Looking for an exciting job with Medidee in Bavaria?

Medical Device Quality Assurance, Regulatory and Clinical Affairs

Project Associate – Munich Area

Medidee Services is the Leading European Expert Consultancy Service supporting Medical Devices and In-Vitro Diagnostics compliance with international regulatory requirements.

We serve clients with hands on help and support for compliance with applicable regulatory requirements of 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.

Based in Switzerland, Germany, Belgium, Denmark and the United States, we are active for clients world-wide.

We are looking for qualified individuals for serving our clients. Applicants should be fluent in German and English (other languages are a plus). Your mission will be to provide the following consulting services to our clients:

- Working on medical device projects with tight certification / submission deadlines in close cooperation with the client and in compliance with the new EU Medical Device Regulation (MDR 2017/745) and In-Vitro Diagnostic Regulation (IVDR 2017/746), as well as US 21 CFR Part 800 Regulations.
- Implementing Quality Management Systems (QMS) in compliance with ISO 13485, US 21 CFR Part 820 (GMP), as well as Medical Device Single Audit Program (MDSAP).

Delivering on-site and remote consulting services including quality management and regulatory affairs.

Working with us

Be part of a small but fast-growing group within Medidee where individual skills matter! Autonomous, self-starter and able to adapt quickly will be required to address a wide variety of projects and customers. Excellence and and attention to detail are important aspects achieving regulatory compliance.

We offer projects involving cutting-edge innovation in MedTech industry that will require quick learning of technical and medical concepts in order to best guide our clients. Your colleagues are other QM, RA and Scientific experts, and opportunities are provided to share experiences and competences. Traveling is also part of the fun! We are looking for individuals with:

- A master degree (or equivalent) in life sciences or in a technical field such as Mechanics, Electronics, Engineering, Chemicals, Software, or other subject matter expertise relevant to medical devices or IVD development.
- Experience working independently, setting own agenda and objectives
- Eager to learn and able to learn quickly
- Strong German & English writing skills; ability to communicate complex technical and medical concepts.

Interested?

Send an email including a CV and a short bio to moritz.hoyer@medidee.com