MC TOX'CON

Consultant – Non-Clinical Development / Toxicology (m/f/d)

Job Profile

Starting date:	As soon as possible
Employment:	Full-time
Position:	Consultant – Non-Clinical Development / Toxicology
Business Area:	Development of drugs and medical devices

Company Information

MC Toxicology Consulting, located in Vienna, Austria, is a growing consulting company with broad and in-depth expertise in the fields of both toxicology and regulatory affairs that provides diversified support in non-clinical drug development and medical device biocompatibility testing. The team has a strong track record in non-clinical development of small molecules, oligonucleotides, medical devices, but also in supporting the non-clinical development, especially of advanced therapy medicinal products (ATMPs), including gene and gene-editing therapies and non-clinical testing of vaccines. Clients, both small- and mid-sized biotech as well as large pharma, are mainly based in Europe and North America.

MC Toxicology Consulting is currently expanding the existing team within the drug and medical device sector.

Position

As an expert for drug and/or medical device development with special focus on safety/toxicology/biocompatibility testing, quality, regulatory, risk management and usability, the Consultant – Non-Clinical Development / Toxicology will be responsible for the strategic planning and monitoring of projects, including regulatory interactions, the management of clients as well as for client acquisition.

Your Role

- Work on drug and medical device projects from early stage to marketing
- Elaborate the appropriate regulatory strategy for non-clinical development of drugs, medical devices or drug-device combinations
- Be familiar with current guidance documents for non-clinical development of drugs (EMA, FDA, ICH) or international standards for biocompatibility evaluation of medical devices (ISO 10993 series).
- Design and monitor non-clinical *in vitro* and *in vivo* studies performed at CROs
- Prepare and conduct regulatory interactions with regulatory Agencies or Notified Bodies
- Prepare and review regulatory documents (Briefing Document, IB, IND, CTD), design control and technical file documentation
- Prepare toxicological expert statements (impurities, excipients, or PDE values)

- Lead and drive client projects and take over responsibility for working closely with project team members to coordinate project activities
- Handle business development activities for future client acquisition

Your profile

- PhD or equivalent in a life sciences discipline (e.g. Chemistry, Pharmacy, Microbiology, Biotechnology, Biology)
- 3+ years of experience in drug / medical device development process and relevant regulations, with demonstrated knowledge and deep experience in two or more of the following areas: non-clinical development, toxicology, pharmacokinetics, regulatory affairs, medical devices
- Consultancy skills and willingness to take responsibility and pro-actively support our clients
- Ability to provide consultancy services independently and successfully in various virtual teams; ability to internally work in a matrix environment, prioritize and manage multiple tasks simultaneously, integrate cross-functional issues and balance competing priorities effectively
- Dedicated and determined with strong interpersonal skills; comfortable in a small company environment, but also as a virtual team member in various client teams
- Strong oral and written English communication skills
- Highly motivated team player
- Willingness to travel moderately
- Sound knowledge of Microsoft Office applications
- A high degree of energy, accuracy and attention to detail alongside a passion for delivering important new products to customers

Our offer

- Be part of a team that is well recognized in the area of non-clinical (bio)pharmaceutical and device development
- Drive projects at the forefront of medical innovation
- Opportunities to make an impact and quickly take on responsibility

Your application

If you are interested in this position, please email your complete application (including cover letter, curriculum vitae, references and certificates) to: info@toxicology.cc.

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