100 High Street, Floor 28, Boston, MA 02210

Position Title:	Executive Director, Clinical Pharmacology
Department:	R&D
Hiring Manager:	Andrew Nichols
Date Opened:	July 2021

We are a team of experts from multiple disciplines who have come together driven to bring hope and life-changing therapies to patients and their families.

Position Overview:

We are looking for a dynamic individual to lead our Clinical Pharmacology organization. Reporting into the CSO, this individual will lead the clinical pharmacology strategy and oversee technical execution across all areas of clinical pharmacology. This position is a key team member in the research and development organization and will serve as a vital part of helping to achieve the company mission: to bring hope with life-changing therapies to patients and families affected by rare diseases. Our company is a place where your input matters -- you will have a direct impact on our science and will help to build our capability as a team. You will also shape the company culture and be a part of a passionate, transparent, and collaborative work environment.

Responsibilities:

- Accountable for the clinical pharmacology strategy for our pipeline, including design and implementation of program specific clinical pharmacology studies, data analysis, internal decision points, and external regulatory interactions.
- Work collaboratively to lead the development and implementation of clinical pharmacokinetic, pharmacodynamic, and modeling and simulation strategies and execution to inform clinical and regulatory decisions through all phases of drug development.
- .
- Demonstrate drive, visibility and influence in key company decisions including development candidate selection, patient dosage selection, clinical strategy, and regulatory filing strategy.
- Manage and be accountable for pharmacokinetic, pharmacodynamic, drug interaction, and anti-drug antibody data generation, analysis and interpretation for all clinical trials.
- Leverage internal and external expertise and your own network to draft, plan, implement, and execute against organizational objectives.
- Actively partner with Clinical Development, Clinical Operations, Nonclinical Development, Pharmaceutical Sciences, and Discovery and Translational Sciences functions in driving asset and company strategy to fruition.
- Build external consultant networks to set the right balance of internal versus external capabilities.
- Contribute to driving the shape of global regulatory filings including preparation of regulatory documentation and active participation in meetings with regulatory agencies.

Qualifications:

- PhD and/or equivalent and experience in one or preferably more of DMPK, clinical pharmacology, pharmacometrics, and pharmaceutics disciplines with at least 10 years of relevant and current technical and leadership experience.
- Experience leading and applying pharmacometric approaches such as population PK, PK/PD, and disease progression models to support research and development.
- Excellent quantitative skills and a vision to leverage the science of dosage projection/simulation, , quantitative systems pharmacology, mechanistic toxicology risk assessment, and pharmaceutics in a cutting-edge discipline.
- Experience with monoclonal antibody development strongly preferred.
- Documented experience in drug development process including multiple regulatory submissions.
- Outstanding interpersonal and communication skills both written and oral and ability to communicate complex information succinctly.
- Excellent analytical and problem-solving skills and ability to manage multiple projects and initiatives simultaneously in a fast-paced environment.
- Effective skills directed toward driving collaboration, achieving results, influencing, and resolving conflicts across internal and external project teams.