Title: Toxicologist

ABOUT THE COMPANY

QurAlis is a clinical-stage biotechnology company developing breakthrough precision medicines for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets.

QurAlis is trailblazing the path to conquering amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets with next-generation precision medicines. QurAlis' proprietary platforms and unique biomarkers enable the design and development of drugs that act directly on disease-causing genetic alterations. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is advancing a deep pipeline of antisense oligonucleotides and small molecule programs including addressing sub-forms of ALS that account for the majority of ALS patients.

Summary of Position

QurAlis is seeking a highly motivated Toxicologist to support their toxicology strategy for successful development of the company's lead molecules across all stages of development. Responsibilities include the design, planning, initiation and successful completion of toxicology studies required for new or marketed drugs for all phases of development. This position will work closely with different teams from Discovery to Clinic within QurAlis.

Primary Job Responsibilities

- Responsibility extends from first concept to regulatory filing of completed studies.
- Accountable for non-clinical safety pharmacology and toxicology activities.
- Manage all aspects of out-sourced activities, including proposal generation and approval, vendor selection, protocol generation, study conduct and monitoring, report review and approval.
- Accountable for selection and management of qualified vendors for non-clinical studies.
- Accountable for oversight and corporate approval of GLP non-clinical research documents including for example non-clinical study synopses, protocols, analysis plans, and study reports.
- May represent the company as non-clinical safety representative at meetings with regulatory bodies.

QurAlis

- Responsible for validity, accuracy, relevance and completeness of scientific content in non-GLP and GLP non-clinical research and regulatory documents.
- Responsible for original writing, editing and review of non-clinical GLP regulatory documents.
- Play a pivotal role in IND candidate selection and all stage gate processes.
- Attend appropriate scientific meetings and stay up to date with relevant scientific literature to maintain expertise.
- Accountable for incorporating relevant recent advances in the field into non-clinical research.
- Responsible for oversight of the conduct of non-clinical studies

Minimum Qualifications Required

- BS/MS degree and DABT with 10 yrs. of relevant experience.
- PhD degree in toxicology or pharmacology with 5 yrs. of relevant postdoctoral experience, DABT preferred.
- Demonstrated drug development experience in non-clinical toxicology, including program design, study protocol development and study execution
- Experienced with non-clinical development programs for small molecules and antisense oligonucleotides or siRNA.
- Experienced in development programs for oral and parenteral therapeutics.
- Proven experience with virtual drug development as it pertains to non-clinical drug development.
- In depth understanding of the drug development process and intimate understanding of non-clinical development.
- In depth familiarity with ICH, FDA and other regulatory guidance and regulations relevant to non-clinical research.
- Excellent written and oral communication, interpersonal, and organizational skills.
- Initiative in producing high quality work product in a small company environment.
- Roll-up-the-sleeves attitude.
- Competence with standard office computer software tools.
- Ability to align activities with company objectives.
- Meticulous nature with high attention to detail
- Able to work independently and work well in a team environment in a fast-paced environment
- Strong organizational skills
- Excellent written and oral communication with key stakeholders and work collaboratively

Please send resume with cover letter to anna.beck@quralis.com.

QurAlis is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, gender, age, religion, national origin, ancestry, disability, veteran status, genetic information, sexual orientation or any characteristic protected under applicable law. QurAlis will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable law.