NOVARTIS

Director, Scientific Governance PKS

Job ID
REQ-10004749
Mai 16, 2024
USA

Summary

About the role:

This position will be located in Cambridge, MA and will not have the ability to be located remotely.

#LI-Hybrid

As the Director, Scientific Governance PKS you will provide regulatory expertise and scientific leadership in the drug development process of Biotherapeutics including Cell and Gene (C&G) therapies, in close collaboration with internal and external partners.

About the Role

Your Key Responsibilities:

- Derive recommendations and propose solutions for tailor-made and integrative drug disposition questions in the Bx arena (Bx Portfolio risk management)
- Support development of an integrated pre-clinical, clinical, and bioanalytical strategy for Bx compounds (incl PK/PD/IG data integration assessment) and, in collaboration with subject matter experts for small molecules, the LMW component of new modalities (as e.g. protein conjugates)
- Propose and review ADME/BA solutions and action plans to guide the drug development process
- Act as a Scientific Liaison to identify, test and implement new and emerging BA-related technologies to enable BA support of a very diverse drug pipeline
- Work with key stakeholders in the Novartis Biologics Research Center (BRC), participate in biotherapeutics consortia (such as IQ), develop a sustainable support model for C&G programs including consideration of BA needs, leveraging of Vendor Center of Excellence expertise, and, in collaboration with line function leaders, optimizing the outsourcing strategy incl. quality assessment of Bx assays
- Support Due Diligence, Asset Integration activities and Deep Dives. Coordinate strategy and execution with all BA functions
- Review of Submission Documentation (e.g. IND, CTD) and responses to Health Authority Queries
- On-demand, resume a (part-time) PTM role for one or more new modalities projects in the pre-clinical and clinical arena. Ad hoc participation in Project GPTs together with PKS PTM
- Connect scientists across PK Science (PKS) department, encourage use of existing tools and processes, leverage models and resources and assure appropriate interpretation and presentation of (non)clinical and bioanalytical data
- Foster optimal compound characterization during (pre)clinical development
- Practice streamlined/consistent development approach in line with internal and external guidelines. Maintains current scientific and regulatory/legal expertise within the scope of Bx
- Recommend on the optimal use of different tools across BA expert areas and line functions. Advice on assay designs and protocols
- Provides training and mentoring opportunities to DD associates for the entire spectrum of technical disciplines
- Capture learnings and themes across projects, leverage experience from one project to another and across TA's

Novartis EVP Manifesto.mp4

Essential Requirements:

- PhD/MD in Natural Biological Sciences or related field.
- In-depth directly related experience in Bx-sciences
- 10+ years of experience in the Bioanalytics/C&G therapeutics field
- Several publications or opinion papers in the field
- Active involvement in inter-company consortia such as AAPS, EBF, IQ, etc.
- Current knowledge of scientific and regulatory areas (including GxPs) affecting Bx issues worldwide
- Familiarity with regulatory agencies/functions
- Excellent interpersonal, leadership and teamwork skills.
- Excellent understanding of drug development processes in Bx arena
- Excellent knowledge of design/structure of Bx studies and good knowledge of closely related areas
- Strong communication and writing skills
- Well-developed, effective organizational skills (e.g. planning, project management, time management)

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 $183,200 - $274,800/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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Biomedical Research
Business Unit
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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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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

EEO Statement :

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber,

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