy for the Sr Director QA/RA.

RA: Supervise pre-and post market regulatory activities to ensure the devices manufactured and distributed by the company are brought to market and maintained on the market globally.

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Leadership

- Support the group QA/RA Leader to define global regulatory strategies to bring new products to market and maintain existing products
- Define your team's goals and objectives, and ensure they are achieved by driving, supporting, mentoring and motivating them.
- Manage the team and allocated resources and budget, in order to ensure the leadership's vision and objectives are achieved
- You'll oversee global regulatory monitoring and ensure compliance with regulatory requirements specific to In vitro diagnostics (IVDs; instruments, software and reagents)
- Overseeing international registrations through connections with local partners, subsidiaries and distributors and ensure compliance with local country regulations
- Being an integral part of the continual work on the transition to the new IVDR (2017/746)
- Effectively communicate and advocate for the company's overall business strategy
- Define and continuously improve QMS documentation relating to Regulatory activities (pre and post market)
- Look for opportunities for continuous process improvement and communicate them to leadership
- Carrying out Regulatory Intelligence: to make sure you are updated on the changing regulatory requirements around the world; in particular in markets of interest.

The requirements

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INTERESTED IN THIS ROLE?

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