Looking for Engineers and Scientific Experts interested in Medical Devices

Medical Devices Verification & Validation 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.

For our office in Lausanne or Olten, we are looking for an engineer with Medical Devices development background. Applicants should be fluent in English (German and/or French is a plus). He/she will be responsible for helping our client to plan and manage the testing and documentation of their products. He/she will work in parallel on various Client projects, sometimes at the strategic level, sometimes down to the choice of labs and the help for preparing protocols.

Brought to evolve in order to take direct accountability for EU and USA compliance 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 on already marketed products.

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

- Support clients with the initial development of the technical documentation and the identification of actual requirements
- Evaluate scientific/technical documentation, identify and address gaps to assure compliance (hardware and/or software)
- Provide help on the test sequence and standards requirements
- 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:

- ETH/EPF engineer, PhD is a plus
- Ease at interacting and coaching others, such as colleagues and clients
- Capable of balancing risks related to the product and project timelines
- 3 years' industrial experience related to the development of MedTech products (electronics, mechatronics, software) in an ISO13485 environment; regulatory / quality experience is a plus
- Knowledge and/or strong interest for the technical requirements and standards related to CE marking (such as product safety, RoHS, EMC Directive, Low Voltage and Machinery Directives)
- Experience on writing technical documentation, including protocols and reports
- Good understanding of the development steps and control; knowledge of the risk assessment

Interested?

Send an email including CV and short bio to Dr Jurjen Zoethout at jurjen.zoethout@medidee.com