Director, Toxicology Immunology Therapeutic Area

Job ID
REQ-10049867

5月 12, 2025

USA

摘要

#LI-Hybrid

About the role:

This position can be located in the US (Cambridge, MA or East Hanover, NJ) or the United Kingdom (London).

The Director Toxicology Immunology Therapeutic Area will 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 Project Team Member leads cross functional associates (i.e. PCS Target Team) to develop and implement integrated nonclinical toxicology study plans, drafts regulatory responses and all required submission documentation and manages the respective project communication strategy within PCS and Novartis

About the Role

Key Responsibilities:

- Leads PCS Target Teams to design, 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
- Recognize the need for a "fit for purpose and modality" nonclinical program as needed and collaborate with line functions outside of PCS to accomplish this goal
- 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.
- Responsible for authoring nonclinical safety sections of internal and regulatory documents supporting clinical development and market approval
- May evaluate in/out-licensing opportunities and carries out technical Due Diligence activities upon request.
- Participates or Leads internal and/or external cross-functional groups on key initiatives focused on PCS objectives and/or current nonclinical safety topics.
- Mentors colleagues on drug development strategy and project-related matters

Essential Requirements:

- Minimum of 5 years experience as a nonclinical safety Project Team member; Demonstrated experience in the preclinical development of small molecule, biotherapeutics and/or gene and cell therapies and the safety issue awareness of these modalities.
- 8+ years experience in a nonclinical drug development scientific discipline (e.g. study director, project team toxicologist or pharmacologist).

- Demonstrated experience in direct or written communication of strategy and data to global health authorities, supporting clinical development and market approval.
- Knowledge of drug development strategy for immunomodulatory drugs
- Leadership in cross-industry organizations (discipline-related or related to drug development).
- Excellent interpersonal, leadership, organizational skills (e.g. planning and time management) and teamwork skills. Excellent oral and written communication and influencing skills. Highly efficient, self-motivated, flexible and able to work independently and efficiently under time constraints.
- Ability to focus and work on several projects simultaneously and to effectively manage conflicting expectations from the line unit, TA Strategy team and project teams in a matrix management environment.
- Customer focused thinking. Recognized ability to represent PCS on Novartis cross functional decision boards or other cross functional project teams.
- Recognized expertise in technical and scientific problem solving in a project driven, multi-

disciplinary international environment.
- Ability to mentor and coach

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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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

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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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 to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or 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.

部门
Biomedical Research

Business Unit
Universal Hierarchy Node

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
East Hanover, New Jersey, USA

Functional Area
Research & Development

Job Type
Full time

Employment Type

Regular

Shift Work
No

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