Director Toxicology - Immunology Therapeutic Area

Job ID
REQ-10061634

9月 10, 2025

Switzerland

摘要

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 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

This hybrid role can be based in Basel or London (White City)

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

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Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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#LI-hybrid

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部门
Biomedical Research

Business Unit
Pharma Research

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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