REGULATORY AFFAIRS MANAGER

Munich, Germany

THE COMPANY

Are you an expert in In-Vitro Diagnostic Devices? Do you want to be part of the exciting IVDR journey? Do you want to work for a company that will leave a legacy within the MedTech industry? We have just the opportunity for you!

We are working with a leading global organisation who ensures that diagnostic and medical device manufacturers meet the requirements set out in European legislation keeping them safe and effective. This is an opportunity to join a growing team, based in Munich, to be a key advisor to international stakeholders on all topics surrounding the IVDR.

This company invests heavily into their employees' development and training so you can expect to be onboarded with a state-of-the-art training programme worth 80,000 euros. You will deepenyour knowledge within IVDR, get qualified as an accredited auditor and learn from some of the best IVD experts in the industry.

THE ROLE

This is an exciting opportunity to advise international stakeholders, from those based in Europe to the US to Japan on all key aspects of the IVDR. You will work cross-functionally with the Clinical, Regulatory Affairs, Quality Assurance and R&D teams in the business. A great opportunity to develop your expertise across a broad range of disciplines.

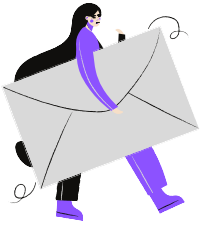
As Regulatory Affairs Manager you will (this is a non-exhaustive list of activities)**:**

- Ensure cross-functional and international compliance with the IVDR within the business
- Identify, assess and analyse regulatory risks and ensure relevant stakeholders are aware of them
- Work closely with the Clinical, Regulatory Affairs, Quality Assurance and R&D teams to ensure processes and procedures are compliant with the relevant regulatory requirements
- Support internal audits
- Assess internal processes and Quality Management documents to ensure any changes are compliant with the IVDR

REQUIREMENTS

Applicants must meet the following:

- Hold at least a Bachelor's degree in a relevant science or engineering
- Minimum 4 years of experience in Regulatory Affairs for IVD devices
- Hands-on, working experience within IVDR
- Business level communication, written and reading skills in both English and German



If you think you can bring any of the above to Elemed we would LOVE to hear from you!

Send your CV to **kristina@elemed.eu** for a confidential career discussion. Good Luck!