SENIOR MANAGER, QUALITY ASSURANCE (full-time contract)

ABOUT THE COMPANY

At QurAlis, we are neuro pioneers on a quest to cure, boldly seeking to translate scientific breakthroughs into powerful precision medicines. We work collaboratively with a relentless pursuit of knowledge, precise attention to craft, and compassion to discover and develop medicines that have the potential to transform the lives of people living with neurodegenerative and neurological diseases. QurAlis is the leader in the development of precision therapies for amyotrophic lateral sclerosis (ALS). In addition to ALS, QurAlis is advancing a robust precision medicine pipeline to bring effective disease-modifying therapeutics to patients suffering from severe diseases defined by genetics and clinical biomarkers.

SUMMARY OF POSITION

The Senior Manager, Quality Assurance, is responsible for ensuring adequate quality assurance activities within all GXP areas at QurAlis Corporation.

In this role, the person will be responsible for ensuring product quality at drug substance and drug product contract manufacturing operations as well as ensuring compliance with GMP regulations, internal policies, procedures and best industry practices at QurAlis.

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, 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, Process and Analytical Development, and Supply Chain Operations teams to maintain drug product supply.

RESPONSIBILITIES

- Primary Quality lead for QRL-201 CMO operations to ensure compliance with applicable GMP standards.
- Review and approve supplier GMP documentation, including deviations, change controls, CAPAs, material specifications, and analytical records.
- Act as primary Quality contact for CMOs, ensuring timely and effective communication and resolution of quality-related issues.
- Support technology transfer, analytical qualification and validation, and risk-based quality activities.
- Conduct batch record review and manage batch disposition for QRL-201 manufacturing campaigns.
- Apply risk-based decision-making approaches to resolve complex or cross-functional quality issues.

- Develop and implement contemporary, phase-appropriate quality programs, policies and procedures that ensure quality compliance and continuous improvement, and in compliance with FDA, EMA and local regulations and guidance, ICH guidelines, QurAlis policies, SOPs and industry best practices.
- Ensure training compliance with internal SOPs, policies, and applicable regulations.

REQUIREMENTS

- B.S./M.S. in life sciences, biotechnology, or a related field.
- 6-8+ years of experience in GMP Quality Assurance or manufacturing roles within the biotech/pharmaceutical industry.
- Proven ability to work cross-functionally across Quality, Regulatory, CMC, and Manufacturing teams.
- Demonstrated leadership, communication, and problem-solving capabilities.
- Experience with phase appropriate application of quality systems and requirements initially focusing on pre-clinical and clinical phases of development.
- Strong working knowledge of current global cGMP regulatory requirements and emerging industry standards.
- Proficient in risk assessment and root cause analysis tools.
- Ability to work independently and as part of a team in a fast-paced environment
- Demonstrated ability to juggle multiple competing tasks and demands
- Experience with electronic Quality Management Systems (eQMS), such as Veeva or TrackWise.

Please send resume with cover letter to Meredith.ball@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.