

Director, Preclinical Safety Neuroscience Therapeutic Area

Job ID
REQ-10050493

5月 11, 2025

USA

摘要

#LI-Hybrid

This position will be located in the US (East Hanover, NJ, Cambridge, MA or San Diego, CA) and will not have the ability to be remote.

The purpose of the role is to provide nonclinical regulatory toxicology expertise on R&D project teams supporting the successful initiation of clinical trials and achievement of registration for drug candidates of various modalities.

The Director level PTM leads cross functional associates (i.e. Preclinical Safety (PCS) target team) to develop integrated nonclinical toxicology study plans, drafts regulatory responses and all required submission documentation and manages the respective project communication strategy within PCS.

About the Role

Key Responsibilities:

- Leads PCS Target Teams to integrate and interpret results of nonclinical safety assessment program including impact to drug development and/or project timeline
- Represents PCS on cross functional R&D project teams to design appropriately compliant and scientifically relevant nonclinical safety package
- Participates in internal Novartis initiatives to improve use of nonclinical/translational safety data for drug development decisions.
- Manages communications and builds relationships between PCS and R&D project teams
- Negotiates with Global Health Authorities (HA) worldwide regarding safety issues, scientific interpretation and acceptability nonclinical safety package to support clinical trials and market approval.
- Evaluates in/out-licensing opportunities and carries out technical Due Diligence activities in collaboration with BD&L.
- Participates or leads internal cross-functional groups on key initiatives focused on Translational Medicine or PCS objectives and/or current nonclinical safety topics.
- Mentors colleagues on drug development strategy and project-related matters
- Responsible for authoring nonclinical safety sections of internal and regulatory documents supporting clinical development and market approval.

Essential Requirements:

- PhD in Pharmacology, Toxicology or a related biological science or an MD/DVM/ PharmD or equivalent with a strong background or equivalent work experience
- Minimum of 5 years experience as a nonclinical safety Project Team member, preferably including experience in all development phases.
- Demonstrated experience in communication of strategy and data to global health authorities (such as IND/NDA submission documentation writing), supporting clinical development and market approval.
- Recognized globally for scientific and regulatory expertise in drug development and safety assessment.
- Recognized for leadership potential and ability to represent PCS on Novartis cross functional decision boards or other cross functional project teams.
- Recognized expertise in problem solving in a project driven, multi-disciplinary international environment.

Desirable Requirements:

- Demonstrated knowledge of drug development strategy for neurodegenerative diseases
- Prior experience working in pharmaceutical industry

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$185,500 to \$344,500/annually however, while salary ranges are effective from 1/1/25 through 12/31/25, 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.

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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>

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Business Unit
Pharma Research

地点
USA

状态
Massachusetts

站点
Cambridge (USA)

Company / Legal Entity
U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Alternative Location 1
San Diego, California, USA

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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