MICROBION CORPORATION

Director, Pharmacology and Toxicology

Are you an experienced Pharmacology/Toxicology leader interested in joining a company developing the first in a new class of therapeutic compounds designed to improve the lives of people living with chronic and life-threatening diseases?

Microbion Corporation (www.microbioncorp.com) is a clinical-stage pharmaceutical company developing the first in a brand-new class of therapeutic compounds designed to address critical unmet medical needs of life-threatening and chronic diseases, including rare (Orphan) diseases. Our drug's potential as a viable therapeutic has been validated through over $67M in funding, including $27M in grants awarded to-date from the National Institute of Health, U.S. Department of Defense, CARB-X, and the Cystic Fibrosis Foundation. Location: Remote, yet Northwest USA or Vancouver, B.C. is preferred.

Position Summary

The individual will utilize his/her highly specialized knowledge and experience for designing and managing preclinical study protocols and engaging with various collaborators/CRO organizations. The individual will contribute to brainstorming with colleagues and other experts and evaluate relevant animal study models for validating the concepts and therapeutic targets. The individual is expected to manage multiple projects and work well with a cross-disciplinary team of Scientists, Project Managers, and Senior Leadership. The individual must be a team player who thrives in a dynamic environment with multiple tasks and aggressive deadlines and contributes to the aggressive R&D goals. The individual must have a great, positive mind set, and flexibility and tolerance to adapt to changes.

Areas of Responsibility

- Responsible for designing and overseeing non-GLP and GLP nonclinical toxicology and safety pharmacology studies, reviewing and finalizing protocols, and managing the studies with collaborators and CROs as needed.
- Provide strategic planning of nonclinical studies to support global regulatory development of various novel chemical entities and drug products across a variety of indications and routes of administration.
- Develop research/project plan, budget, study protocols, and reports as needed for *in vitro* and *in vivo* pharmacology and toxicology projects.
- Coordinate timely delivery of projects including arranging shipping and receiving of samples working with scientists and with shipping and receiving team.
- Analyze, interpret, and summarize nonclinical safety and toxicology data and present data to internal project teams and leadership while providing strategic guidance and interpretation.
- Data management of raw data, author reports and help teams with data-driven decision making.
- Write and review nonclinical sections for all regulatory filings including IND, CTA, BLA, NDA, IB, etc.
- Participate in the preparation of abstracts and manuscripts for publication.
- Represent preclinical toxicology on project teams and interface with internal stakeholders, as well as with external stakeholders and regulatory agencies.
- Contribute to intellectual property documents, draft patent applications, evaluate prior art, and respond to patent office actions, as required.
- Author high quality regulatory documents including IND, CTA, BLA, NDA, IB, etc.
- Lead investigative efforts into mechanisms of toxicity as needed.
- May be required to perform other related duties as required and/or assigned.

- Perform all duties in keeping with the Company's core values, policies and all applicable regulations.

Requirements

- PhD in Toxicology, Pharmacology or related scientific discipline
- 10+ years of biotech/pharmaceutical/industrial drug discovery/development experience
- Expert knowledge of small molecule toxicology in Drug Development
- Subject matter expert in the conduct of pre-clinical safety pharmacology and toxicology studies
- Strong scientific background and scientific aptitude
- Excellent critical thinking and project prioritization skills
- Demonstrated leadership in taking programs to clinic (IND-enabling studies); preference for experience in non-clinical development to an NDA
- Demonstrated ability to work effectively and collaboratively on cross-functional project teams
- Solid track record of publications, leadership, and management experience
- Proven experience in designing non-GLP and GLP safety studies
- Proven experience in writing for and interacting with regulatory agencies
- Demonstrated experience in managing CROs and programs with aggressive goals
- Demonstrated project/program management skills
- Excellent oral, presentation, and written communication skills
- Ability to work in a fast-paced and varied environment
- You must already be authorized to work in the United States or Canada without requiring sponsorship

How to Apply

Click on this link to be redirected to our application portal on LinkedIn. We request that all interested and qualified candidates please submit a cover letter and CV as a single document. We thank all applicants for their interest, however, only candidates selected for interview will be contacted.

Microbion Corporation does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.