Product Specialist IVD

GERMANY

The Company

Do you want to further develop your career in the newest innovations across in vitro diagnostic technology?

Think about joining a Notified Body! This company is one of the global leaders for assessing whether diagnostic manufacturers meet the requirements set out in European legislation, ensuring their products are safe and effective. This is a great chance to really be at the centre of the most cutting edge in vitro diagnostics technology entering the market.

This is a newly created role and a unique chance for an in vitro diagnostic professional with experience in R&D, Quality or Regulatory Affairs to use those skills in a new context. You will get access to advanced training, learning about the new In Vitro Diagnostic Regulation. This is a chance to be part of and central to the biggest change affecting the Diagnostics industry in the last 50 years.

Why this company?

- Gain invaluable experience in the IVD sector with one of the top market companies.
- Work alongside a diversified, young and passionate team.
- Build your internal career based on your true interests.
- Work from home, anywhere in Germany.
- Enjoy the international environment, while using English as a main language connecting all.

Activities associated with this role

As IVD Product Specialist, you will:

- Technical: Review and assess Technical Documentation for in vitro diagnostic.
- Provide product demonstration and ensure compliance to the IVD conformity assessment scheme and applicable Standards.
- Act as internal EU expert for all questions and queries relating to In Vitro Diagnostic products and providing information to colleagues with regard to standards, regulatory and technical requirements for compliance with standards and the respective regulatory system.
- Preparing product reports and documentation for submission to the certification committee of the Notified Body.
- Project management: Supporting multiple product-related projects, audits and answering specific questions relating to your area of expertise.

Job requirements:

- Minimum 4 years' experience in R&D, Regulatory Affairs or Quality for IVD.
- Good knowledge of in vitro diagnostic products.
- Scientific MA or PhD degree.
- Fluency in English, German is a plus.
- Ability to independently work from home and deliver designated tasks in a timely manner.
- Eligibility to work in EU.

Are you looking to transform your career alongside top industry professionals? If you have a strong appreciation of different cultures and a desire to really immerse yourself in the field of companion diagnostics, apply to this role!

Interested in further conversation?
Please send your CV to monika@elemed.eu
to arrange a confidential career discussion.

Elemed is a truly niche recruitment business dedicated solely to QA/RA for the European Medtech Industry. We serve within the Medical device, diagnostic and combination device arena, working with Managers up to VP of Quality, IVD and Regulatory. We are proud to have one of the largest RA/QA/IVD Medtech networks in Europe, comprising of individuals from key Competent Authorities and Notified Bodies, experts from industry associations such as EUCOMED, RA/QA Directors of corporate giants and CEOs of Medtech start ups. Our network, expertise and quality of service is what sets us apart.