Regulatory Affairs Manager

HOME-BASED IN GERMANY, NETHERLANDS, FRANCE, UK, BELGIUM, ITALY OR SPAIN

THE COMPANY

This company is fast growing global organisation, with an incredible class III cancer therapy device. If you're looking for the chance to work on something never seen before and really innovative and complex (from a regulatory point of view) - then look no further! This product truly improves patient lives and working here will give you an incredible sense of purpose

They are passionate about providing a fantastic onboarding experience and development opportunities, so that you'll feel embedded in the business from day one with ongoing support for your professional growth.

They also live and breathe their values in everything that they do, every day. So if you're a values-led individual, this could be the perfect opportunity for you!

The role

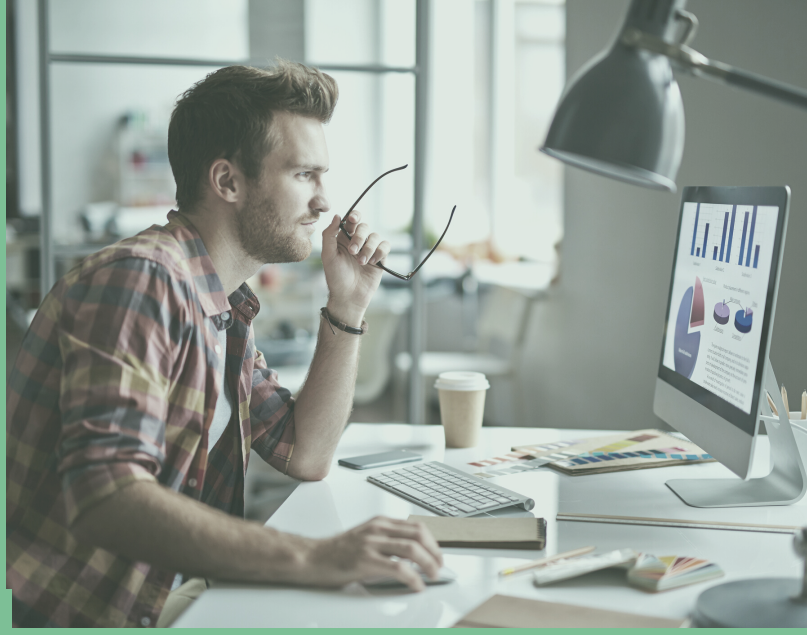
As Regulatory Affairs Manager, you can work remotely from Germany, Netherlands, Belgium, UK, France, Italy or Spain! You'll be the main person responsible for driving and executing the regulatory strategy for the EMEA region, as well as ensuring that the regulatory documentation is developed, maintained and applied in a practical, coordinated and effective manner, in alignment with company goals and global regulations.

The Responsibilities

Develop regulatory strategies for new product introductions and changes to existing products

- Represent the regulatory function on new product development projects, providing support and guidance on EU regulations and requirements so as to ensure successful submissions
- Supporting the transition from MDD to MDR
- CE marking & maintenance of technical documentation
- Support post market and regulatory compliance activities, as well as evaluating events for report-ability, and undertaking regulatory reporting as required
- Support with global regulatory activities in other highly regulated markets (i.e USA/Canada)

(not an exhaustive list)



Interested?

Get in touch with Elena at elena@elemed.eu

GET IN TOUCH WITH ELENA

THE REQUIREMENTS

- Class III medical device experience
- Experience authoring a technical file OR driving a section from start to end Experience negotiating & liaising with a Notified Body
- Fluent English reading, writing and speaking

IF YOU WANT TO FIND OUT MORE ABOUT OUR OTHER ROLES...

VISIT OUR VACANCIES PAGE