REGULATORY AFFAIRS MANAGER

→ LYON, FRANCE

→ Contact: clarisse@elemed.eu

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THE COMPANY

Ready for something extremely dynamic and different from the norm? We are recruiting for a super high-growth molecular biology IVD startup that has not doubled, not tripled, not quadrupled, but has enjoyed a 10x growth in the last 2 years! With its team of molecular and mechatronic experts, it designs, produces, and markets high added value reagents and automation systems for medical biology laboratories in France and abroad.

Do you love collaborative working environments? This startup was founded by one of the best molecular biology minds in the business and has enjoyed exponential and explosive growth in the last few years, due to the COVID pandemic. This startup company dominates a large percentage of the French market through high-ticket strategic partnerships and exclusive distribution agreements.

As they reach the next stage of their company growth, the goal is to reinvest the profits back into the business with a new, ambitious plan: to transform their current business model from one of distributor to one of legal manufacturer, bring a new and expanded product portfolio to the market, and to grow the RA team.

Calling a Regulatory Affairs Manager!
Your mission: to enable this ambition to be realised.

YOUR ROLE

In this role as Regulatory Affairs Manager you will be implementing and evolving the policy and strategy for export registration and CE marking of their products, in line with the other policies and strategies of the company (HR, purchasing, marketing, and sales, etc).

You will also be responsible for developing the regulatory team!

You will ensure communication with the competent authorities of the countries for all issues related to the registration for sale of the products in the countries as well as issues related to the post-marketing follow-up.

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→ RESPONSIBILITIES

- Ensure that the technical documentation for products developed and manufactured under the company's name is complete and up to date at all times
- Ensure the notification of the organization for changes envisaged by the company on products and processes
- Participate in the definition of the registration strategy for new markets
- Coordinate the follow-up of registrations abroad, in conjunction with local partners
- Ensure the completion of notarisation, legalisation, and apostille actions for export product registrations
- Coordinate regulatory monitoring
- Validate product materials before their use
- Ensure compliance of commercial documentation with regulatory requirements
- Be responsible for entering product information into the EUDAMED database

REQUIREMENTS

- 5+ years of experience in a Regulatory Affairs role in Medical devices or IVD company
- Fluent written English

GET IN TOUCH

Interested to explore this further?

Please send your CV to **clarisse@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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