

Regulatory Affairs Combination Device

Remotely Based

Are you excited by new product development? Do you have experience with combination devices? Need a new, exciting project to sink your teeth into? We have just the thing!

We are working with a global life science and healthcare company driven by a passion for discovery and research. This company has a huge portfolio of devices to solve global challenges in the healthcare industry but they don't stop there!

As a result of consistent investment into R&D and innovation, they are currently developing a new combination device. You will provide regulatory support throughout the development project to ensure alignment with regulatory requirements, define submission timelines and then submit documentation to the Health Authorities. This is a 12 month project (possibility of extension) with very high visibility, a well defined scope and clearly outlined goals. Perfect for if you like working towards something clear and specific!

In this project you will (not limited to):

- Use your expertise in Regulatory Affairs for combination products to support the new ongoing product development project
- Collaborate with the European site Head to ensure alignment on the necessary requirements throughout the project
- Define and outline the various milestones and submission timelines to have clear set goals to work towards
- Work with various teams in the business during the project
- Create and submit the regulatory documentation to necessary Health Authorities



Requirements:

- Strong experience supporting the development of new combination devices
- Expertise and experience with registering medical devices in European and US markets (Notified Bodies and FDA)
- Clear understanding of the MDR requirements for drug/device combination devices
- Fluent English language speaking, reading and writing skills

We'd love to hear from you!

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



Only applicants who meet the requirements above will be considered for the role. Unless otherwise stated we are not able to consider applicants without EU work authorization.

Elemed is an executive search firm, specialized in finding and representing exceptional talent in medtech. To find out more about our Candidate Services click here:<https://www.elemed.eu/candidates/>