Director/Senior Director, Regulatory Affairs

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.

Reporting to the CMO & EVP Development, the Senior / Director of Regulatory Affairs will be accountable for both the strategy and operational delivery of regulatory affairs for compounds in the Mission portfolio. Working in an SME transitioning into clinical development, this role will need to provide key input into non-clinical and clinical aspects of regulatory preparation, delivering and executing regulatory strategy for novel therapeutics in areas of high unmet need, including rare diseases. Predominantly working in an outsourced model, expertise and effective management of outsourced components of regulatory operations is essential.

Key Responsibilities of the role will include

- Planning and delivery of a global regulatory strategy for lead clinical assets.
- Providing leadership and guidance to internal multi-disciplinary teams (e.g. Non-Clinical functions, Development Operations, DMPK, Clinical Strategy) on the regulatory requirements to support clinical development.
- Leading multi-disciplinary teams in the authoring of regulatory communications such as regulatory briefing packages, applications for Scientific Advice Meetings, Clinical Trial submissions, etc.
- Accountable for submission (either directly or through vendors) of high-quality regulatory packages for CTAs, INDs, with subsequent coordination and provision of responses.
- Development of best practices internally to support regulatory documentation readiness, and development and maintenance of regulatory SOPs.
- Effective management of development safety update reports.
- Taking the initiative to monitor, analyse and disseminate intelligence on regulatory policy and guidelines and make recommendations for impact to projects or organisational practices.

Qualifications, Skills and Experience

- Bachelor's or advanced degree in life sciences or a science related field preferred, and/or other appropriate knowledge or experience.
- 10+ years in regulatory affairs roles in the biotechnology or pharmaceutical industry.
- Knowledge of GMPs, GLPs and GCPs.
- Must have previous experience in leading Major Health Authority interactions (e.g. Scientific advice, pre-NDA/BLA, EOP2 meetings, etc).
- Extensive experience of regulatory drug development, particularly early product development.
- Experience in relevant therapy area(s) with small molecules would be a benefit.
- Proven leadership and program management experience.
- Ability to think strategically and critically evaluate risks to regulatory activities.
- Comfortable with both developing strategy and operationally executing strategy
- Ability to work strategically within a complex, business critical and high-profile development program.
- Successful contribution to a major regulatory approval.

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.