Company:
Urica Therapeutics, Inc. ("Urica") is a clinical-stage biopharmaceutical company that focuses on the development and commercialization of pharmaceutical products to treat gout and other conditions associated with hyperuricemia. Urica acquired the rights to develop and commercialize Dotinurad, a potentially best-in-class URAT1 inhibitor, in the United States, United Kingdom, European Union, Canada, Middle East and North Africa (MENA) and Turkey from Fuji Yakuhin. Dotinurad has been approved to treat gout and hyperuricemia in Japan and is currently in a Phase 1 clinical trial in the United States. Urica was founded by Fortress Biotech, Inc. (Nasdaq: FBIO).

We are looking for a motivated and experienced Director or Senior Director of CMC Quality Assurance with small molecule experience. As CMC Quality Assurance Director, you will lead the CMC function for a development-stage pharmaceutical company. You will have hands-on responsibility for the oversight and execution of CMC-related activities for drug manufacturing through all stages of clinical development and commercial-readiness to support regulatory requirements and serve as a quality expert to provide support for GxP operations to our (3P) third-party manufacturing facility(s).

Position & Location:
- Director or Senior Director of CMC Quality Assurance position reports to the Chairman and Chief Executive Officer
- Offices in Miami, FL, Waltham, MA and New York City, but the position location is flexible

Job Description

Key Responsibilities:
- Manage technical assessment of CMC including source documentation and responds to technical questions on document content
- Ability to review CMC submission sections of IND/IMPD and marketing applications
- Proactively identify potential CMC program and/or submission risks and implement appropriate mitigation strategies to support successful submissions
- Oversee and ensure compliance at CDMOs with quality assurance and regulatory requirements
- Involvement in preparation for and management of CDMO's CMC interactions with Health Authorities
- Manage consultants, contract staff, and vendors, as needed to support CMC regulatory activities
- Create, manage and ensure compliance of CDMO Quality Technical Agreements (QTAs) and business agreement (related to manufacturing)
- Collaborate with CDMO's Heads of Quality, Supply Chain, and Regulatory Affairs, and/or project manager

Requirements / Qualifications:
- Strong organizational and leadership skills in managing teams/vendors in a cross-functional and fast-paced environment
- Comprehensive knowledge of finished products, stability, validation and raw material samples with prior experience in method transfer/improvement

- Knowledge of Solid dosage related process (understanding SOPs, Batch Records, Protocols, Equipment, and Manufacturing facilities)
- Bachelor's degree in a scientific discipline or equivalent
- A minimum of 15+ years of pharmaceutical or biotechnology industry experience with a focus on CMC, with demonstrated increasing expertise and responsibility
- A minimum of 5+ years of relevant experience in a Quality Assurance function
- A solid understanding of FDA regulations and ICH guidance with prior experience in IND and NDA submissions
- Ability to handle multiple projects and exercise good judgment in prioritizing tasks
- Ability to work independently and within a group setting, and to interact effectively with various external partners
- Strong communication skills (oral, written, and interpersonal) and the ability to identify and recommend solutions to problems
- High level of attention to detail, and proficiency with Microsoft Office applications

Compensation:

- Compensation is commensurate with experience to include base salary, bonus potential, equity, and an attractive benefits package. The annual base salary for this position ranges from $175,000.00 - $250,000.00. The range displayed reflects the minimum and maximum salary for this position, and individual base pay will depend on your skills, qualifications, experience, and location. Additionally, this position is eligible for the annual bonus plan and eligible to participate in our long-term equity incentive program.

Urica Therapeutics, Inc. is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, sexual orientation, gender identity, disability status, protected veteran status, or any other characteristic protected by applicable law.

To apply for this position, please send your cover letter and resume to info@uricatx.com.