CARTERMACKAY

Recruiting | Consulting Services

https://www.cartermackay.com/jobs/scientist-sr-scientist-clinical-pharmacology-remote/

Scientist/Sr. Scientist Clinical Pharmacology-REMOTE

Hiring organization
CarterMacKay

Employment Type
Full-time

Date posted
September 27, 2021

Description

This position will participate in clinical pharmacology strategy and execution for candidate drug products from early development (pre-IND) through late stage development (Phase 3 and NDA filings) using pharmacokinetic, pharmacodynamic, DMPK, and drug therapeutic principles, and knowledge of drug regulatory processes. This position contributes to and supports the company's research and development efforts to create high value therapeutics to address unmet medical needs.

Demonstrated success in technical proficiency, scientific creativity, collaboration with others and independent thought. Serve as a clinical pharmacology representative for clinical studies, manage clinical pharmacology aspects of the clinical studies. Work on complex problems in which analysis of situations or data requires an in-depth evaluation of various factors. Exercise judgment within broadly defined practices and policies in selecting methods, techniques and evaluation criteria for obtaining results. May determine methods and procedures on new assignments. Ensure schedules and performance requirements are met.

- Assist in developing clinical pharmacology plans, design and direct clinical pharmacology and clinal studies, and work cross-functionally to establish clinical protocols.
- Provide scientific leadership in the preparation, conduct and reporting of clinical pharmacology studies.
- Independently draft clinical pharmacology study reports and summarize them for regulatory submission documents. Assist in integrating and interpreting nonclinical and clinical pharmacology, DMPK, and translational medicine knowledge;
- In the preparation of nonclinical and clinical pharmacology write-ups and regulatory documents (IND, IMPD, IB, BLA/NDA CTD); and in defending the package in interactions with Regulatory Agencies.
- Collaborate with pharmacometricians in the modeling of emerging PK and PK/PD data. Participate in writing publications and making scientific presentations consistent with development strategies.
- Maintain knowledge of relevant scientific, regulatory practices and trends, and ensure that clinical pharmacology aspects of development programs are contemporary. Other duties as assigned.

Qualifications

A Pharm. D. or PhD in a scientific discipline is required. Equivalent experience may be accepted. A minimum of 0-5 years work experience in an industry research and/or development environment is required. Post-doctoral work may serve as experience. Exceptional non-PhDs with demonstrated capabilities and/or significant experience may also be considered. Biomarker knowledge is a plus. Must be able to demonstrate significant success in technical proficiency, scientific creativity, collaboration with others and independent thought. Must be able to clearly communicate scientific information both written and oral. Ability to present technical information to both technical and non-technical audiences is required.

Must be able to demonstrate sound judgment. Must be able to demonstrate problem solving capabilities. Strong organizational skills are required. Experience working in an FDA regulated environment and knowledge of current GMPs as they apply to laboratory practices are highly desired. Must have hands-on experience with data analysis, non-compartmental and compartmental PK/PD analysis and using data processing software such as Phoenix WinNonlin, R, NONMEM, or MONOLIX. Good working knowledge of graphing software such as SigmaPlot, Prism, R is required.

Contacts

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

Brenda Roseberry
Division Manager-Scientific
Preclinical/Clinical–PK, Pharmacology, Pharmacometrics, Biomarkers
720-328-9526 – Office
315-415-4353 – Mobile (preferred)
720-475-1176 – Fax