**Title: Vice President, Clinical Operations**

## 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

We are seeking a motivated experienced Vice President of Clinical Operations with a strong clinical trial background to oversee the transition of our discovery projects into clinical trials. The individual in this position will be responsible for timeline management, risk assessment, risk mitigation planning, and cross-functional communication in a largely externalized environment.

## Primary Job Responsibilities:

***Spearhead and Champion Clinical Operations***

- Oversee and manage all operations and staff involved in clinical operations, data management and other groups as assigned.
- Ensure that clinical trials are properly resourced, managed, executed and inspection ready in accordance with timelines, good quality practices and applicable regulatory requirements.
- Apply your expertise to develop a life-cycle strategy and evaluation of new programs to be prioritized or advanced into clinical development.
- Participate in the review, planning and implementation of clinical trials. Evaluate hypotheses, objectives, study design, feasibility and regulatory requirements, and identify medical and logistical problems that may impede the study.
- Develop clinical timelines, budget forecasts, and ensure accountability for tracking and deliverables.
- Oversee CROs and vendors from identification and selection to close of contracts.
- Collaborate with others on the development of protocols, annual safety reports, clinical study reports, publications, presentations and regulatory submissions.
- Review relevant master service agreements, statements of work and quality agreements.
- Regularly present clinical operations updates and strategy to QurAlis' executive committee

***Evolve the Clinical Operations Department Infrastructure***

- Lead initiatives to build the clinical operations department infrastructure.
- Plan clinical operations headcount and hiring needs to meet program workload demands.
- Represent and advocate for clinical operations needs and resources at the Executive Committee level.

***Mentor Your Team and Develop Their Talents***

- Lead the members of the clinical operations team by example.
- Implement best practices and standards for trial management, including establishment of SOPs, in collaboration with other members of the clinical operations team.
- Provide leadership, mentorship and development opportunities to others within QurAlis.

**Primary Job Requirements:**

- Minimum of 15 years clinical operations experience in the pharmaceutical/biotech industry, with at least 8 years direct line management experience.
- BS/MS in a scientific discipline or equivalent experience.
- Experience in and understanding of end-to-end management of clinical trial conduct, the pharmaceutical industry, clinical drug development, clinical trials operations and regulatory components is essential. A thorough understanding of drug development from IND to NDA
- Proven success in leading and coordinating cross-functional clinical operations teams. (e.g., clinical operations, data management, clinical supply chain).
- Experience working on complex studies involving biomarkers and activities across multiple vendors.
- Knowledge and experience with developing, negotiating and managing contracts (vendor and site).
- Experience in regulatory inspection.
- Experience in developing RFPs, selection of CROs/vendors, and management of external resources
- Demonstrated ability to manage international clinical trials within designated program budgets and timelines
- Proven success participating in cross-departmental clinical strategy, planning and implementation activities. (Departments include senior management, regulatory, QA,

CMC, program management, finance, business development, medical affairs, clinical development and medical writing.)

- Strong working knowledge of FDA, EMA regulations and expectations, Good Clinical Practice, ICH guidelines, and clinical operations best practices.
- Demonstrated independence, problem-solving abilities, self-motivation, resourcefulness and ability to work in a fast-paced team environment.
- Experience with building clinical operations infrastructure including writing of SOPs.
- Excellent communication skills with an ability to efficiently and productively communicate both orally and in writing. Experience presenting to the senior leadership team is a plus.

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.*