Ready to take a new challenge? Bored doing all days the same? Eager to learn?

Medical Device Project Associate – Germany

(regions Hamburg / Berlin / Mannheim / Stuttgart / Frankfurt / München / Nürnberg)

Medidee Services is the leading expert consultancy service for Medical Devices and In-Vitro Diagnostics (IVD) internationally. We serve manufacturers, competent authorities, and public organizations with hands-on support for compliance with applicable regulatory requirements. Our services cover the entire life cycle of Medical Devices and IVDs, from design and development through clinical validation, regulatory clearance and post market surveillance activities.

With offices in Switzerland, Germany, Belgium, Denmark, APAC and the USA, Medidee Services is everywhere close to the client.

We are looking for teammates with a background in Medical Device regulatory or quality affairs, working on tasks within Medical Device projects in the framework of the current regulatory changes.

Your mission will be to:

- Manage and provide on-site / off-site hands on regulatory support and coaching to clients related to quality system compliance (Reg.EU 2017/745, ISO13485) – prepare clients for audits
- Assess technical documentation, to identify gaps and to provide hands on support for GSPR, V&V and improvement – prepare clients for conformity assessment
- Coach and assist clients in successfully managing process validation for manufacturing processes or CSV in the field of manufacturing and quality system software
- Participate in the development of services and the maintenance of Medidee service quality
- Participate in Medidee training programs and represent Medidee as subject matter expert in virtual and presence trainings

Working with us

We offer projects involving cutting-edge innovation in the MedTech industry that will require quick learning of technical and medical concepts to best guide our clients. Within our international team of engineers, scientific and clinical experts, you share experiences and complement your and your colleagues' competences. Traveling is also part of the experience.

We are looking for individuals with:

- a successful track record in the development or industrialization of Medical Devices
- a scientific or engineering background
- a first experience in Regulatory Affairs and / or ISO13485 QMS implementation and / or supplier qualification and management
- good communication and networking skills
- an excellent command of German and English (any other language skills are a plus)

Interested?

Send an email including CV and short bio to Michael Maier: michael.maier@medidee.com