Title: AD/Director, Clinical Supply Chain

ABOUT THE COMPANY

QurAlis is applying precision medicine to advance a novel therapeutic pipeline for the treatment of amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD) and other neurodegenerative diseases. Our stem cell technologies can test efficacy of various therapies and provide a transitional bridge to the clinic enabling target validation, discovery, and molecule selection. We are advancing three antisense and small molecule programs addressing sub-forms of ALS that account for most patients. Together with a world-class network of thought leaders, drug developers, and patient advocates, our growing team is at the leading edge of neurodegenerative research and development.

This past year we were honored to win the Fierce15 and the New England Venture Capital Association's NEVY award for Best Emerging Life Science Company in New England's startup ecosystem. We are pioneers in neurodegenerative disease biology, stem cell and antisense oligonucleotides (ASO) technology, biomarkers, and small molecule design. We are honest and empathetic to our patient community, science, colleagues, and ourselves sharing a common passion to urgently discover new medicines for ALS and FTD. We represent a diversity of backgrounds and value collaboration. We believe that success in treating neurodegenerative diseases will be achieved by being precise - targeting the right patients, identifying the right disease mechanism, and carefully developing disease-modifying, clinically meaningful therapies to improve the lives of patients.

Summary of Position

QurAlis seeks an experienced and highly motivated individual to jump-start its Clinical Operations team. The candidate should be experienced in supporting all aspects related to Investigational Product and ancillary supplies for global clinical trials. The candidate will be responsible for managing Interactive voice response (IVR) and drug distribution vendors for clinical trials including packaging, labeling, distribution, return, reconciliation and destruction activities, development of the Pharmacy Manual and labels for clinical trial materials (Investigational Medicinal Product, IMP), sourcing appropriate ancillary products required for the delivery of IMP, vetting site pharmacy SOPs where required and ensuring IMP is available at sites for dosing of patients during the study. The appropriate candidate should excel in working in a team-oriented, fast-paced and cross-disciplinary biotech environment.

Responsibilities:

May include some or all of the following:

- Working with CMC to ensure timely availability of IMP for all clinical trials sponsored by QurAlis
- Source all ancillary supplies required for delivery of IMP
- Ensure all testing of said supplies is conducted in a timely manner
- Development of the Pharmacy Manual
- Selection, set-up and management of IVR and Drug Distribution vendors
- IMP label development
- Identify requirements for site pharmacies, and vet said pharmacies as required to support the clinical trials
- Manage availability of IMP and related products at sites throughout the trials
- Manage temperature excursions
- Act as Subject Matter Expert (SME) during regulatory inspections
- Collaborate on SOP development
- May include line management of team members

Education / Experience:

- B.S. in a scientific, healthcare, or related field. Pharmacy degree preferred, but not required.
- Ideally, a minimum of 5 years (Associate Director) or 10 years (Director) of relevant experience in Pharmaceutical, Biotech or CRO company
- In-depth knowledge of Pharmacy requirements for clinical trials, including applicable regulatory requirements globally
- Domestic and International travel may be required occasionally
- Strong interpersonal skill set necessary to create and maintain internal and external collaborator relationships, including vendors, CROs, etc.
- Ability to work independently and as part of a team in a fast-paced environment
- Demonstrated ability to juggle multiple competing tasks and demands
- Strong attention to detail
- Must be authorized to work legally in the United States

Please send resume with cover letter to careers@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.