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Career Opportunity

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

Medidee Services is the Leading European Consultancy Services supporting Medical Devices and In-Vitro Diagnostics compliance with international regulatory requirements. We serve clients with hands-on 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, Denmark, Belgium, Germany and the United States, Medidee Services is active worldwide. For serving our clients located in Scandinavia, we are looking for a dynamic personality, fluent in Danish and English, with good social and interpersonal skills. Your mission will be to:

- Ensure consulting services provision to our Clients by:
  - 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) and IVD Regulation (MDR 2017/746)
  - Delivering on-site and remote consulting services including scientific writing, regulatory & clinical affairs, Quality Management Systems (QMS) setup.
  - Support for scientific and clinical activities including literature searches, literature reviews, study design, monitoring and reporting
  - Support for customer product development, verification and validation, design transfer
  - Support for risk management activities, technical and regulatory compliance
  - Support for technical documentation and file compilation
- Contribute to the business development of Medidee by
  - Conduct and execute promotion and marketing activities
  - Representing Medidee in divers' organizations and meetings

Working with us

Being part of a small but fast-growing group where individual skills matters. Autonomous, self-management and able to adapt quickly you will be required to address a large 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 to 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 degree (or equivalent) in life science or in a technical field such as Mechanics, (Bio-)Engineering, Electronics, Chemicals, Software, or other subject matter expertise relevant to medical devices.
- Familiar with medical regulations and directives environment.
- Strong English writing skills; ability to communicate complex technical and medical concepts. Native Danish, Swedish a plus.

- A first QA experience, ISO 13485 or medical CE mark process is a plus.

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