



Title: Director, Translational Biomarkers

ABOUT THE COMPANY

At QurAlis, we are neuro pioneers on a quest to cure. We work with a relentless pursuit of knowledge, a precise attention to craft, and an optimistic mindset to discover and develop effective precision medicines that will alter the trajectory of amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), and other neurodegenerative diseases. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is a clinical-stage biotechnology company advancing a pipeline with therapeutic candidates that target specific components of ALS and FTD pathology and defined patient populations based on both disease-causing genetic mutation(s) and clinical biomarkers.

SUMMARY OF POSITION

The primary responsibilities of this position are to ensure the timely development and execution of PK/ PD and biomarker assays to support clinical trials. Role will also perform technical and strategic assessment of new and innovative biomarker platforms to support the QurAlis pipeline. This position requires in depth knowledge in assay development, qualification and validation, a broad understanding of regulatory expectations supporting assay performance across various stages of clinical development and direct experience managing external CROs and specialty labs. Ideally, the candidate will have experience in biomarkers as endpoints or surrogate endpoints supporting clinical development as well as some experience in development of assays for use as companion diagnostics. The individual in this position will need to work as part of a global matrix-based organization effectively collaborating with internal and external resources to efficiently deliver PK/ PD biomarker assay solutions and results in a timely and cost-effective manner. The candidate must have effective project management skills and communicate progress and risks toward the timely testing of biomarkers in clinical development programs.

Primary Job Responsibilities:

- Independent contributor in the development, transfer and execution of biomarker assays for clinical development including: 1) identify appropriate biomarker tests and technology solutions to support ongoing and planned clinical trials; 2) provide input on biomarker related sections of clinical study protocols 3) operationalize biomarker tests and ensure results are delivered and archived per clinical development needs; 4) Drive overall biomarker development strategy to support clinical development plans across the QurAlis portfolio



- Collaborate with preclinical biomarker discovery in the evaluation and development of clinical biomarker assays and vendor selection for early projects. Effectively identify, manage, and communicate risks to stakeholders in a clear and timely fashion.
- Collaborate with program team lead, regulatory and medical directors, in the review of clinical protocols, investigator training, clinical sample analysis, and regulatory submission activities for QurAlis clinical development.
- Contribute to proposals, establishment, and optimization of more productive standardized working processes for clinical biomarker assay development and support.

Primary Job Requirements:

- Must have at least 15 years' experience in fit-for-purpose clinical biomarker assay development, validation, and implementation in support of multi-site clinical trials. Global implementation experience is highly desirable.
- Must have experience overseeing the establishment of biomarker assays at CROs in a GLP And GCP (GXP) environment
- Experience and expertise in spatial platforms are desirable.
- A strong preference for a candidate with broad technical knowledge and experience analyzing complex data.
- Ability to work independently as well as collaboratively in an international matrixed team environment.
- Strong communication and presentation skills. Strong interpersonal skills and knowledge of intercultural differences.
- Ability to adjust priorities in a fast-paced environment.
- Strong organizational and networking skills.

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.