Looking for scientific experts interested in MedTech

Medical Device Regulatory, Quality, and Clinical Affairs
Project Associate – Copenhagen, Denmark

Medidee Services is the leading European expert consultancy service supporting Medical Devices and In-Vitro Diagnostics (IVD) compliance with international regulatory requirements.

We serve clients with hands-on support for compliance with applicable regulatory requirements in 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, Denmark, Belgium, Germany and the United States, Medidee Services is active worldwide.

We are looking for qualified individuals with scientific backgrounds for serving our clients located in Denmark. Applicants should be fluent in English (Danish is a plus) with a proven track record of medical and scientific writing and public speaking. 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 Medical Device Regulation (MDR 2017/745).
- Implementing Quality Management Systems (QMS) in compliance ISO 13485 / Medical Device Single Audit Program (MDSAP).
- Delivering on-site and remote consulting services including scientific writing, regulatory & clinical affairs.

Working with us

Be part of a small but fast-growing group where individual skills matter. Autonomous, self-management will be required to address a wide variety of projects and customers. Scientific excellence 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 scientific experts, and opportunities are provided to share experiences and competences. Traveling is also part of the fun! We are looking for individuals with:

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

Interested? Send an email including a CV and a short bio to kim.rochat@medidee.com