Title: Associate Director, Quality Control

ABOUT THE COMPANY

The QurAlis mission is an unrelenting commitment to enhance patients' lives through development and commercialization of next-generation precision medicines for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases. QurAlis is applying precision oncology-like approaches in neuroscience, understanding and identifying sub-groups of patients for the right therapy.

QurAlis is building a fully-integrated, next-generation, high performance precision medicine company. 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 advancing both antisense and small molecule programs addressing sub-forms of ALS and frontotemporal dementia (FTD) that together account for most patients. Our two main programs are aimed to start clinical trials in H2 2022. We have developed two proprietary platforms: the QR43™ TDP43 platform and the FlexASO™ antisense oligonucleotide (ASO) splice modulator platform.

QurAlis is 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 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, QC will be responsible for directing validation of analytical methods, summarizing release data and managing stability programs at our partner sites (CMOs) to ensure testing activities occur in an appropriate and cGMP compliant manner while fostering QurAlis vision and values.

One of the key responsibilities will be managing QurAlis stability programs at our partner CMOs. Responsibilities include, review/author stability protocols, reports, data trending, maintenance of data table to support stabilities studies and shelf-life activities.

Substantial work with Microsoft Excel requiring the ability to statistically analyze data and perform trending analysis. Helps with resolving problems related to the generation of lab data, applies thorough analysis and evaluates intangible variables to reach logical conclusions.

Primary Job Responsibilities:

May include some or all of the following:

- Establish and oversee stability programs for clinical products and ensure stability studies are performed according to approved protocols and procedures.
- Coordinate and facilitate monthly stability review meetings with all relevant stakeholders to foster collaboration and bring visibility to potential issues and risks. Ensure timely write-up and review of stability testing assays including populating the stability folders and associated spreadsheets.
- Oversee analytical testing at CTLs to ensure testing is timely and performed in compliance with cGMP, established procedures and regulatory applications. Prioritize resources appropriately to meet commitments on-time.
- Author, review, and approve data, QC SOPs, analytical methods, qualification/validation protocols and reports.
- Review all quality system records such as OOS/OOT investigations, laboratory deviations, change controls and CAPAs at our partner sites.
- Establish and maintain specifications and sampling plans for in-process, drug substance, drug product, and finished drug product; collaborate on preparation of justification of specifications.
- Prepare interim and final reports to confirm and extend product shelf life.
- Generate Certificates of Analysis for product release, and other certificates of GMP testing. Identify critical parameters that impact manufacturing and quality of ASOs, define key raw material attributes to control variability and risk of contamination by impurities and perform risk assessments.
- Participate in compliance related teams working towards the goal of continuous improvement.
- Strong knowledge of US and EU cGMP regulations/guidance and some experience with regulatory agency inspections.
- Extensive knowledge of analytical methodologies such as liquid chromatography and mass spectrometry and applying/interpretation of GMP requirements.

Minimum Qualifications Required:

- Bachelor's degree with 8-10 years or MS with 6-8 years in a biotechnology discipline
- Experience with oligonucleotide therapies is highly desired.
- 2 - 3 years of experience in a cGMP/GxP environment is preferred.

- Previous experience with stability studies and with data trending and statistical programs (JMP, MiniTab, Excel, etc) highly desired.
- Proficient knowledge in current regulations and guidance documents including cGMP, ICH, USP, and other applicable regulatory guidance (US and EU).
- Has effective communication skills, both verbal and written.
- Works independently under general supervision and direction. Ability to succeed in a team-oriented environment under very dynamic conditions.
- Good interpersonal skills plus the ability to work in a diverse working community.
- Demonstrated ability to juggle multiple competing tasks and demands with a 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.