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ADME Scientist – Assay Development/Support, Cambridge, MA

Job ID 261526BR

Job Description
One ADME Scientist is all it takes to contribute to advancing new therapies to improve patients lives. At the Novartis Institutes for Biomedical Research (NIBR) we are reimagining medicine using science-based innovation.

The PK Sciences group is seeking a highly qualified multi-disciplinary team-oriented Scientist with emphasis in the area of in vitro drug transport and disposition with experience in bioanalytical and laboratory automation technologies.

PK Sciences (PKS) is a global organization of about 300 associates, situated within Translational Medicine (TM), the clinical research arm of NIBR. PK Sciences plays a pivotal role in bringing innovative medicines to patients, by building on research advances to develop new therapies, bridging drug discovery and clinical application. PK Science is an enterprise organization, working across both NIBR and the Global Drug Development (GDD) organizations to advance the scientific knowledge of pharmacokinetics, metabolism and clinical pharmacology.

In this role, you will impact the selection of development candidate molecules and interact with project team representatives to design specific assays to validate/invalidate hypotheses.

The successful candidate will have three main responsibilities:

(1)Developing cell-based assays aimed at investigating drug transport and permeability properties on new drug candidates (2) Developing assays to examine the in vitro metabolic disposition of new drug candidates using medium-throughput automated systems, including trouble shooting, scheduling maintenance (3) Developing bespoke biochemical assays aimed at investigating addressing mechanism-specific to support early drug discovery project teams. A good understanding of the DMPK and biochemical principles underlying in vitro ADME testing is essential and experience validating and implementing automated assays is desirable. The successful candidate must demonstrate strong experimental and problem solving skills, excellent collaboration and communication skills (both written and oral), and an eagerness to learn. Demonstration of meeting timelines and excellent time management is favored. The ability to work in a team-based drug discovery/ development environment is essential.

Minimum requirements What you'll bring to this role:

A B.S. degree in Chemistry/Biochemistry/Analytical Chemistry or a closely related discipline with 2 plus years experience (or an M.S. with a minimum of one year of experience) in running in vitro biochemical assays, basic programming and technical support of automated laboratory robotic systems, and assay development/routine support in drug metabolism, permeability, or related fields is required. Demonstrated strong understanding of bioanalysis utilizing LC-MS with special emphasis on the application of high throughput in vitro ADME sample analysis in the drug discovery setting. Experience in programming laboratory automated systems is an additional asset.

Why consider Novartis?
927 million. That’s how many lives our products touched in 2017. Moreover, while we’re proud of that fact, in this world of digital and technological transformation, we must ask ourselves this: how can we continue to improve and extend even more people’s lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you’re given opportunities to explore the power of digital and data. Where you’re empowered to risk failure by taking smart risks, and where you’re surrounded by people who share your determination to tackle the world’s toughest medical challenges.
We are Novartis. Join us and help us reimagine medicine.

Contact: guiqing.liang@novartis.com

NOVARTIS

Investigator III, Discovery Bioanalytical Sciences, Cambridge, MA

Job ID 262204BR

Job Description

6500! That's the number of associates in the Novartis Institutes for BioMedical Research (NIBR). This division is the innovation engine of Novartis, focusing on powerful new technologies that have the potential to help produce therapeutic breakthroughs for patients.

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In the role of Investigator III, Discovery Bioanalytical Sciences within PKS you will:

• Analyze samples in the laboratory, evaluate and interpret bioanalytical data and results from Discovery Pharmacokinetic and Pharmacodynamics (PK/PD) studies primarily on biologics, cell and gene therapy drug candidates across all therapeutic areas.
• Independently develop new technological and scientific processes or approaches, incorporating latest technologies and knowledge into research activities to achieve efficient and timely fit for purpose bioanalytical results to discovery scientist partners.
• Participate in teams together with scientists from other units in Novartis and with external partners to evaluate pharmacodynamic properties of drug discovery candidate molecules
• Support Novartis drug development goals by setting strategy, designing and implementing scientific and technological processes to achieve platform goals, and directing activities of group members to achieve results
• Represent team and results to internal groups, provide detailed study reports to include Non-Compartmental Analysis, and publish and present at external meetings

Minimum requirements What you will bring to this role:

• A PhD and post-doctoral training in a relevant scientific discipline plus a minimum of 4 years post-graduate experience. Some industry experience preferred.
• Understanding of principals of bioanalytical analysis, with specific expertise in ligand binding testing and an understanding of cell based assays.
• Demonstrate creativity and resourcefulness in applying new bioanalytical methodologies and techniques
• Possesses and maintains an exceptional scientific expertise in bioanalysis by reviewing current literature and technical trends, both internal and external to discipline, that could impact projects

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Investigator I, Discovery Bioanalytical Sciences, Cambridge, MA

Job ID 262200BR

Job Description

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In the role of Investigator, Discovery Bioanalytical Sciences within PKS you will:

• Analyze samples in the laboratory, evaluate and interpret bioanalytical data and results from Discovery Pharmacokinetic and Pharmacodynamics (PK/PD) studies on primarily on small, low molecular weight, drug candidates across all therapeutic areas.
• Design and perform bioanalytical experimental work independently and engage in challenging research questions with partner drug discovery scientists.
• Identify and develop innovative solutions and technologies to experimental/scientific questions
• Generate rapid and accurate bioanalytical data to enable Drug Discovery decisions.
• Provide process and technical improvements to bioanalytical procedures to increase throughput and efficiencies while maintaining high quality and fit for purpose accuracy of laboratory measurements.
• Network internally and externally in order expand scientific knowledge and optimize contributions to projects and exploratory research
• Train junior members of team and actively coach them
• Act as back up for supervisor during absences on lab related decisions
• Present results internally/externally
• Write final reports and internal/external publications
• May have additional tasks (e.g. instrument calibrations) or responsibilities

Minimum requirements You will be required to:

Possess a PhD in a relevant scientific discipline and/or related equivalent experience including some hands-on post-graduate experience.
Working knowledge in bioanalytical sciences and quantitative measurements to support PK and PD assessments.
• Working knowledge in bioanalytical sciences and quantitative measurements to support PK and PD assessments.
Have hands on bench experience in mass spectrometry and or ligand binding quantitation assays.
• Demonstrate Novartis Values & Behaviors
• Understand principals of bioanalytical analysis, with specific expertise in mass spectrometry quantitative assays.
• Possess a knowledge of the bioanalytical field including the scientific background and literature as well as relevant health authority guidelines.
• Have general knowledge of pharmacokinetic data relevance and interpretation in drug discovery environment.
• Be familiar with concepts of data handling and interpretation.
• Operate and perform routine trouble-shooting maintenance on instruments and evaluation of new equipment and technologies.
• Conduct activities in the laboratory and supervise lab operations in compliance with Novartis safety, waste disposal and other regulatory guidelines

Decision Making

• Independently conceive, execute in the laboratory and interpret a complete range of experiments in bioanalytical sample testing
• Provide direction on improved methodologies and process improvements.
• Identify complex problems and provide innovative solutions
• Act as back up for supervisor on lab related decisions

Collaboration/Connectivity/Organizational Know-how

• Network extensively with Novartis internally with colleagues in all Novartis therapeutic areas.
• Focus on partner needs in Drug Discovery research areas
• Possess a strong teamwork orientation, working both collegially and collaboratively

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PKS Investigator, Discovery through Development, Cambridge, MA

Job ID 258870BR

Job Description

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PK Sciences (PKS) is a global organization of about 300 associates, situated within Translational Medicine (TM), the clinical research arm of NIBR. PK Sciences plays a pivotal role in bringing innovative medicines to patients, by building on research advances to develop new therapies, bridging drug discovery and clinical application. PK Science is an enterprise organization, working across both NIBR and the Global Drug Development (GDD) organizations to advance the scientific knowledge of pharmacokinetics, metabolism and clinical pharmacology.

We are seeking a project team member to join the PKS team at the **Cambridge, MA location**. He/she will collaborate with business partners to select and characterize new chemical and biologic entities from research and advance promising entities into the clinic. The qualified candidate will represent the PK/PD/ADME discipline on discovery and development project teams, and suggest and implement strategies and tactics to advance high-quality entities as part of the overall program(s).

The position is an individual contributor in therapeutic areas that focus on, but are not limited to, indications in liver, kidney and hematologic diseases. The NIBR portfolio consists of projects using several therapeutic modalities including small molecules, biologics, gene therapy and cell-based therapies.

Responsibilities include:

• The individual will represent the PK/PD/ADME discipline, and serve as the primary source of scientific expertise on global cross-functional project teams, leading the design, execution, and analysis of PKS preclinical and clinical studies.
• Working with subject matter experts in PKS and partner groups, support the efficient application and integration of modeling and simulation tools to advance lead optimization and clinical candidate selection.
• Make use of PKS resources across NIBR organizations to drive project efforts; ensure an aligned position on research strategy and in particular human PK/PD and dose projections as candidates transition into the clinic.
• Support PKS components of preclinical and clinical study protocol designs, preclinical and clinical study reports, and investigator brochures, etc. Prepare for Health Authority calls/meetings/discussion and be responsible as PKS representative in these settings.
• Collaborate with other NIBR and GDD functions, bring innovative ideas and approaches, and a leadership, enterprise mindset that inform and influence the overall drug discovery and development process.

Minimum requirements

• PhD in pharmacology/physiology, biochemistry, chemistry, pharmacokinetics/pharmaceutical sciences, or related sciences.
• A good understanding of the drug discovery and development process, with a minimum of 3+ years in a drug discovery setting in industry.
• Familiarity with standard ADME/PK modelling tools such as Phoenix, GastroPlus, etc.
• Hands-on project experience with low molecular weight and biologics modalities desirable; and cell-based and/or gene-based therapies highly desirable.
• Experience in authoring regulatory documents, knowledge of global regulatory requirements and guidances desired.
• Excellent written and oral communication skills is a must.

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PKS Investigator, Neuroscience/Musculoskeletal Disease Team, Cambridge, MA

Job ID261996BR

Job Description

450 projects straddling discovery through development in PK Sciences (PKS) for you to represent the PK/PD/ADME discipline on discovery and development project teams. As a project team member, you will also suggest and implement strategies and tactics to advance high-quality entities as part of the overall program(s).

PK Sciences (PKS) is a global organization of about 300 associates, situated within Translational Medicine (TM), the clinical research arm of NIBR. PK Sciences plays a pivotal role in bringing innovative medicines to patients, by building on research advances to develop new therapies, bridging drug discovery and clinical application.

We are seeking a project team member to join the PKS Neuroscience/Musculoskeletal Disease team in Cambridge, MA.

In this role you will collaborate with business partners to select and characterize new chemical and biologic entities from research and advance promising entities into the clinic. You will also serve as an individual contributor in therapeutic areas that focus on neuroscience and musculoskeletal diseases.

The NIBR portfolio consists of projects using several therapeutic modalities including small molecules, biologics, gene therapy and cell-based therapies.

Major Accountabilities will be to:

• Represent the PK/PD/ADME discipline, and serve as the primary source of scientific expertise on global cross-functional project teams, leading the design, execution, and analysis of PKS preclinical and clinical studies.
• Work with subject matter experts in PKS and partner groups, support the efficient application and integration of modeling and simulation tools to advance lead optimization and clinical candidate selection.
• Make use of PKS resources across NIBR organizations to drive project efforts; ensure an aligned position on research strategy and in particular human PK/PD and dose projections as candidate transition into the clinic.
• Facilitate constructive collaboration within the Line Function and between Global Project Team and the early project teams.
• Support PKS components of preclinical and clinical study protocol designs, preclinical and clinical study reports, and investigator brochures, etc. Prepare for Health Authority calls/meetings/discussion and be responsible as PKS representative in these settings.
• Collaborate with other NIBR and GDD functions, bring innovative ideas and approaches, and a leadership, enterprise mindset that inform and influence the overall drug discovery
and development process.

• Be responsible for the compilation, seeking of approval and updating of Line Function specific elements of development plans to support the TPP (Target Product Profile).
• Independently manage and coordinate relations with regulatory authorities, line function, unit heads and Drug Regulatory Affairs.
• Manage the preparation/presentation of all internal and external (e.g. Investigator’s Brochure, IND, CTD) documentation.
• Evaluate in-licensing opportunities and carries out Due Diligence activities as required.
• Advise and mentor part-time Project Team Representatives and less experienced Project Team Representatives:
• Co-lead nonclinical subteam with Toxicology, BMD and Research counterpart

Minimum requirements What you will bring:

• A PhD in pharmacology/physiology, biochemistry, chemistry, pharmacokinetics/pharmaceutical sciences, or related sciences.
• A good understanding of the drug discovery and development process, with a minimum of 3+ years in a drug discovery setting in industry with focus in neuroscience and musculoskeletal diseases.
• Familiarity with standard ADME/PK modelling tools such as Phoenix, GastroPlus, etc.
• Hands-on project experience with low molecular weight and biologics modalities desirable; and cell-based and/or gene-based therapies highly desirable.
• Experience in authoring regulatory documents, knowledge of global regulatory requirements and guidances desired.
• Possesses a broad knowledge of overall drug development aspects outside own area of expertise.
• Proven record as team player/leader with superior negotiation skills.
• Ability to manage conflicting expectations in a matrix environment.
• Excellent project management skills.
• Excellent knowledge of drug development guidelines.
• Ability to coach and advise colleagues in project related matters.
• Fluent English (oral and written).
• Excellent written and oral communication skills is a must

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Senior Investigator, PKS Oncology Biologics, Cambridge, MA

Job ID 260622BR

Job Description

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The Senior Investigator, PKS Oncology supports oncology biologics drug discovery and development by providing DMPK and clinical pharmacology expertise.The major focus of this role will be in drug discovery for biologics modalities. This individual represents the PKS global line function on cross-functional teams driving the design, execution, and analysis of DMPK and clinical pharmacology studies.

In this role you will:

- Support for the efficient application and integration of PK and ADME studies in support of clinical, candidate selection and lead optimization programs
- Contribute expert pharmacokinetic / DMPK input into key pre-clinical, clinical and regulatory documents including clinical study protocols, clinical study reports, investigator brochures, IND / IMPD's within agreed timelines, and meeting all regulatory requirements under minimal guidance from manager.
- Design clinical pharmacology strategy for assigned program and coordinates pharmacokinetic / DMPK related elements for projects. Identifies potential project hurdles, suggests solutions and establishes contingency plans. Represent TCO Clinical Pharmacology on Early Project Teams (EPTs).
- Ensure constructive collaboration within EPTs and with other internal business partners including, Global Discovery Chemistry, Preclinical Safety, Technical Research and Development, Biostatistics and Data Management, Drug Regulatory Affairs, and Modeling and Simulation (M&S).
- Ensure constructive collaboration within EPTs and with other internal business partners including, Novartis Biologics Center, Preclinical Safety, Technical Research and Development, Biostatistics and Data Management, Drug Regulatory Affairs, and Modeling and Simulation (M&S).
- Define, update and perform as appropriate the PK, PK/PD, DMPK biopharmaceutical and M&S aspects of development plans.

Minimum requirements

- a PhD in natural /biological sciences, DVM, PharmD or equivalent with biological background or equivalent training on the job.
- a minimum of 8 years drug discovery experience with at least 3 years of experience as Senior Project Team Representative (Global Project Teams or early development teams) within a relevant Line Function in industry working on the PK/PD aspects.
- Extensive knowledge of biologics (e.g., monoclonal antibodies, bispecifics, fusion proteins, antibody-drug conjugates, etc.) drug discovery with demonstrated experience in guiding the PK/PD and bioanalytical strategy for selection of clinical candidates; knowledge of protein engineering practices is preferred
- Knowledge and experience in either oncology, immunology, and/or tumor immunology are desired.
- Working knowledge of PK/PD software (e.g., WinNonlin, NONMEM, ADAPT II, SimBiology, etc) and the ability to analyze and critically assess PK/PD data is essential.
- A proven record as team player/leader with superior negotiation skills with the ability to manage conflicting expectations in a matrix environment. Excellent project management skills.
- the ability to coach and advise colleagues in project related matters.

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Quantitative Systems Pharmacologist, NIBR PK Sciences, Cambridge, MA

Job ID 263946BR

Job Description

Interested in the Quantitative Understanding of Biological Systems ? Join our Quantitative Systems Pharmacology Team within NIBR PK Sciences. The Modeling & Simulation function at NIBR was newly formed in 2018 and is embedded within PK Sciences and Translational Medicine. Our main objective is to enable quantitative and rigorous decision making from target identification to first-in-human studies. The ideal candidate is always looking for innovative ways modeling and simulation can be applied to drug discovery, is extremely collaborative, a great communicator and self-motivated. Since we support all therapeutic modalities and all therapeutic areas – there are a lot of novel and exciting scientific questions to address. If you want to help shape this new function – come and join us !

The Novartis Institutes for Bio Medical Research (NIBR) is the innovation engine of Novartis, focusing on powerful new technologies that have the potential to help produce therapeutic breakthroughs for patients. NIBR includes about 6500 associates across 7 locations worldwide. 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) partners across both NIBR and the Global Drug Development organizations to advance the scientific knowledge of pharmacokinetics, metabolism and clinical pharmacology, and bring it to bear on drug discovery and development challenges throughout R&D.

Your responsibilities in this role will include but are not limited to:

• Identify high-impact research questions
• Develop and apply a range of (innovative) modeling and simulation approaches to support and influence critical decisions in drug discovery and development across disease areas
• Participate in defining PKS strategy for compound progression and development.
• Identify potential project hurdles, suggest solutions and contribute to contingency plans.
• Publish or present internally or externally as a contributor to enhance Novartis and PK Sciences visibility.

Minimum requirements: What you will bring to the role:

Minimum requirements include a PhD in Bio Engineering, Pharmaceutical Sciences, Mathematics, Physics or closely related field or equivalent related experience.

Skills and Professional Requirements:
• Good understanding of cell biology and physiology
• Experience working with large and/or complex datasets
• Innovative and independent thinker that excels in a highly collaborative and intellectually challenging environment
• 5 plus years of Industry experience
• Demonstrated ability to communicate modeling results to non-experts to facilitate strategy and decision-making
• Proficiency in a scripting language (e.g. MATLAB, R, Python) and statistical software (JMP, R, etc.)
• Skilled in parameter estimation, mathematical problem solving, data analysis & visualization

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Portfolio and Strategy Director, PKS, East Hanover, NJ

Job ID 258987BR

Job Description

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The Portfolio and Strategy Director (PKS) is a critical role for ensuring the strategic management and effective operations of the PKS leadership team and as a key leader and coordinator of internal operations and strategic projects within PKS. This position will report directly to the Global Head of PKS and will be based in East Hanover, NJ. The successful candidate will work very closely as a regular member of the PKS LT and key assistant to the Global Head to define strategy, internal business operations, managing interfaces with key business partners, and coordinate the execution and tracking of strategic projects. The candidate will also work closely with the Global Head of Operations in Translational Medicine to align on global TM strategies and goals.

Depending on the candidate, career background and interests, she/he may also continue to serve part-time in a scientific line function role.

Specific responsibilities will include:

• Provides strategic input and insight to PKS to implement the vision of the Function
• Drives operational excellence through oversight internal department operations (including travel), organizing and coordinating the strategy associated with resource and headcount planning in cooperation with TM Operations and PKS Global Head
• Ensures coordinated support of the PKS portfolio, in close collaboration with the Head of preclinical Business Operations and Planning
• Organizing and participating in global TCs with PKS-LT
• Organizing and participating in F2F / VC global PKS-LT meetings
• Organizing and participating in local F2F PKS management meetings
• scheduling, agenda & notes of the meetings above
• Coordinating PKS global objective setting. Works with the LT to define, implement and track PKS global metrics consistent with the strategy
• Partners with TM Global Head and Portfolio Management to ensure efficient and effective allocation of resources, so that Function expertise is available when and where it is needed
• Ensures successful implementation of strategic initiatives
• Works with the Global Head and LT to continuously reinforce PKS strategy.
• Serves as Chief of Staff for the Function Head by independently representing Function Head's views informally or when officially delegated and communicates back items requiring the Function Head's attention
• Partner with relevant groups, e.g. DAs, Program Office, Finance, HR, NLT, etc to oversee and monitor performance against agreed goals for PKS
• Works closely with the LT and global HR generalist on organizational development initiatives
• Assists the Global Head on a multitude of tasks, such as preparing for strategic meetings and executive presentations (function reviews, FTF meetings with partner groups, external reviews and collaborations, etc.

In addition, there would be regular ad hoc assignments (historical examples: benchmarking with several of the large pharmaceutical companies; managing relocation initiatives;).

Minimum requirements

• Ph.D. (or equivalent) preferred in a PKS or related discipline
• 5+ years' experience in a pharmaceutical or biotech based company or academic center including multiple years in a project management role with a solid comprehension of compound (project) development
• Strategic thinking: ability to create technology innovations, influence peers and management, clear and logical presentation of complex strategic issues.
• Self-motivated and ability to collaborate with NIBR scientists and external consultants, scientists, and academics

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