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Senior Director/VP Clinical Pharmacology- REMOTE

Hiring organization
CarterMacKay

Employment Type
Full-time

Date posted
July 28, 2021

Description

- Be a strategic leader developing and growing the clinical pharmacology function
- Build, mentor and lead a team of clinical pharmacology representatives on clinical stage programs
- Develop clinical pharmacology strategy for clinical programs to secure global regulatory approvals.
- Lead the analysis, interpretation, integration and reporting of clinical pharmacokinetic & pharmacodynamic data and work closely with pharmacometricians to develop model-based justifications for optimal doses selected for pivotal clinical trials, while working in close partnership with DMPK scientists and Clinical Development physicians and statisticians.
- Develop an understanding of the relationship between clinical data and preclinical findings to inform individual development programs as well as broader technology platform research initiatives.
- Work closely with Alnylam's Bioanalytical Sciences group to understand analytic methods, method validations, project plans, and data reports in support of drug concentration and PK data.
- Develop regulatory strategies for special patient populations (e.g. hepatic- or renally- impaired patients), need for thorough QTc studies, DDI evaluations, or clinical mass balance studies.
- Design and oversee the conduct of clinical pharmacology studies (either standalone or within broader clinical trials) to generate high quality and relevant data.
- Network with external expert consultants, CRO partners and academic sites to problem solve and develop scientific solutions to clinical pharmacology issues.
- Lead and prepare appropriate documents or sections of clinical protocols, Investigator Brochures, Clinical Study Reports with respect to Clinical Pharmacology studies or data
- Participates in Clinical Pharmacology data analysis and interpretation and in preparation of documents for IND and NDA filings and draft clinical pharmacology sections of drug labels.
- Participates in the preparation of abstracts and manuscripts for publication
- Closely partner with all Clinical functions, Regulatory, Project Management, and other R&D functions.

Qualifications

Ph.D. in Pharmacokinetics, Pharmacology, Pharmaceutics or other relevant field with at least 10 years' experience in the biopharmaceutical or pharmaceutical industry, or M.D or Pharm.D. with equivalent experience.

Experienced in leading and managing teams. Strong knowledge of pharmacokinetics and modeling, pharmacodynamic principles, ADME concepts,

bioanalytical principles, and late stage clinical development requirements for clinical pharmacology evaluation. Proficient in using WinNonlin or other pharmacokinetic and modeling software. Experienced in shaping and negotiating clinical pharmacology development strategies with health authorities. Successful NDA filing and registration experience highly desirable.

Contacts

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

Brenda Roseberry
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