Looking for a Senior Associate – RA / QA consulting and Business Development - Horsham PA, USA

Medical Devices and/or IVD

Medidee Services is a leading European RA, QA and Clinical consulting firm supporting Medical Devices and IVD compliance internationally. We serve clients ranging from startups to global players with hands-on support for compliance with applicable regulatory requirements.

Our services support the whole lifecycle of Medical Device and IVD development, from the initial device idea, design & development, industrialization, V&V testing towards to clinical validation, regulatory clearance, and post market surveillance activities. With offices in Switzerland, Belgium, Germany, Denmark, India, APAC and in the USA, Medidee Services is active worldwide.

For our office in Horsham, Pennsylvania, we are looking for an established RA and/or QA professional with a MedTech background and a strong orientation towards business development and project management. Should you reside in another East Coast state, we are ready to adapt.

You will play an essential role in the deployment of our services on the East Coast. Initially directly supported by the top management of Medidee, you will gradually be empowered to build a significant independency, suiting well a strong leadership profile.

About one half of the workload (estimation) will be related to the following business development activities, supported by our subject matter experts based in Europe and other regions:

- Organizing trainings and events in the MedTech ecosystems (both startups and larger companies) to build awareness on Medidee services
- Profiling business targets for development and proactively developing contacts with decisions makers
- Navigating target accounts, pursuing leads, and closing deals.

The other half of the mission will be related to consulting operations:

- Delivering strategic and tactical consulting services in the domains you already master, such a RA, or Clinical or in a recognized technical matter related to medical devices or IVD
- Supporting clients with the initial review / development of the technical documentation and the identification of actual requirements
- Providing regulatory support for EU CE marking, or interfacing with the Medidee SMEs in Europe and supporting EU clients for FDA clearance
- Assuring cross-functional Project Management (internal and external).

Working @ Medidee

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. Your colleagues are other engineers, RA, clinical and scientific experts, and daily opportunities for sharing experiences are at hand. Traveling is also part of the experience.

We are looking for individuals the following profiles:

- You have an engineering degree or you are lifetech scientist, PhD is a plus
- You have 5 years' industry experience RA and/or QA in relationship with the development of MedTech products
- You own a good understanding of the product development steps and controls
- You are experienced in interacting with regulatory stakeholders such as FDA or Notified Body
- You like interacting and coaching others, such as colleagues and clients
- You like a wide variety of activities

- Your profile is complemented with the capability of balancing risks related to product and project timelines
- You have an absolute client focus.

We offer you a job with a purpose, within a growing team of dynamic professionals in a very international cultural setup. We value learning from each other and growing together.

Interested?

Send an email including CV and short bio to Philippe Etter at philippe.etter@medidee.com