Director, CMC (Chemistry, Manufacturing, and Controls)

Are you an experienced Chemistry, Manufacturing, and Controls leader interested in joining a company developing the first in a new class of therapeutic compounds designed to improve the lives of people living with chronic and life-threatening diseases? Microbion Corporation is seeking a Director, CMC (Chemistry, Manufacturing, and Controls) to manage and oversee the development and manufacturing of cGMP drug substances and drug products for deployment in pre-clinical, early- and late-stage clinical trials.

Microbion Corporation (www.microbioncorp.com) is a clinical-stage pharmaceutical company developing the first in a brand-new class of therapeutic compounds designed to address critical unmet medical needs of life-threatening and chronic diseases, including rare (Orphan) diseases. Our drug's potential as a viable therapeutic has been validated through over $72M in funding, including $28M in grants awarded to date from the National Institute of Health, U.S. Department of Defense, CARB-X, and the Cystic Fibrosis Foundation. Location: Remote, yet Northwest USA or Vancouver, B.C. is preferred.

Position Summary

This position reports to the Chief Scientific Officer and will be a crucial member of a highly collaborative internal team. This individual will be primarily managing programs and manufacturing campaigns through CDMOs and CROs. They will have proven leadership ability in a fast-paced, multi-location environment. The ideal candidate will have a strong track record of productive interactions with all levels of internal staff and external stakeholders, including but not limited to consultants, CDMOs, and CROs. The position will be virtual/semi-virtual, but preference will be given to candidates located in either Vancouver, BC, Canada, or in the U.S. Pacific Northwest. Other locations may be considered for an exceptional candidate.

Areas of Responsibility

- Manage and oversee the development and manufacturing of small molecule drug substances and drug products in accordance with applicable quality and regulatory standards.
- Manage formulation, process research, and development activities, and, as appropriate, technology transfer, through CDMOs including process validation and the establishment of suitable specifications for excipients and finished drug products
- Manage early and/or late-phase drug substance and drug product analytical activities at contract development laboratories (method development, method qualifications/validations, method transfers, analytical investigations support)
- Review and/or author analytical technical / development and method qualification/validation reports as well as release and stability data packages
- Manage drug substance and drug product stability programs (Q.C. and technical review of stability data packages, including stability data trending)
- Manage reference materials and reference standards inventory and (re)qualification testing
- Evaluate and select drug product packaging, as suitable, for clinical development and commercial purposes.
- Evaluate, recommend, and manage qualified CDMOs for the manufacture of drug substance and drug products for clinical trials, scale-up, validation, and commercial use. In conjunction with Quality Assurance, manage and oversee audits and inspections of CDMOs.
- Author and/or act as a key reviewer of core CMC documents/modules and other forms of submissions and responses to FDA and other Competent Authorities providing strategic oversight

and consistency for regulatory interactions, including, but not limited to, IND/NDA/MAA/IMPD filings and periodic updates.
- Maintain current knowledge of issues relevant to pharmaceutical development, drug development, Competent Authority regulations, and guidance, as well as competitive trends to inform input and recommendations.
- Plan and manage CMC-related budget proposals and approved project budgets in accordance with the Company's strategic and operating plans and Finance policies.

Requirements

- Ph.D. in Chemistry, Pharmaceutical Sciences, Pharmaceutics, or other relevant disciplines, with a minimum of 10 years of directly-related experience in a pharma or biotech environment. Candidates with an MSc and relevant experience may be considered.
- Deep and broad experience in managing development-stage drug substance and drug product manufacturing activities for inhalation and topical dosage forms.
- Experience acting as strategic lead for key CMC sections in US and European regulatory submissions for inhalation and topical dosage forms.
- Extensive knowledge of cGMP-related regulations, guidance, principles, and best practices pertinent to drug substance and drug product.
- Experience with CDMO selection, vendor management, contracting, issue resolution, and management
- Excellent oral and written communication, leadership, and interpersonal skills, and the ability to build credibility and trust inside and outside the Company.
- Proven ability to build and develop high-performing teams; excellent delegation and conflict resolution skills.
- Be science- and data-driven, while at the same time creative and flexible in strategic thinking and problem-solving.
- Demonstrated ability to work effectively and collaboratively on cross-functional, distributed project teams
- Ability to work in a fast-paced and varied environment
- Ability and willingness to travel up to 15% of the time, both domestically and internationally.
- You must already be authorized to work in the United States or Canada without requiring sponsorship

How to Apply

Click on this link to be redirected to our application portal on LinkedIn. We request that all interested and qualified candidates submit a cover letter and CV as a single document. We thank all applicants for their interest; however, only candidates selected for an interview will be contacted.

Microbion Corporation does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.