Clinical Pharmacology Lead

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:

This position will serve as the clinical pharmacology lead on several clinical development program teams providing strategic leadership and execution of clinical development plans that include characterization and prediction of the pharmacokinetics, pharmacodynamics and drug metabolism (PPDM) of the drug candidate in selected preclinical and all clinical areas. This individual will provide rationale for dose regimen selection, safety margin assessment and identification of circumstances where dose adjustment or patient selection/stratification should be considered. This role will be responsible for overseeing outsourced PPDM activities and will work cross-functionally with clinical and discovery teams within QurAlis.

Reports into the QurAlis Chief Medical Officer.

Primary Job Responsibilities:

- Drive the development and execution of the Clinical Pharmacology Strategy and Plan of several clinical development and/or program teams.
- Provide key components of the Early Development Plan, advises teams on Clinical Pharmacology Strategy and science and provides input to line management.
- Work with research/discovery, clinical development and/or study/program teams to achieve program goals and provide deliverables in approved timeframes.
- Lead clinical pharmacology efforts (e.g., study design, protocol concepts/protocols preparation, clinical phase oversight, data analysis, and reporting) within assigned programs to yield high value PK/PD insight for critical decisions.
- Analyze results, interprets, and recommends action based on study results.
- Provide extensive regulatory strategy expertise for drug filings and is responsible for Clinical Pharmacology sections of regulatory documents.

- Maintain cutting edge knowledge of best regulatory practices, Clinical Pharmacology technology and drug development precedent.
- Engage in cross-functional activities providing Clinical Pharmacology input and provide a source of Clinical Pharmacology expertise and advice to other functions across the Company. Participate in and provides Clinical Pharmacology perspective to cross-functional committees and activities.
- Maintain extensive scientific awareness and presence in Clinical Pharmacology, publishes multiple manuscripts and posters, presents at Scientific Conferences and other scientific forums.
- Provide scientific monitoring and guidance on outsourcing studies for the method transfer, development, troubleshooting, qualification, validation and report
- Oversee Clinical Research Organizations or other applicable vendors in relation to outsourced PPDM activities
- Engage with consultants and advisors in the field, as well as the scientific community at large

Minimum Qualifications Required:

- Ph.D., M.D./Ph.D., or Pharm.D. in Clinical Pharmacology, pharmacokinetics, or a related field
- 8+ years of industry experience in Clinical Pharmacology & PPDM.
- Solid experience in developing Clinical Pharmacology strategy, designing/implementing Clinical Pharmacology studies
- Strong knowledge of the drug development process and overall familiarity with the regulatory process.
- Direct experience in preparing regulatory submissions and responding to health authority questions.
- Extensive record of publications, presentations, invited lectures, and other scientific activities
- Active knowledge of advanced methods for Quantitative Pharmacology and PMx analyses
- Demonstrates strong teamwork in a multidisciplinary, cross-functional environment
- Experience with use of PK/PD software packages such as -Phoenix WinNonlin, SimCYP, NONMEM, Monolix, R, Adapt, MATLAB, SAS

Please send a resume with a 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 provide reasonable accommodation for qualified individuals with known disabilities, in accordance with applicable law.