Looking for a Project Associate – RA / QA consulting – Combination Products

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, IVD and Combination Products 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, Spain, India, APAC and in the USA, Medidee Services is active worldwide.

For our office in Lausanne, Switzerland, we are looking for an established RA and QA professional with previous exposure and understanding of marketing authorization of pharmaceutical products, combined ideally with experience in Design Control process for Medical Devices.

You will play an essential role in the deployment of our services targeted at this specific industry segment, triggered by new regulatory requirements for Combination Products (pre-filled syringes, drug-delivery systems, drug-eluting implants, etc).

Your mission will be to:

- Delivering strategic and tactical consulting services to pharmaceutical companies developing combination products;
- Supporting the same clients with the implementation of Design Control processes and building evidence of compliance against regulatory requirements for the device part of the product (product development, testing, risk management, design transfer);
- Follow-up international regulation and guidance (mostly EU and US) and trends with regard to requirements for combination products;
- Interact with regulatory bodies (Notified Bodies, EMA, FDA);
- Assuring cross-functional Project Management (internal and external);
- Maintain, develop and support promotion of this service segment.

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. Reasonable traveling is also part of the experience.

We are looking for individuals the following profiles:

- You have an Industrial Pharmacist or Engineering degree, or you are lifetech scientist;
- You have 3 years' relevant industry experience RA and/or QA in relationship with the development of pharmaceuticals;
- You own a good understanding of the Market Authorization process for pharmaceuticals;
- You own a good understanding of the product development steps and controls;
- 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 and sales acumen.

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