# Safety Assessment Expert (Associate Director)

Job ID
REQ-10008765
Sep 03, 2024
USA

## Summary

Safety Assessment Expert (Associate Director)

#LI-Hybrid

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

MULTIPLE POSITIONS AVAILABLE

About the role:

In the role of Safety Assessment Expert you will be part of the Preclinical Safety (PCS) group within TM supporting a variety of therapeutic areas and will be located at the Novartis Institutes for Biomedical Research (NIBR) site in Cambridge, MA.

## About the Role

Key Responsibilities:

· Represent PCS on project teams of a wide variety of therapeutic modalities and assure appropriate design and execution of nonclinical safety assessment plans to meet team objectives and that the PCS support to all assigned projects is optimal in quality, timing and cost.

· Assemble and lead Target teams to ensure appropriate PCS input to project plans and appropriate resource planning within PCS. Oversee nonclinical strategy to enable initiation of clinical trials and achievement of registration for drug candidates.

· Evaluate and determine need for a “fit for purpose and modality” nonclinical program as needed and collaborate with line functions outside of PCS to accomplish this goal

· Communicate to PCS and project teams regarding the theoretical or observed safety effects, their impact and proposed plans to address them, resource requirements to execute nonclinical safety assessment plan. Convey clear, concise and correct communication of nonclinical safety results and their impact to Health Authorities and investigators.

· Partner with the PCS Therapeutic Area Head for alignment with PCS Therapeutic Area Strategy Teams, PCS line functions and NIBR/Novartis Development project/program teams in managing the preparation and presentation of nonclinical safety data in internal and external documents (e.g. Investigator’s Brochure, IND,

CTD, IMPD, Health Authority briefing books) and in negotiation with Health Authorities.

· Evaluate in-licensing opportunities and participate in due diligence activities upon request.

Essential Requirements :

· Education: PhD in Pharmacology, Toxicology or a related biological science. An MD/DVM/ PharmD or equivalent with a strong background or equivalent work experience will be considered.

· Demonstrated experience in the preclinical development of small molecule, biotherapeutics and/or gene and cell therapies and the safety issue awareness of these modalities.

· Awareness of global health authority guidance and expectations for nonclinical programs supporting regulatory applications.

· Experience in direct or written communication of strategy and data to global health authorities. 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.

· 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.

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Benefits and Rewards:

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

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 $151,200 and $226,800/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
Pharma Research
Location
USA
Site
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
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