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

## Medical Device Senior 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, willing to drive complex Medical Device projects in the framework of the current regulatory changes.

Your mission will be to:

- Provide strategic and hands on regulatory support to clients related to compliance (Reg.EU 2017/745, MDSAP, ISO13485)
- Assess complex scientific / technical documentation, to identify gaps and to provide support for improvement
- Manage projects in a structured way in direct contact with Clients, Competent Authorities and Notified Bodies - during audits, conformity assessments and with product specific regulatory issues
- Coach clients on implementation and remediation activities for QMS, technical documentation
- Assist clients in successfully managing nonconformities, complaints, recalls, FSN, FSCA
- Participate in the strategic development of service activities within Medidee
- Participate in Medidee training programs and represent Medidee in congresses and fairs

**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
- at least 2 years of experience in Regulatory Affairs and / or ISO13485 QMS implementation
- good communication and networking skills, ease to speak in front of an audience
- 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