

Associate Director, M&S PBPK

Job ID
393342BR
May 23, 2024
USA

About the Role

Hybrid

This position can be based at our East Hanover, NJ or Cambridge, MA campus and will not have the ability to be located remotely.

About the role:

Translational Medicine (TM) is the clinical research arm of NIBR, and includes about 1000 associates globally. TM plays a pivotal role in bringing innovative medicines to patients, by building on research advances to develop new therapies, and bridging drug discovery and clinical application. PK Sciences (PKS), within TM, collaborates across both NIBR and the Global Drug Development organizations to advance the scientific knowledge of pharmacokinetics, metabolism and clinical pharmacology.

The Modeling & Simulation group within PK Sciences is looking for an Associate Director, to develop and apply translational physiologically based pharmacokinetic (PBPK) modeling along with data analysis techniques to facilitate drug discovery, development, and translational research across disease areas. The candidate's core responsibilities will include PBPK modeling to integrate in vitro and in vivo data for drug-drug interaction (DDI) assessments, impact of biopharmaceutics properties on absorption, and pharmacokinetic (PK) predictions in humans as well as in specific populations (e.g. disease, organ impairment, pediatrics). The ultimate goal of this work is to be on the forefront of applying PBPK models to inform the safe administration of our drug candidates in the clinic, to optimize clinical trial designs, and waive clinical trials, ultimately, to get our medicines to patients faster.

Your Key Responsibilities:

- Expert PBPK modeler to provide translational modeling support for global drug discovery and development projects
- Perform translational PBPK analyses to predict clinical drug exposure in specific populations, assess potential for DDI, understand clinical impact of disease on drug exposure, as well as apply biopharmaceutic PBPK modeling to support formulation changes and achieve clinical biowaivers
- Integrate PK/ PD data, ADME and DDI findings
- Ability to interpret and communicate modeling results and potential impact to project teams
- Prepare summary documents for use in regulatory submissions and ability to respond independently to health authority questions

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$166,400 - 249,600/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.

Diversity & Inclusion / EEO

We are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Accessibility and Reasonable Accommodations: Individuals in need of a reasonable accommodation due to a medical condition or disability for any part of the application process, or to perform the essential functions of a position, please let us know the nature of your request, your contact information and the job requisition number in your message:

- Novartis: e-mail us.reasonableaccommodations@novartis.com or call +1 (877)395-2339
- Sandoz: e-mail reasonable.accommodations@sandoz.com or call: +1-609-422-4098

Role Requirements

As an Associate Director in PBPK you will have a deep understanding of ADME/DMPK principals and biopharmaceutics knowledge, experience with industry standard PBPK modeling packages (such as GastroPlus or Simcyp), have experience with regulatory submissions and in successful regulatory interactions, interdisciplinary thinking and great attention to detail. You will work in a dynamic and multidisciplinary environment to build, verify and apply quality translational/biopharmaceutical PBPK models.

Essential Requirements:

- PhD in pharmaceutical sciences or related discipline with experience in ADME/DMPK sciences, biopharmaceutics, and modeling and simulation
- 5+ years in pharmaceutical industry including demonstrated knowledge and experience with PBPK modeling.
- Hands on experience with PBPK modeling tools such as PK-Sim, Simcyp, or GastroPlus is required. In addition, experience with modeling software such as Monolix, R, Phoenix, or Nonmem is desired.
- Experience in authoring regulatory documents, knowledge of global regulatory requirements and guidance
- Broad knowledge of drug discovery and development, e.g., pharmacokinetics, drug delivery, formulation, ADME, DDI, etc.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

<https://www.novartis.com/careers/benefits-rewards>

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

Accessibility and Reasonable Accommodations: The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here:

<https://talentnetwork.novartis.com/network>

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

Division

Biomedical Research

Business Unit

Translational Medicine

Location

USA

Site

East Hanover, NJ

Company / Legal Entity

Novartis Pharmaceuticals

Functional Area

Research & Development

Job Type

Full Time

Employment Type

Regular

Shift Work

No

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