Regor Therapeutics Group

Regor Therapeutics Group was formed in 2018 as an independent, private biotech company. At Regor, we are dedicated to developing new small molecule-based therapeutics to improve human life. We use the latest scientific knowledge and apply novel approaches to discover new ways of treating disease. We encourage cooperation and support a high level of scientific freedom to find the best answers to biological questions.

Position: Principal Scientist/Director, Toxicology

Location: Shanghai, China

Summary

The primary responsibility of this position is to provide strategic preclinical safety expertise and representation for nonclinical and clinical development programs from IND enabling through post-marketing in a biotech organization. The successful candidate will report to the VP of Preclinical Research.

Job Description

- Extensive experience applying in-depth theoretical knowledge from multiple areas of expertise to devise solutions to complex problems with a sustained track record of applying problem solving skills to move projects forward.
- Apply a broad understanding of toxicology, pharmacology, DMPK and regulatory sciences to design all types of toxicology studies required to support clinical development of biopharmaceuticals.
- Serve as Preclinical Safety team leader for multiple programs and contribute to the program's goals and deliverables.
- Ensure that the preclinical safety plan is aligned with the clinical development plan, and applicable regulatory guidelines (e.g. FDA, GLP and etc.)
- Serve as a subject matter expert within their field of sub-specialization to provide input on other programs and studies, including external partnerships.
- Collaborate with other functional groups internally or externally (study management, clinical, regulatory, research, translational sciences, DMPK, CMC, etc.) on program-related tasks and objectives.
- Prepare high quality nonclinical regulatory documents to support regulatory submissions and clinical development is a plus.

Qualifications:

- An MS/Ph.D in Chemistry or Chemical Engineering or related technical field.
- 10+ years relevant experience in CMC operational roles, preferably in an MNC or bio-tech environment.

- 5-10 years of combined toxicology, drug development and regulatory experience in a biotech, biopharmaceutical or CRO setting.
- Demonstrated experience and expertise with both GLP and non-GLP compliant in vitro and in vivo toxicology study conduct and reporting.
- A high degree of familiarity with applicable regulatory guidelines (ICH, FDA, GLP, etc.) and prior experience with regulatory agency interactions is preferred
- Proven leadership, organizational and time management skills, including the ability to interact effectively with contract research laboratory personnel and internal/external experts for the conduct of toxicology studies.
- Must possess good communication and technical writing skills in English. Capable of engaging in scientific dialog among large groups of scientists, senior management, and external scientific experts.

Education

- Ph.D. or equivalent in Toxicology or closely related field.
- Toxicology board certification is a plus.

Employment Category

- Full-Time Regular

Compensation/Benefit

- Market competitive

ORGANIZATION AND REPORTING RELATIONSHIPS

- Reports to VP of Preclinical Research