Director, CMC & Pharmaceutical Development

Mission Therapeutics is an early-stage drug development company targeting the ubiquitin pathway for the treatment of neurodegenerative disease, rare mitochondrial diseases and fibrosis. The Company has built a leading platform for the discovery and development of first-in-class, small molecule drugs that selectively target deubiquitylating enzymes (DUBs) – an emerging drug class that is attracting significant commercial interest in the area of protein homeostasis.

The Director of CMC & Pharmaceutical Development is responsible for leading all CMC and pharmaceutical development activities for Mission's portfolio of development compounds. The position leads CMC & Pharmaceutical Development activities across multiple therapeutic areas and dosage forms. Specifically, this involves managing the technical and quality aspects in the following areas:-

- Active Pharmaceutical Ingredient process development and manufacture.
- Formulation development and manufacture
- Packaging and labelling of Investigational Medicinal Product (IMP) for use in clinical trial, as agreed and in collaboration with the Clinical Team.
- Analytical development and validation associated with the activities above as agreed and in collaboration with Mission chemists.

The position interacts across the entire R&D organisation and takes the lead on CMC & pharmaceutical development activities from supporting candidate selection through to clinical development, partnering closely with key stakeholders within and outside Mission to work collaboratively across multiple functional areas. In particular, the position leads activities related to formulation, analytical development, stability testing, secondary formulation and packaging development for pharmaceutical dosage forms. This includes materials selection, formulation design and in in vitro/in vivo evaluation of pharmaceutical products. Furthermore, the position entails overseeing the scale-up of drug candidates and ensuring processes are developed and controls in place for use in GLP and GMP studies.

The position also leads in developing specifications, documents and maintaining compliance consistent with GLP and cGMP standards for preclinical, early and late stage clinical development.

Key Responsibilities of the role will include

- Lead pharmaceutical development planning and implementation and support for all development compounds ranging from those approaching nomination through all stages of clinical development
- Define and select appropriate formulations for molecules according to their characteristics and stage of development
- Work with a cross-functional team to design, manufacture, and evaluate API and drug products that meet required specifications for both regulated non-clinical and human clinical studies
- Key interface with medicinal chemistry group and external process development consultants to develop scalable manufacturing processes and supporting analytical methodologies for API across multiple therapeutic areas
- Evaluate, select and manage multiple vendors across drug substance and drug product development and manufacturing to deliver product on time and within budget
- Interface with internal and external customers to develop manufacturing processes and analytical methods for drug products across multiple therapeutic areas
- Identify CQAs and develop API and drug product specifications
- Provide support to Non-Clinical Development with provision of Test Item to support Non-Clinical studies (non-GLP and GLP) including development of suitable formulations and that supporting analytical methodology is in place
- Sourcing of APIs, excipients and pharmaceutical packaging; management and distribution of regulated drug product supplies to internal and external collaborators
- Author and review technical documents for internal use and for the CMC section of regulatory filings, including INDs
- Where required, author or review SOPs, policies or guidelines covering Mission's CMC & pharmaceutical development processes
- Create CMC project plans and timelines and provide leadership to ensure all projects are appropriately prioritised and key goals are met on time

- Conduct preformulation, formulation, analytical development, stability and other studies in support of pharmacology and toxicity studies for drug discovery programs
- Develop and maintain an in-depth knowledge of preformulation, formulation, and pharmaceutical development; and the associated regulatory requirements and guidance related to drug development
- Communicate project status and concerns to management and project leadership, together with suggested solutions
- Effectively lead with cross-functional team leaders to achieve corporate and programme goals

Qualifications, Skills and Experience

- Degree in appropriate technical subject (e.g. Chemistry, Biochemistry, Pharmacy). Postgraduate qualification would be a benefit
- 10 years' experience in biotech / pharma CMC, with a focus on small molecule pharmaceutical and formulation development. Less than 10 years' experience may be considered for an exceptional candidate
- Knowledge of GMP requirements for drug substance and drug product manufacturing, as well as analytical method development and validation.
- Extensive experience of managing CDMOs, generating and compiling regulatory documentation, and ensuring quality
- Excellent verbal and written communication skills
- Comfortable taking responsibility and making recommendations regarding program direction
- Must be capable of being both a team player and leading a team
- Must thrive in a fast-moving biotech environment

Benefits

We offer a competitive salary along with a contributory pension scheme and other excellent benefits.

If you would like to apply for the position, please send your CV with a covering letter to **recruitment@missiontherapeutics.com**.

The closing date for applications is 31 January 2022.

In order to comply with UK employment legislation, all applicants for positions at Mission must have the right to work in the UK. In the event that a job offer is made, you will be required to provide evidence of your right to work in the UK before you commence employment with Mission.

All applications received will be managed in accordance with our Job Applicant Privacy Notice available to view on the Careers page of our website **www.missiontherapeutics.com**

No agencies, thank you.