Looking for Engineers and Scientific Experts interested in IVD

IVD Project 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 IVD engineering background. Applicants should be fluent in English (German and/or French is a plus). They will be responsible for the assessment and implementation of IVD technical documentation for EU and USA, including hardware and software.

Brought to evolve in order to take direct accountability for EU and USA registrations projects, you will gradually act as an interface with clients 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:

- Evaluate scientific/technical documentation, identify and address gaps of IVD product to assure compliance (hardware and/or software)
- Support clients with the initial development of the technical documentation
- Provide regulatory support for EU and/or USA
- Assure cross-functional Project Management (internal and external)

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:

- 3 years' experience related to the development of IVD products (hardware and/or software) in an ISO13485 environment; regulatory and or quality experience is a plus
- Knowledge of the technical requirements related to the registration of IVD in EU and/or USA
- Experience with writing technical documentation, including protocols and reports
- Knowledge of the technical product compliance (such as product safety, RoHS Directive, Electromagnetic Compatibility Directive, Low Voltage Directive and Machinery Directive)
- Very good understanding of the development steps and related controls; knowledge of risk assessment

Interested?

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