QurAlis

We are searching for a **CMC Leader** to join our team in Cambridge, MA!

QurAlis is bringing hope to the ALS community by developing breakthrough precision medicines for this devastating disease. Our stem cell technologies generate proprietary human neuronal models that enable us to more effectively discover and develop innovative therapies for genetically validated targets. We are advancing three antisense and small molecule programs addressing sub-forms of the disease that account for the majority of patients. Together with a world class network of thought leaders, drug developers and patient advocates, our team is rising to the challenge of conquering ALS.

Our team consists of the very best in class researchers, industry veterans and clinicians. QurAlis has already won two Golden ticket awards and receives strong support by a syndicate of institutional and strategic investors. We maintain solid partnerships with clinical, science and patient organizations to ensure our success in bringing a meaningful therapy to ALS patients.

We believe in our core values of:

- Success
- Innovation
- Excellence
- Collaboration
- Empathy
- Drive

Learn more at http://www.quralis.com

CMC Leader: We are looking for a CMC Leader to join the growing team. This individual will be responsible for overseeing the development and implementation of our CMC strategy for therapeutic product development. The CMC Leader will provide regulatory CMC leadership across both ASO and small molecule projects, and will provide strategic and operational leadership for regulatory CMC activities including submissions, reviews, and health authority interactions.

Key Responsibilities:

- Design, develop and implement CMC strategy.
- Deliver strategy objectives, including operational risk management.
- Work collaboratively across teams to develop and implement CMC strategies.
- Interface with internal and external Regulatory Affairs personnel on regulatory strategy and filings.
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- Work with cross-functional project teams to facilitate the timely submissions and approvals of regulatory documents.
- Provide internal expertise on CMC and cGMP regulations.
- Assess project plans and timelines and assign and manage both external and internal team effectively to ensure projects are appropriately prioritized and goals are met.
- Evaluate current processes and communication links and assess opportunities for improvement.

Minimum Qualifications:

- Ph.D. with 8-plus years of relevant biotech/pharmaceutical development work experience.
- Experience in either preclinical or early clinical-phase company.
- Minimum of 5 years of experience working in CMC function.
- Experience in leading CMC submission preparation and Health Authority interactions.
- Strategic thinking and strong problem-solving skills.
- Strong interpersonal skills and the ability to communicate effectively cross-functionally.
- Strong oral and written communication skills.
- Sound understanding of CMC related issues.
- Strong sense of planning and prioritization, and the ability to work with all levels of management in a matrix environment.
- Proven ability to work with interdisciplinary teams and dealing with unfamiliar situations.

Preferred qualifications:

- Experience with antisense oligonucleotides, additional small molecule experience a plus.
- Proficiency in regulatory environments including FDA and EMA.

Please send your resume with cover letter to careers@quralis.com.