Looking for a Project Associate – Biocompatibility Expert with Chemistry background

Medidee Services is a leading European RA, QA and Clinical consulting firm supporting Medical Devices and IVD compliance internationally. We serve clients ranging from startups to global players with hands-on support for compliance with applicable regulatory requirements.

Our services support the whole lifecycle of Medical Device, IVD and Combination Products development, from the initial device idea, design & development, industrialization, V&V testing towards to clinical validation, regulatory clearance, and post market surveillance activities. With offices in Switzerland, Belgium, Germany, Denmark, Spain, India, APAC and in the USA, Medidee Services is active worldwide.

To strengthen our team of biocompatibility experts, we are looking for a chemist who wants to be part of a dynamic team. You will play an essential role in the deployment of our services targeted at the Medical Device industry segment.

Your mission will be to:

- Apply technical expertise to solve biocompatibility/ toxicological questions, utilizing ingenuity, experience and independent judgment;
- Evaluate the biological risks of medical device, including substance-based devices and combination products according to ISO 10993-1 (and FDA) and elaborate Biological Evaluation Reports;
- Establish toxicological risk assessments for materials, chemicals, products.
- As required, support and interact with your colleagues in the areas of Regulatory, Quality and Clinical within Medidee, who are working on projects which require your expertise and advice.

Duties & Responsibilities

- Evaluation of material and product safety for medical devices for the Client as per ISO 10993-1 and FDA requirements;
- Ensuring appropriate documentation is established & maintained;
- Ensuring that testing meets all international & domestic test requirements according to ISO (International Organization for Standardization), FDA (Food & Drug Administration) & GLP (Good Laboratory Practice);
- Define biological safety testing strategies in collaboration with our clients;
- Supporting & coordinating activities related to initiation & generation of study proposals (in vitro and in vivo) supporting material biocompatibility testing for regulatory submissions;
- Overseeing, designing, implementing, & analyzing testing systems, procedures & test results for biocompatibility/toxicology evaluation;
- Interacting with test laboratories on behalf of our clients to ensure proper project development;
- Interacting closely and providing consultative direction and technical guidance to the client's R&D, Clinical and/or Regulatory Affairs;
- Summarizing & interpreting raw data from reports as per ISO 10993 series (chemical characterization, cytotoxicity, irritation, sensitization, pyrogenicity, systemic toxicity, implantation…);
- Contributing to development of Medidee's internal processes for Biological Evaluation
- Assuring cross-functional Project Management (internal and external)

Education & Experience Requirements

- Minimum of a Doctoral degree in chemistry or a related scientific field is required
- Excellent spoken and written English. Any other language is a plus
- Experience in the Medical Device and/or Pharma industry is a plus
- Word processing, project planning, presentation, e-mail & spreadsheet software

Soft skills:

- The ability to work collaboratively as a team member across various functions in a challenging and changing environment is required
- Communication - complex issues & concepts in a clear, concise manner
- Tenacity - overcome major obstacles
- Decision making - make sound decisions with limited facts, precedence or policy

Working @ Medidee

Autonomy and self-management are required to address a wide variety of projects and customers. Inspiration for excellence and attention to detail are important aspects for Medidee. Your colleagues are other engineers, RA, clinical and scientific experts, and daily opportunities for sharing experiences are at hand. Reasonable traveling is also part of the experience.

We offer you a job with a purpose, within a growing collaborative team of dynamic professionals in a very international cultural setup. We value learning from each other and growing together.

Interested?

Send an email including CV and short bio to Jurjen Zoethout at jurjen.zoethout@medidee.com