Looking for Engineers and Scientific Experts interested in IVD

IVD Senior Associate - Switzerland

Medidee Services is the leading expert consultancy service supporting Medical Devices and In-Vitro Diagnostics (IVD) compliance internationally. We serve clients with hands-on support for compliance with applicable regulatory requirements in our clients' target markets. Our services cover all steps of Medical Device and IVD development, from the initial project idea, design and development, through to clinical validation, regulatory clearance and post market surveillance activities.

With offices in Switzerland, Belgium, Germany, Denmark, APAC and in the USA, Medidee Services is active worldwide.

We are looking for qualified individuals with an in-depth IVD regulatory background. Applicants should be fluent in English (German and/or French is a plus). They will be responsible for implementing complex IVD projects within the scope of the current regulatory changes.

You will quickly act as an interface with clients on multiple projects in parallel and possibly with Notified Bodies to support new product market access and/or to address challenges of already marketed products.

Your mission will be to provide the following consulting services to our clients:

- Act as one of the Subject Matter Experts within the company for IVD related topics
- Provide strategic regulatory support related to the compliance of IVD in EU (2017/746 EU) and USA
- Evaluate high complexity scientific/technical documentation, identify gaps and provide support for improvement
- Manage projects in a structured way and act as an interface with external clients, Competent Authorities and Notified Bodies during audits, conformity assessments and with product specific regulatory issues
- Provide consultancy and active support for our clients during the development of new products
- Participate to the strategic development of IVD activities within Medidee
- Participate to Medidee training programs and represent Medidee in congresses and fairs

Working with us

Autonomy and self-management are required to address a wide variety of projects and customers. Inspiration for excellence and attention to detail are important aspects for Medidee.

We offer projects involving cutting-edge innovation in the IVD industry that will require quick learning of technical and medical concepts in order to best guide our clients. Your colleagues are other engineers and scientific experts, and opportunities are provided to share experiences and competences. Traveling is also part of the experience. We are looking for individuals with:

- Successful track in the R&D of IVDs in the industry, with a scientific, or engineering background capable of understanding and assessing the technical documentation under IVDR and US regulatory systems
- 2-3 years of experience in Regulatory Affairs related to IVD in EU and USA
- Agile on both the IVD equipment and reagents sides
- Knowledge of QMS implementation under ISO13485

- Experience in the Design and Development process requirements for IVD (particularly design control, risk assessment and verification)
- Enjoying networking and having facilitation skills
- Fluent in English, both oral and written (German and/or French is a plus)

Interested?

Send an email including CV and short bio to Dr Silvia Anghel at silvia.anghel@medidee.com