Arkuda – Scientist / Senior Scientist, Nonclinical DMPK

October 2021

Recent advances in the understanding of neurodegenerative disease are providing new opportunities to delay disease onset, slow progression and even improve brain health. Arkuda is advancing the discovery of novel therapeutics to delay the onset and slow the progression of neurodegenerative disease. Our initial program is focused on restoring healthy levels of progranulin in people with *GRN*-related frontotemporal dementia (FTD-*GRN*). Building on Arkuda's expertise and commitment to improving treatments for neurodegenerative conditions, our goal is to identify and advance multiple approaches aimed at improving lysosomal function and health.

We are currently seeking to complement the Arkuda team with an experienced nonclinical DMPK Scientist; the exact title will be commensurate with the experience. The successful candidate will design, monitor, and interpret nonclinical ADME/DMPK studies as an integral member of the Discovery teams. In this role, the successful candidate will work closely with other functional areas to advance compounds from Discovery through the Regulatory Submission process.

Responsibilities

- Responsible for ADME/DMPK studies for all Arkuda projects in nonclinical development including design, oversight of conduct and data interpretation for in vitro and in vivo pharmacokinetic/toxicokinetic, ADME and in vitro drug-drug interaction studies
- Directly interface with contract research organizations (CROs) to request quotes and derive cost estimates and timelines, provide scientific input during protocol development and report generation/finalization, and monitor study activities
- Work closely with Research, Toxicology, Regulatory and Clinical to develop an overall nonclinical ADME/DMPK development plan that supports appropriate selection and efficient transition of small molecule candidate molecules into clinical development
- Provide problem-solving of ADME issues in lead compounds and lead series in drug discovery
- Communicate PK results to cross-functional program teams and to the broader organization
- Review nonclinical study proposals to ensure that they fulfill the requirements of the program development plan
- Contribute to the writing of internal reports and regulatory submission documents
- Maintain a current understanding of DMPK literature, methodology and regulatory recommendations/requirements
- Work with external partners for modeling and simulations. The individual will additionally provide the relevant reference documents, develop specifications, address data issues, communicate analysis expectations and timelines to the external partner, as well as provide oversight, direction, and QC of their work

- Maintain a robust network of ADME/DMPK consultant relationships to ensure support to respond to program needs at all stages of nonclinical development

Minimum Qualifications

- Bachelor's or Master's degree in pharmacology/pharmacokinetics/pharmaceutical sciences or a related field with 5 - 8 years of pharmaceutical industry experience or equivalent
- Experience designing, monitoring, and interpreting ADME/DMPK studies
- Demonstrate a sound knowledge of DMPK, ADME and PK/PD principles
- Effective communication, interpersonal and multi-tasking skills
- It is expected that the individual be highly self-motivated and likes to contribute toward problem-solving

Experience or knowledge in one or more of the following is highly desirable

- Knowledge of regulatory guidelines as they pertain to the study design and interpretation of nonclinical DMPK studies, especially in vitro drug-drug interaction studies
- Understanding of PK data flow process and experience with Phoenix WinNonlin
- Experience writing ADME/DMPK sections of regulatory submission documents (INDs, IBs, CTAs)