CLINICAL REVIEWER FOR IVDR

Hamburg, Munich or Home based in Germany

The Opportunity

The In Vitro Diagnostic Regulation is THE biggest change that the IVD industry has seen. Experts have estimated that over 80% of the IVDs will need the input of a Notified Body, compared to just 20% that we see today.

This has created a great opportunity for IVD professionals to be part of a pioneering change impacting the industry. The clinical reviewer for IVDR is a newly created position at one of the world's leading Notified Bodies. This is a chance to be part of something new, in a company driven by ethics, not profits. You'll be surrounded by highly qualified professionals, experts in their respective fields. You'll also have the chance to see, first hand, some of the most innovative technology in the IVD world.

The Company

This is a pioneering role in one of the most successful Notified Bodies in the world - offering regular hours, great stability and a global working environment. Recently named "Top employer in Germany", the leadership style is co-operative and really focussed on collaboration. In this role, you'll join a highly successful team, which has enjoyed 50% year on year growth. Reporting directly to the head of the group (physician by background), you can be sure, you'll have a high amount of exposure and visibility! You'll be constantly learning and expanding your area of expertise and have access to world class in depth training on the new IVDR.

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Desired profile

According to the requirements set out under the IVDR, we are looking for candidates who fulfill 100% of the non-negotiable criteria:

- University degree as physician, medical degree or medical doctor
- 4 years of professional experience in IVD industry; medicine, or laboratory medicine
- 2 years: Working in Clinical Studies of IVD devices or Testing/ clinical evaluation of IVDs
- Direct work experience in patient care
- Proficiency in English and (preferably German)- Based in Germany

As Clinical Reviewer for IVDR, your role will cover 4 major pillars of responsibility; conducting file reviews, project management, customer service, and developing your expertise.

In this role you will:

- Review and scientifically challenge the clinical data presented by the manufacturer in the clinical evaluation and any clinical investigations
- Assess the manufacturer's clinical evaluation reports and corresponding documents
- Draw up reports demonstrating the result of the relevant conformity assessment activities
- Based on the above activities, you'll make an expert recommendation to the Notified Body's decision maker
- Take responsibility for managing multiple projects, and responding to questions from internal and external partners on standards, regulatory and technical requirements to achieve compliance with the relevant regulatory system
- Develop strong communication skills by issuing quotes and supporting customers with relevant information and answering questions
- Continuously build and maintain a high level of expertise relating to present and pending regulatory requirements and standards, by attending internal and external training courses and reading scientific articles.

Interested to explore this further?

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

PLEASE NOTE!!!
ELEMED HAS EXCLUSIVE AGENCY RIGHTS TO RECRUIT THIS ROLE.