Title: AD/Director of External Manufacturing (Small Molecule)

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 AD/Director of Small Molecule External Manufacturing at QurAlis plays a pivotal role in supporting the development and optimization of chemical processes for small molecule production and overseeing the refinement of external manufacturing processes for Active Pharmaceutical Ingredients (API), drug products, and primary packaging. As a key member of the CMC team, this leader collaborates with process development, quality, analytical, and supply chain teams, and coordinates with Contract Manufacturing Organizations (CMOs). The responsibility is critical to ensuring the consistent delivery of high-quality drug products for clinical and commercial use, adhering to stringent regulatory standards. By optimizing manufacturing strategies and fostering collaboration with cross-functional teams, the Director enhances efficiency, quality, and safety, drives innovation, and ensures that manufacturing practices align with QurAlis's core values.

Primary Job Responsibilities:

- Oversee the operation of API, drug product (solid oral dosage form, oral solution, and suspension), and primary packaging (Stick Pack, sachet, and commonly used packaging configurations) manufacturing at our CMOs, ensuring compliance with all regulatory, safety, and quality standards.
- Support and optimize scalable manufacturing operations at our CMOs, focusing on efficiency and quality standards.
- Support the planning and implementation of manufacturing process development, scale-up, technology transfer, and validation efforts in API, drug product, and primary packaging, ensuring strategic alignment and operational excellence.
- Collaborate with cross-functional teams, including analytical development, process development, quality assurance, and regulatory affairs, to ensure seamless project progression.

- Manage relationships with CMOs, ensuring they meet our quality and production requirements. Oversee technology transfer of API or 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 API budget, ensuring efficient use of resources and cost-effective processes.

Primary Job Requirements:

- Advanced degree in Chemistry, Chemical Engineering, Pharmaceutical Sciences, or a related field, with experience in solid oral dosage forms like tablets/capsules or powders. Experience in enabling technologies to enhance API solubility by Hot Melt Extrusion (HME), Spray-Dried Dispersion (SDD), and Stick Pack formulations.
- Proven track record in API and solid formulation process development, including scale-up and technology transfer, with a robust understanding of HME and SDD chemistry.
- Hands on experience in material characterization using advanced analytical tools is a plus.
- 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 lindsey.harris@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.