elemed

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

REGULATORY AFFAIRS MANAGER

GET IN TOUCH AT KRISTINA@ELEMED.EU

THE COMPANY

It’s here: the chance to work with some of the most unique and fascinating AIMD technology we’ve ever seen! This dynamic, global company combines medical devices with other innovative therapies to fight disease and give patients more time with their loved ones.

This company is 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!

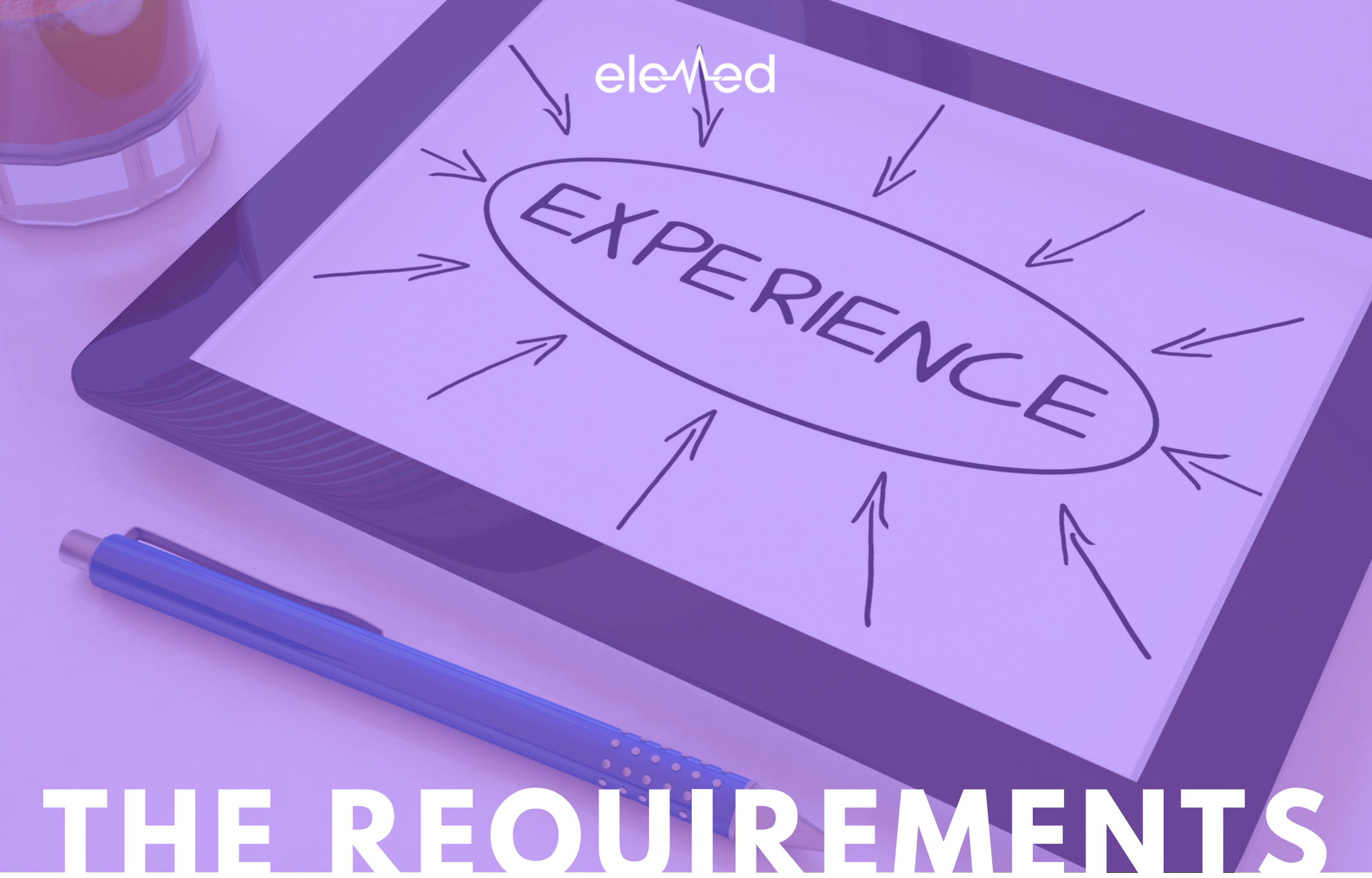
THE OPPORTUNITY

As Regulatory Affairs Manager, you can choose to work from Germany, Netherlands, Belgium, UK, France, Italy or Spain! You'll be the main person responsible for Regulatory Affairs in Europe and lead a new CE mark for the AIMD, driving the whole European RA project forward and working alongside the commercial team in Europe and other RA managers across the world.

If you're ready to take ownership of Regulatory Affairs in Europe for a fast-growing, values-led AIMD company then this is the role for you! You will have high exposure to other key parts of the business and will be working on an amazing product that really does impact the lives of patients that use it. You will be making a direct difference to their quality of life through your work.

As Regulatory Affairs Manager you will:

- Create and implement regulatory approval strategies for new and revised medical device products
- Create CE-marking documentation in line with MDR and ensuring its maintenance over time
- Provide support for post market activities
- Audit events for compliance and reportability, and completing the necessary reporting when required
- When required, work independently on complex submissions for international markets
- Collaborate with the product development teams to create regulatory submission-ready documents and with the wider business to ensure advertising material is compliant



THE REQUIREMENTS

As Regulatory Affairs Manager, you will have:

- 4+ years of regulatory affairs experience
- Class III medical device experience
- Experience authoring a technical file OR driving a section from start to end OR negotiated and liaised with a Notified Body
- Fluent English reading, writing and speaking

INTERESTED IN FURTHER CONVERSATION?

PLEASE SEND YOUR APPLICATION DIRECTLY TO KRISTINA@ELEMED.EU