Senior Director, Drug Product Development

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 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, to navigate the development of oligonucleotide and traditional small molecule therapeutics for neurodegenerative diseases.

Primary Job Responsibilities:

- 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.

- 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.
- 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.
- 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 judgment 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.

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
- Experience evaluating change proposals for global regulatory impact and plans global variations and amendments.
- Experience with small molecule therapeutics.
- Knowledge of regulatory environment (ICH/FDA/EMA regulations) and experience with organizing and writing regulatory submissions.
- Direct experience with managing third-party partners for process development and manufacturing in support of CMC activities.
- Proven ability to liaise with Regulatory Agencies, having experience in CMC submissions and product development meetings; interactions with regulatory agencies; international experience preferred.
- Ability to work independently and as part of a team in a fast-paced environment
- 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.
- Excellent written and verbal communication skills and the ability to work in a diverse working community
- 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 a resume with a 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.