Looking for a Senior Associate – Biocompatibility and Toxicology Expert

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.

We are looking for a knowledgeable toxicologist with biocompatibility experience 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…);
- Interacting with regulatory bodies (Notified Bodies, EMA, FDA);
- Contributing to development of Medidee's internal processes for Biological Evaluation
- Contributing to the coaching and development of team members within Biological Evaluation
- Contributing to external training provided by Medidee for Biological Evaluation
- Assuring cross-functional Project Management (internal and external)

Education & Experience Requirements

- Minimum of a Doctoral degree (e.g. PhD, PharmD, MD or equivalent degree) in toxicology, chemistry, biology or a related scientific field is required
- A minimum of 5 years of experience in biocompatibility and/or toxicology in a medical device, pharmaceutical, and/or consumer product industry is required
- Track record of performing scientific biological and toxicological safety assessments for medical device, consumer products or pharmaceuticals is required
- Experience leading safety evaluation for multiple projects, managing priorities and time management is required
- Excellent spoken and written English. Any other language is a plus
- Board Certification in ATS, DABT, DACVP, or related certification is a plus
- Working within the medical device product development is preferred

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

Knowledge of:

- Conduct & interpretation of in vivo and in vitro studies
- Quality procedures
- ISO & FDA guidelines as related to biocompatibility testing
- Word processing, project planning, presentation, e-mail & spreadsheet software

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