Clinical Operations Biomarker 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:

The Clinical Operations Biomarker Lead will serve as the interface between the biomarker bioanalytical development scientists, preclinical study managers, global clinical operations and development, and various vendors. They will oversee the testing of clinical and preclinical samples in routine and specialized clinical assays, including pharmacokinetics (PK), immunogenicity and specialized biomarker assays. The Clinical Operations Biomarker Lead will oversee bioanalytical method development, validation, testing, analysis and reporting. They will develop and maintain the biomarker plans, timelines and budget for the QurAlis clinical portfolio.

This role would report to the Head of Clinical Operations.

Primary Job Responsibilities:

- Develop and maintain program specific biomarker plans and timelines to be incorporated into clinical development plans; develop and/or review and provide insight on study-specific clinical sample management plans
- Assume primary responsibility for interfacing between the biomarker bioanalytical development scientists, preclinical study managers, global clinical operations, clinical development and other functions (biostats, regulatory, etc.) and various external partners (biorepositories, central labs, study sites, etc.)
- Oversee testing of clinical and preclinical samples in routine and specialized clinical assays, including pharmacokinetics (PK), immunogenicity, and biomarker assays.
- Oversee bioanalytical method development, validation, testing, analysis and reporting.

- Support clinical trials study management and operational aspects of outsourcing to CROs by coordinating study activities and effectively meeting study and program specific timelines and milestones, with emphasis on overseeing bioanalytical assays at CROs.
- Manage outsourcing budgets, agreements and timelines as needed. Initiate bioanalytical development, transfer, validation and testing work orders. Facilitate establishment of vendor contracts with CROs selected to perform bioanalytical sample testing.
- In close collaboration with Clinical Operations and other applicable functions, be accountable for the planning, coordinating and overseeing of all operational activities required to manage the lifecycle of biomarker specimens, including oversight of sample collection at site, shipment to central lab vendor, shipment to specialty labs for analysis, sample reconciliation and final sample disposition
- Contribute to the development and review of clinical study documents such as the study protocol, scope of work (SOW), informed consent forms (ICF), laboratory manuals and specifications, clinical report forms (CRFs), clinical study reports (CSR), and data transfer agreements (DTA), with emphasis on bioanalytical assays.
- Work effectively in a dynamic environment with cross-functional stakeholders

Minimum Qualifications Required:

- BS, MS or PhD in biology, biochemistry, pharmacy, or other related pharmaceutical sciences
- Significant experience (5+ years) of relevant work experience in drug development, sample/biospecimen management or clinical trial project management
- Deep knowledge of clinical trials and understanding of the role of biomarkers in clinical studies
- Working knowledge of FDA & ICH/GCP and GLP regulations
- High level of communication (written and verbal), interpersonal, organizational, and cross functional collaboration skills
- Strong attention to details, timelines and quality
- Ability to work independently and build working relations throughout the organization and with business partners to achieve business goals
- Ability to manage multiple projects in a fast-paced environment
- Skilled in multiple computer-based tools, in addition to software programs such as Word, PowerPoint, Excel, etc.

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.