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AD/Director DMPK-REMOTE

Hiring organization
CarterMacKay

Employment Type
Full-time

Date posted
September 27, 2021

Description

Will strategically design studies to support development of compounds in development pipeline. The Director of ADME will possess deep knowledge and expertise in metabolism and pharmacokinetics with ability to identify and follow up on issues that may present a hurdle to clinical development and/or affect human safety. The incumbent will play a pivotal role on cross-functional teams, and author and edit regulatory documents.

Responsibilities

- Hands on study design, study management, data analysis and presentation for nonclinical studies required to support development activities
- Represent ADME as the subject matter expert for nonclinical development.
- Support programs at different stages with in vitro metabolism and in vivo ADME studies to ensure complete understanding of the metabolism, tissue uptake/distribution and excretion profiles of drug candidates across species, and potential drug-drug interactions.
- Conceive of and develop strategic plans for metabolite identification and characterization
- Deliver the preclinical and translational DMPK work package to support projects in lead optimization and clinical candidate selection.
- Perform human PK projection and contribute to the analysis of preclinical PK/PD data for selection of FIH dose levels.
- Develop PK models and simulations and manage CROs in the conduct in vitro/in vivo ADME and DMPK modeling studies, and analyze, interpret, integrate, and report on nonclinical DMPK data generated with external vendors/CROs.
- Lead and prepare DMPK components of preclinical and clinical study protocol designs, nonclinical and clinical study reports, and investigator brochures.
- Collaborate with Clinical Development to characterize human pharmacokinetics, metabolism, and biopharmaceutics of clinical compounds.
- Partner with other departments as needed to advance drug development.
- Author and edit key pre-clinical and regulatory documents including study protocols and reports, investigator brochures, IND/IMPDs, CTAs and NDAs within agreed timelines.
- Monitor timelines, objectives, and budgets.
- Ensure rapid and effective communication of high-quality data and results to project teams.
- Manage junior team members.
- Other duties as assigned.

Qualifications

- PhD in Chemistry, Pharmacology, Pharmacy or related field required.
- 10+ years industry experience with particular experience in regulated drug development.
- Small molecule drug development experience across multiple therapeutic areas including central nervous system disorders is strongly preferred.
- Strong knowledge of ADME concepts, pharmacokinetic modeling, pharmacodynamic and bioanalytical principles.
- Deep expertise in metabolism, metabolic pathway identification and knowledge of regulatory guidance and work streams related to metabolite characterization
- Strong strategic understanding of the appropriate timing of studies and data needed to enable relevant stage of clinical development.
- Working knowledge of pharmacokinetic and other analysis software (e.g., WinNonlin, NONMEM, etc.) and demonstrated ability to plan, organize, and critically assess and/or perform PK/PD data analysis.
- Experience working with multiple national and international CROs.
- Experience in authoring regulatory submissions and preparing detailed science-based responses to regulatory questions.
- Working knowledge of CMC and product quality, to enable impurity assessment and justification of specifications.
- Ability to manage multiple work streams and projects concurrently.
- Ability to problem-solve, research issues, and propose solutions.
- Excellent interpersonal and communication skills, both written and oral, and ability to communicate complex information succinctly.
- Effective and constructive collaborator.
- Ability to function independently in fast-paced, virtual environment.
- Strong working knowledge of GxP, FDA, and ex-US regulatory requirements

Contacts

For a more comprehensive list over over 25 total openings, please contact Brenda Roseberry directly

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