Title: Director of Drug Substance Manufacturing

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 Director of Drug Substance Manufacturing at QurAlis plays a pivotal role in developing and optimizing chemical processes for Oligonucleotides production and overseeing the refinement of external manufacturing processes. This leader is tasked with steering a team through process development, scale-up, analytical, and technology transfer to manufacturing sites, including managing operations and coordinating with Contract Manufacturing Organizations. His responsibilities are critical to ensuring the consistent delivery of high-quality drug substances for clinical and commercial use, adhering to stringent regulatory standards. By optimizing manufacturing strategies and fostering collaboration with cross-functional teams, the Director plays an instrumental role in enhancing efficiency, quality, and safety, driving innovation, and ensuring that manufacturing practices are in sync with QurAlis' core values.

Primary Job Responsibilities:

- Oversee the operation of drug substance manufacturing at our Contract Manufacturing Partners, ensuring compliance with all regulatory, safety, and quality standards.
- Develop and optimize scalable chemical processes for the synthesis of drug substances, focusing on efficiency, yield, and purity.
- Direct the planning and implementation of process development, scale-up, technology transfer, and validation efforts in drug substance manufacturing, ensuring strategic alignment and operational excellence.
- Collaborate with cross-functional teams, including analytical development, formulation development, quality assurance, and regulatory affairs, to ensure seamless project progression.

- Manage relationships with contract manufacturing organizations and ensure they meet our quality and production requirements. Oversee technology transfer of drug substance processes to CMOs.
- Prepare technical reports and presentations to communicate results and progress to internal and external stakeholders. Contribute to the preparation and filing of IMPD, IND, and NDA documentation.
- Develop and manage the DS budget, ensuring efficient use of resources and cost-effective processes.
- Implement continuous improvement initiatives to enhance manufacturing efficiency, reduce costs, and improve product quality.
- Collaborate with regulatory affairs to support regulatory submissions and inspections.
- Stay informed about industry trends, technological advancements, and regulatory changes to ensure our manufacturing processes are competitive and compliant.

Primary Job Requirements:

- Advanced degree in Chemistry, Chemical Engineering, Pharmaceutical Sciences or equivalent, with significant experience in Oligo chemistry.
- Proven track record in Active Pharmaceutical Ingredient process development, including scale-up and technology transfer, coupled with a deep understanding of synthetic organic chemistry. Proficient in synthesizer operation, chromatography, and principles of process optimization and scale-up.
- Deep understanding of regulatory requirements and quality standards in pharmaceutical manufacturing.
- Experience in working with CMOs and managing external partnerships.
- Excellent communication, organizational, and project management skills.
- Ability to think strategically and solve problems effectively.
- Commitment to fostering a collaborative and inclusive work environment.

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.