Medidee Services India
Hyderabad,
500015 - India

PHONE I +91 – 807 424 87 72
EMAIL I *koushik.ayalasomayajula@medidee.com*
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Career opportunity

Consultant – Medical Device Regulatory and Clinical Affairs – Specialist in toxicology
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 Regulations in Europe (EU 2017/745 – MDR & EU 2017/746 - IVDR), US, Australia.
  - Delivering remote consulting services including scientific writing, regulatory & clinical affairs.
  - Responsible for establishing toxicological safety assessments for materials, chemical and product constituents to ensure safety for pre-marketed and marketed medical device products.
  - Responsible for writing of final toxicological and biocompatibility (ISO 10993) reports where necessary to support the client's medical device products for registration, inlcuding test plan design considering both chemical and biological endpoints.
  - Support for scientific and clinical activities including literature searches, literature reviews and study design
  - 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 training, exhibitions 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.

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:

- Bachelor degree, Master degree or PhD (or equivalent) in life sciences, with subject matter expertise relevant to medical devices or pharmaceutical.
- Specialisation in toxicology as part of education and as part of professional experience is required

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- 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*

Note: Applications with fully furnished details as requested above shall be considered in the process. Additionally, candidates meeting the requirements shall receive a response.