REGULATORY AFFAIRS SPECIALIST

Hamburg Area, Germany (with home-office)

VERONICA@ELEMED.EU

THE COMPANY

Come and join a global leader that was one of the first companies to be certified under the IVDR and is setting the gold standard in the IVD industry.

This is a company that, in 35 years, has grown from a family business to a globally renowned brand thanks to their passion for development & innovation, and their investment in people. Their vision is to empower laboratories across the world and empower their employees to achieve their full potential which is just one of the reasons why they have been awarded “Great Place to Work”.

THE OPPORTUNITY

We are looking for an expert in Regulatory Affairs to join this team in a newly created position!

This is an opportunity to navigate the challenges of a broad portfolio of IVD devices from Class A - D under IVDD/IVDR, support key activities in the transition to IVDR such as liaising with Notified Bodies, and be responsible for technical documentation.

You will have the opportunity to manage worldwide registration and also work closely with the R&D team to guide them on regulatory matters.

THE RESPONSIBILITIES

As Regulatory Affairs Specialist you will (this is a non-exhaustive list of activities):

- Create regulatory strategies and evaluate projects
- Update and create technical files under the IVDR to maintain their regulatory status
- Submit new registrations and maintain existing registrations for the IVD portfolio Class A - D globally (CE mark, MDSAP countries etc)
- Liaise with R&D, Quality, and Regulatory teams on various projects and support Quality Management and PMS activities
- Build and nurture key relationships with European Authorities and Notified Bodies as the regulatory contact person for projects relating to the IVDR
- Submit data to key databases such as FDA, EUDAMED
- Review and release marketing materials, IFUs, and labels
- Execute clinical and regulatory tasks

YOUR QUALIFICATIONS

- 3+ years of Regulatory Affairs experience in the IVD/medical device industry
- Fluent speaking, reading, and writing skills in English

INTERESTED TO EXPLORE THIS FURTHER?

If you are interested in this exciting role, please send your application directly to **veronica@elemed.eu**

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/