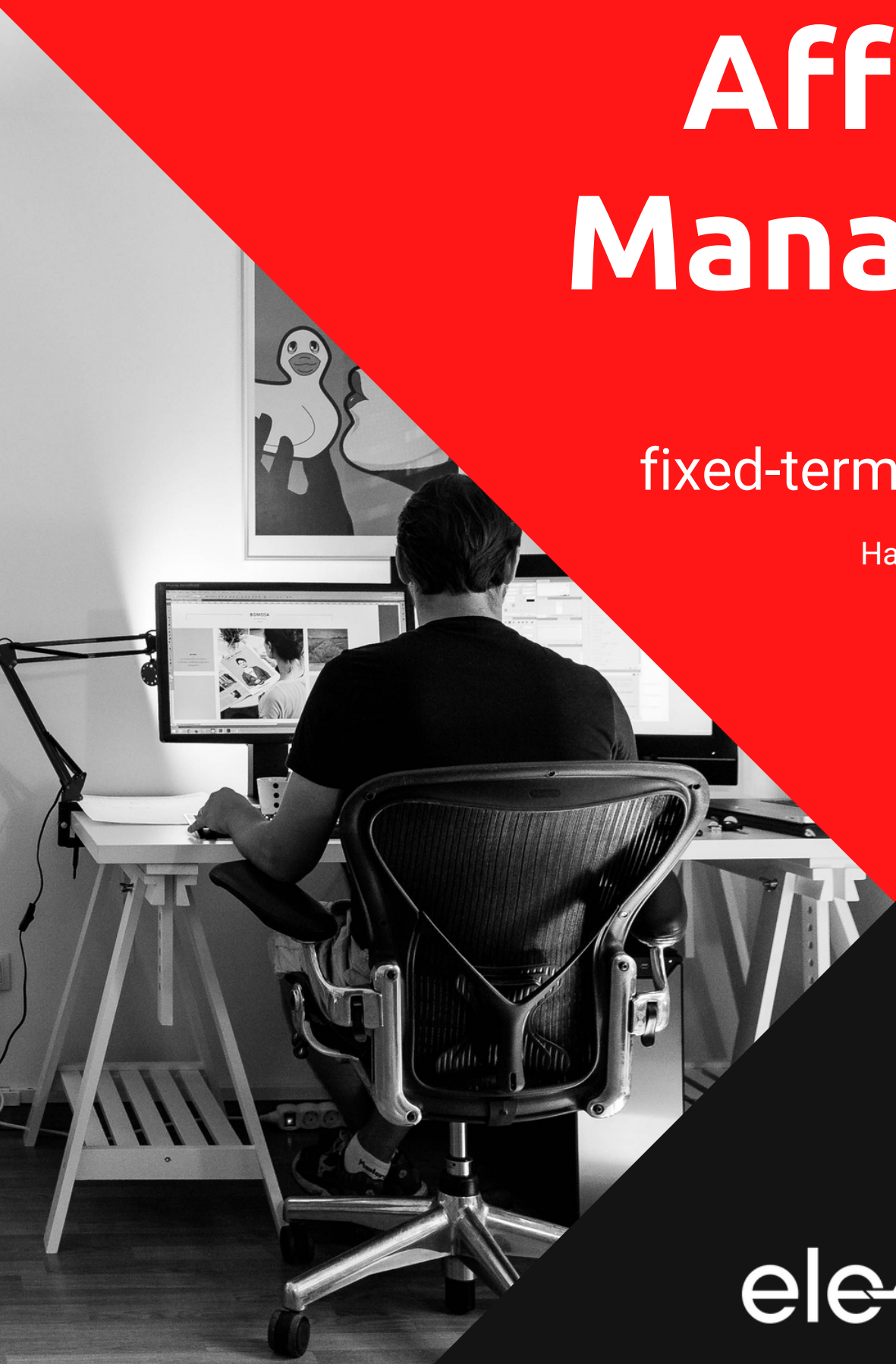
Regulatory Affairs Manager

2 year
fixed-term contract

Hamburg, Germany



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The Company

If you are looking for an opportunity to gain critical experience working on the transition to IVDR, look no further! Come and join a global leader who 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 into 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 for a 2 years fixed-term contract! This is an opportunity to navigate the challenges of a broad portfolio of IVD devices from Class A - D under IVDD/IVDR. As well as supporting key activities in the transition to IVDR such as liaising with notified bodies, you will also work closely with the R&D team to guide them on regulatory matters.

As Regulatory Affairs Manager

This is a non-exhaustive list of activities:

- 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

Requirements

Applicants must meet the following:

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

Interested in further conversation?

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