Title: Senior Director, Drug Product Development

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 Senior Director of Drug Product Development will be responsible for drug product related activities across QurAlis' portfolio including formulation development and drug product manufacturing from early phase development through commercial launch. This position will collaborate with members of the CMC team and Regulatory Affairs to develop and implement drug product manufacturing and regulatory strategies for QurAlis' drug product candidates. The Senior Director of Drug Product Development will be well-versed in formulation technologies, formulation development, as well as FDA and

EMA regulations, in order to navigate the development of oligonucleotide therapeutics for neurodegenerative diseases.

Primary Job Responsibilities:

May include some or all of the following:

- Drug Product Management: Manage contract manufacturing/research organizations to plan and execute the production of drug product for clinical trials. Provide a critical detailed review of specifications, analytical procedures, manufacturing batch records, product labeling, and other drug product data.
- Formulation Development: Direct formulation development activities with contract manufacturing/research organizations for QurAlis' clinical candidates.
- Drug Product Analytical Methods and Specifications: Collaborate with QurAlis' CMC and contract manufacturing organizations to develop analytical methods and establish phase appropriate specifications for drug products.
- Drug Product Manufacture: Work with Clinical and Regulatory Affairs to establish drug product delivery timelines to meet company goals. Manage contract manufacturing organizations to deliver drug product to meet clinical timelines.
- Upon request, generate figures, presentations and publications to communicate results with scientific community, investors, and collaborators. Support the development of patents and grants relevant to on-going research.
- Quality: Assist the Head of CMC and Head of Quality to ensure that contract manufacturers operate under cGMP in the manufacture and release of drug product for the use in QurAlis' clinical trials.
- Identify, assess and communicate potential project challenges and conduct risk mitigation strategies pertaining to drug product activities. Coordinate and outline the necessary drug product activities in line with the overall development plan of individual assets. As directed by Head of CMC, author, review and finalize drug product documents for IND and NDA submissions, as well as annual reports. Maintain a current knowledge of CMC regulations and guidance.
- Member of global cross-functional team, which require experienced interpretation of applicable EMA/FDA/ICH/WHO/Global regulations to ensure CMC compliance within the organization.
- Ensures project team colleagues, line management, and key stakeholders are apprised of developments that may impact regulatory success, exercising sound judgement and communicating in a professional and timely manner. Provides solutions to prevent recurrence of issues.
- Stays abreast of current and evolving regulatory CMC requirements, applies this knowledge to assigned projects, and shares knowledge and experience with others to support their development.
- Proven ability to liaise with Regulatory Agencies, having experience in CMC submissions and product development meetings; interactions with regulatory agencies; international experience preferred.

Minimum Qualifications Required:

- 10+ years of relevant industry experience, with experience in a drug product development function. At a minimum bachelor's degree with an advanced technical/science degree preferred
- Develops and maintains constructive relations with key internal and external colleagues, e.g., cross functional colleagues within QurAlis, their Partners, and Health Authority representatives.
- As directed by Head of CMC, evaluates change proposals for global regulatory impact and plans global variations and amendments.
- Maintain the confidentiality of all the company deliberations and plans.
- Must be team-science oriented, data-driven, and patient-centric engendering credibility and confidence within and outside the company.
- Good interpersonal skills plus the ability to work in a diverse working community
- Excellent written and verbal communication skills
- Ability to work independently and as part of a team in a fast-paced environment
- Demonstrated ability to juggle multiple competing tasks and demands
- 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.