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# Principal Scientist, Clinical Pharmacology and M&S-REMOTE

**Hiring organization**
CarterMacKay

**Employment Type**
Full-time

**Date posted**
September 27, 2021

## Description

The Principal Scientist of Clinical Pharmacology will be responsible for the development and implementation of the Clinical Pharmacology and Modeling Simulation strategies for cutting-edge novel modalities including Bi-specific T-cell engagers, antibody-drug-conjugates, CAR-T cells, oncolytic virus & listeria based immunotherapies in addition to small molecule & mono-clonal antibodies. The Principal Scientist will be a member of cross-functional global drug development teams as the Clinical Pharmacology, Modeling & Simulation department representative & will be Subject Matter Authority who will apply cutting-edge Quantitative Pharmacokinetic/Pharmacodynamic (PK/PD) approaches to ensure development of safe & effective dosing regimens for various patient sub-populations & also ensure optimal drug development. The Principal Scientist will also be responsible for designing integrated Clinical Pharmacology Modeling & Simulation plans & designing, planning and execution of clinical pharmacology studies in support of these plans.

## Qualifications

- PhD (in Pharmacokinetics or Pharmaceutical Sciences or Pharmacology) or (MD or PharmD)
- 6 years experience as Clinical Pharmacology Modeling & Simulation functional representative on product development teams in the Biotechnology/Pharmaceutical Industry.
- Experience in designing strategic integrated clinical pharmacology & modeling simulation plans in support of development of small molecule and/or protein therapeutics.
- Experience in leading the design and execution of clinical pharmacology studies including bioequivalence, drug-drug interaction, special population, ethnic sensitivity, ADME and pediatric studies and integrating results into regulatory filings, and product labels.
- Established track record of Model Based Drug Development. Hands-on experience in population PK/PD & PBPK modeling and simulation.
- Experience with PK and PK/PD strategies, data analysis, interpretation, and reporting of PK and PK/PD data from clinical studies.
- Established track record of interaction with global health authorities, authoring regulatory documents, knowledge of global regulatory requirements and guidance.

## 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**
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