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Executive Director DMPK

Hiring organization
CarterMacKay

Date posted
September 9, 2025

Description

- Provides strategic, functional leadership and oversight to the Preclinical DMPK function within Preclinical Development
- Responsible for the development and enablement of departmental strategies to evaluate Preclinical Pharmacokinetics including ensuring continued expansion and/or updating of training, techniques and/or equipment
- Leads and manages the conduct, interpretation and reporting of preclinical pharmacokinetic studies
- Works with Research and Preclinical Development colleagues to establish optimal lead candidate characteristics, develop appropriate testing schemes, and design, conduct and report on preclinical studies intended to characterize potential drug candidates
- Designs & conducts Preclinical Pharmacokinetic and Toxicokinetic/Pharmacokinetic/Pharmacodynamic studies in support of clinical development compounds
- Oversees the preparation of Preclinical Pharmacokinetic sections of regulatory documents (IND, NDA, briefing books, Investigator Brochures, etc.).
- Actively leads/participates in research-stage and development-stage program teams from both a strategic and tactical level
- Prepares data summaries and presents results to peers, colleagues, the Management Committee and regulatory agencies
- Prepares Standard Operating Procedures (SOPs) as needed to guide the Preclinical Pharmacokinetics activities
- Performs other duties as assigned

Requirements:

- PhD in Pharmacokinetics, Pharmaceutical Sciences, or closely related discipline or PharmD and 15+ years of similar experience noted above
- Demonstrated leadership of a Preclinical Pharmacokinetic/DMPK function
- Extensive experience in managing preclinical Contract Research Organizations
- Excellent knowledge of preparation of INDs, CTAs, NDAs, and MAAs
- Working knowledge of in silico modeling and simulation tools

Job Benefits

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