Title: Director, Clinical Supply Chain

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

QurAlis is seeking an experienced and highly motivated individual to join 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.

Primary Job Responsibilities:

- 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

Primary Job Requirements:

- 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

Please send resume with cover letter to Anna.Beck@techcxo.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.