Stability Coordinator

ABOUT THE COMPANY

QurAlis is a clinical-stage biotechnology company developing breakthrough precision medicines for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets.

QurAlis is trailblazing the path to conquering amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases with genetically validated targets with next-generation precision medicines. QurAlis' proprietary platforms and unique biomarkers enable the design and development of drugs that act directly on disease-causing genetic alterations. Founded by an internationally recognized team of neurodegenerative biologists from Harvard Medical School and Harvard University, QurAlis is advancing a deep pipeline of antisense oligonucleotides and small molecule programs including addressing sub-forms of ALS that account for the majority of ALS patients.

Summary of Position:

The Stability Coordinator will be responsible for managing stability programs at our partner sites (CMOs/CROs) to ensure testing activities occur in an appropriate and cGMP compliant manner while fostering QurAlis vision and values.

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 the stability sample planning/shipments and facilitate monthly stability review meetings with all relevant stakeholders to foster collaboration and bring visibility to potential issues and risks.
- Oversee analytical testing for stability studies to ensure testing is timely and performed in compliance with cGMP, established procedures and regulatory applications. Prioritize resources appropriately to meet commitments on-time.

- Ensure timely write-up and review of stability testing assays including populating the stability folders, associated spreadsheets, tracking and trending stability data.
- Prepare stability documentation for regulatory filings.
- Prepare interim and final reports to confirm and extend product shelf life.
- Help to generate Certificates of Analysis for product release, and other certificates of GMP testing.
- Help to 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.
- 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.

Minimum Qualifications Required:

- Bachelor's degree with 10 years or MS with 8 years in a biotechnology discipline
- Experience with oligonucleotide therapies is highly desired.
- 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.
- Demonstrated ability to juggle multiple competing tasks and demands with a strong attention to detail.
- 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.

Please send resume with cover letter to anna.beck@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.