Title: Senior Director, Quality Assurance

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 Senior Director, Quality Assurance is responsible for ensuring adequate quality assurance activities within all GxP areas at QurAlis Corporation. The expert role is mainly within Good Manufacturing Practice however the responsibility in the role includes coordination and support of all GxP activities within the company.

In this role, the person will be responsible for ensuring product quality of drug substance (DS), drug product (DP) and finished goods (FG) at contract manufacturing organizations (CMOs) as well as ensuring compliance with GMP & GLP regulations, internal policies, procedures, and best industry practices at QurAlis. This person will also be responsible to maintain QA and compliance programs and build a phase-appropriate Quality Management System (QMS) infrastructure including a Standard Operating Procedures (SOPs) system and training program. He/she will establish and maintain vendor management and supplier qualification program, oversight of external GMP vendors (through appropriate Quality Technical Agreements (QTA), audits, SOPs etc.)

The individual must be well organized and have excellent oral and written communication skills to effectively interact with external manufacturers to ensure QurAlis quality compliance needs are met in a timely manner. This includes collaborative interactions such as due diligence, establishing and maintaining quality agreements, review of change controls, deviations, CAPA and metrics as well as providing support to build effective quality systems and supporting continuous improvement activities. This individual will work closely with CMOs, CMC, Regulatory, Clinical, Quality Systems, Validation and Supply Chain Operations teams to maintain drug product supply.

Primary Job Responsibilities:

- Develop, implement, and monitor quality management programs, policies and procedures to ensure compliance with cGMP/GxP standards, FDA, EMA and other regulatory requirements, ICH guidelines, QurAlis policies, SOPs, and industry best practices
- Facilitate and develop a robust, phase-appropriate and efficient Quality Management System including site change control, deviation and CAPA processes
- Perform timely and compliant batch disposition of intermediate Drug Substance, Drug Product and Finished Goods to support clinical requirements. This will include review and approval of master production/batch records, product specifications, analytical test methods qualification/validation protocols/reports, stability protocols/reports, executed batch records, change controls, packaging/labeling label proofs, and all non-conformances/deviations/OOSs
- Ensure all contract manufacturing's non-conformances/deviations, out-of-specifications, and complaints are thoroughly investigated, proper corrective measures are implemented and monitored
- Design, develop and lead efforts for QA oversight of the manufacture of pre-clinical, clinical, and commercial DS, DP and FG at CMOs in partnership with Chemistry, Manufacturing and Control (CMC)/Technical Operations, QC, Supply Chain and other related functions
- Establish and maintain a vendor management and supplier qualification program, with oversight of external GMP vendors through audits and appropriate Quality Technical Agreements (QTA)
- Oversee internal and external GMP audits and serve as the internal advisor on GxP compliance matters
- Implement, support, and oversee a document control system, including document review, approval, release, and archiving activities of GxP policies and procedures
- Develop, continuously assess, and revise interactive training curricula for New Hire Onboarding, annual training as well as all other departmental training needs as necessary to ensure compliance to training program
    - Support training execution for GxP trainings, new hire onboarding, train the trainer, etc. and create quiz/exam for training items as requested by the users
    - Manage training schedules, maintain GxP training records, and provide general administration support
    - Ensure training compliance with internal SOPs, policies, and applicable regulations and ensure all training records and reference documents are tracked
    - Identify and communicate any gaps, needs, and plans of action for training curricula improvements to training manager
- Develop and implement contemporary, phase-appropriate quality practices that ensure quality compliance and continuous improvement

- Lead interactions with senior management and internal and external customers to negotiate actions impacting supply of quality product to patients from early development stages to on-going commercial operations through development of Quality KPIs/Metrics
- Author/Review INDs/IMPDs and other relevant regulatory dossier sections based on area(s) of knowledge and expertise. Strategize responses to regulatory questions during the review period and product lifecycle
- Author and review CMC QA standards/SOPs. Own, review, approve and support deployment of Quality Standards/SOPs

Minimum Qualifications Required:

- 10-15+ years of relevant industry experience, with leadership experience in a QA function. At a minimum bachelor's degree with an advanced technical/science degree preferred
- In-depth understanding of GMP, GLP and industry specific guidelines for compliance. Experience with phase appropriate application of quality management systems and requirements initially focusing on pre-clinical and clinical phases of development
- Experience in setting up QMS is highly desired
- Demonstrate quality mindset and ability to influence across the entire organization.
- Proficient in risk assessment and root cause analysis tools
- Good interpersonal skills plus the ability to work in a diverse working community
- Excellent written and verbal communication skills
- 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
- Authorized to work legally in the United States

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.