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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
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