

Director, Scientific Governance PKS

Job ID
REQ-10004749
Mag 16, 2024
USA

Sommario

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.

