

Sr/Exec. Director Clinical Pharmacology

Hiring organization
CarterMacKay

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Description

We are seeking a **Senior Director of Clinical Pharmacology** to provide strategic and scientific leadership in clinical pharmacology. In this high-impact role, you will drive the development of clinical pharmacology plans, lead PK and PK/PD analyses, and play a key role in advancing our portfolio of peptide-based therapies across all phases of clinical development. Reporting into the Chief Medical Officer, you will play a vital role in shaping the clinical pharmacology approach. Additionally, this position will inspire a high-performing team and promote an innovative, collaborative culture throughout the organization.

Key Responsibilities

- Serve as the primary clinical pharmacology lead for all programs and effectively participate in cross functional teams to ensure integration of modern clinical pharmacology principles into project plans and study design
- Develop and advise on PK and PK/PD study designs to optimize data collection and inform dose recommendations across all clinical phases.
- Craft analysis plans, conduct advanced PK and PK/PD evaluations, and translate data into actionable insights that drive development decisions.
- Generate high-quality clinical PK/PD reports and contribute to key regulatory documents, including Investigator Brochures (IBs), Clinical Study Reports (CSRs), Briefing Packages, and CTD Modules.
- Partner with clinicians, biostatisticians, and data managers to ensure timely delivery of analysis specifications and other critical outputs.
- Manage relationships with and oversight of external clinical pharmacology vendors
- Present findings at scientific conferences, foster collaborations, and publish in peer-reviewed journals.

Education & Qualifications

- MS, PharmD, or PhD in PhD degree in clinical pharmacology, pharmacokinetics, pharmaceutical sciences, pharmacology, chemistry, biochemistry, or related field.
- 10+ years of experience designing and executing clinical development plans.
- Experience with Peptide/Protein is preferred
- Demonstrated excellence in preparing regulatory documents and engaging with regulatory agencies.
- Strong proficiency in PK/PD analyses and modeling across all clinical stages, from FIH to registrational studies.
- Proven ability to build strong relationships across internal teams and external stakeholders.
- Quick thinker with the ability to navigate scientific and strategic challenges effectively.
- Detail-oriented leader with strong organizational skills and a commitment to

high-quality work.

Contacts

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