Medidee Services India
Hyderabad
500015 - India

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Career opportunity

Consultant – Medical Device Regulatory and Clinical Affairs
Project Associate – Remote, India

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, India and the United States, Medidee Services is active worldwide. For serving our clients mainly on regulatory, scientific and clinical aspects, we are looking for a dynamic personality, fluent in English, with excellent writing skills and 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 project manager and in compliance with Medical Device Regulationsin Europe (EU 2017/745 – MDR & EU 2017/746 - IVDR), US, Australia.
  - Delivering remote consulting services including scientific writing, regulatory & clinical affairs.
  - Responsible for authoring Clinical/ Performance Evaluation Plans and Reports as per MEDDEV 2.7_rev4 / MDCG / IMDRF guidances and/ or Biological Evaluation Plans and Reports as per applicable regulatory requirements
  - Responsible for authoring Post Market Surveillance (PMS) / Periodic Safety Update Report (PSUR) in accordance with applicable regulatory requirements
  - Support for scientific and clinical activities including literature searches, literature reviews, study design, remote 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 in India
  - Representing Medidee in divers' organizations and meetings when needed.

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.

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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:

- Completed a PhD (or about to complete one soon) in life science or in a technical field such as Mechanics, (Bio-)Engineering, Toxicology, Electronics, Chemicals, Software, or other subject matter expertise relevant to medical devices.
- Familiar with medical device regulations and policies and idealy with existing competences on India, MDSAP (Canada, US, Brazil, Australia and Japan) and EU regulatory frameworks.
- Strong English writing skills; ability to communicate/ present complex technical and medical concepts.
- A first experience in life science or in the market access of medical devices is a plus.

Interested? Send us an email including your CV, salary expectations, earliest available date and a short bio to *koushik.ayalasomayajula@medidee.com*