Associate Director, Quality Assurance

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.

We are honored to have won 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:

The Associate 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 at drug substance, drug product and finished goods contract manufacturing operations 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 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:

May include some or all of the following:

- Develop, implement, and monitor quality management programs, policies and procedures to ensure compliance with cGMP standards, FDA, EMA and other regulatory requirements
- Facilitate a robust and efficient Quality System including site change control and deviation process
- Timely and compliant disposition of intermediate Drug Substance, Drug Product and Finished Goods to support clinical requirements. This will include review and approval of master production records, product specification, executed batch records, and all non-conformances
- Ensure all contract manufacturing 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 FDP at CMOs in partnership with Technical Operations, QC, Supply Chain and other functions
- Oversee internal and external GMP audits and serve as the internal advisor on GxP compliance
- Implement, support, and oversee a document control system, including document review, approval, release, and archiving activities
- 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
- Author/Review INDs 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
- Design, develop, and review CMC QA standards. Own, Review and support deployment of Quality Standards
- Ensure activities and deliverables are in compliance with FDA, EMA and local regulations and guidance, ICH guidelines, QurAlis policies, SOPs and industry best practices

Minimum Qualifications Required:

- 8+ years of relevant industry experience, with 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

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.