

Associate Director, Pharmacokinetic Sciences (PKS)

Job ID REQ-10005158 Mai 15, 2024 USA

Summary

#L1-Hybrid

About the role:

This position will be on-site with preference for Cambridge, MA and will not have the ability to be located remotely.

In the role of Associate Director in PKS you will provide ADME /PK/PKPD project support in the Cardiovascular and Metabolic Therapeutic Area by contributing to the transition of drug projects from discovery to First-in-Human studies and further clinical development. In this unique role you will collaborate and partner with PKS functions including in vitro and in vivo ADME, biotransformation, bioanalytics and modeling & simulation (M&S) and represent the PKS organization within project teams.

About the Role

Key responsibilities:

- Support teams in developing the strategy for, and coordinate the implementation of, the characterization of drug candidates with favorable PK/ADME properties, elucidating PK/PD relationships driving efficacy/safety and contribute to human PK prediction and dose and regimen selection.
- Provide matrixed leadership across the organization to align and influence across the cross-functional team to identify and mitigate key project issues related to the PKS discipline (e.g., PK, PK/PD, metabolism and clinical pharmacology).
- Proactively contribute to develop candidate drug products by providing expert pharmacokinetic / drug metabolism / biopharmaceutics and clinical pharmacology input and plans.
- Be responsible for the PK, PK/PD and M&S component of study protocols, reports, project summaries and development plans, and author pharmacokinetic/clinical pharmacology/biopharmaceutics sections of IND/IMPDs and NDAs within agreed timelines and which meet regulatory requirements as well as prepare appropriate responses to Health Authority questions (globally).
- Oversee or perform PK and PK/PD analyses using a variety of tools and approaches and integrate, interpret and report data to project teams and other customers. Our organization further offers the opportunity to seamlessly gain exposure to different stages of development, different drug modalities and cross-train in multiple indications.

Novartis EVP Manifesto.mp4

Essential Requirements:

- Ph.D. or Pharm.D. with relevant experience in clinical pharmacology, drug metabolism and pharmacokinetics or a related biologic background.
- A minimum of four to six plus years in early/late drug development including 2 plus years of experience in a lead role overseeing ADME/DMPK strategy of drug development, clinical protocol and report writing, clinical pharmacology plans, modeling strategies, Health Authority interactions.
- Extensive and in-depth knowledge of pharmacokinetics including, drug metabolism and PK/PD evaluation, experience in working in project teams (preferably global) as well as sound awareness of recent developments in drug development and regulatory sciences.
- $\bullet \ Proficient \ in \ the \ application \ of \ PK \ and \ PK/PD \ analysis \ with \ working \ knowledge \ of \ software \ such \ as \ WINNONLIN/Phoenix \ and \ such \ analysis \ with \ working \ knowledge \ of \ software \ such \ as \ WINNONLIN/Phoenix \ analysis \ with \ working \ knowledge \ of \ software \ such \ as \ WINNONLIN/Phoenix \ analysis \ with \ working \ knowledge \ of \ software \ such \ as \ WINNONLIN/Phoenix \ analysis \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \ with \ working \ knowledge \ of \ software \ such \ as \ with \ working \$
- · Hands-on project experience with low molecular weight and biologics is required with oligonucleotide experience optional in drug development.
- Proven record as leader with good negotiation, organizational and project management skills.
- · Strong coaching and mentoring skills desired.

Benefits and rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$151,200 - \$226,800/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

https://www.novartis.com/about/strategy/people-and-culture

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Division

Biomedical Research

Business Unit
Pharma Research
Standort
USA
Site
Cambridge (USA)
Company / Legal Entity
U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular

Shift Work No Apply to Job

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Associate Director, Pharmacokinetic Sciences (PKS)

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