Principal Scientist 2 - Preclinical Safety

Job ID
REQ-10006001
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Inde

Résumé

The Preclinical Safety (PCS) department within the Novartis Biomedical Research - Translational Medicine Unit provides non-clinical safety strategy of products in -discovery, -development and -market, globally, with state-of-the-art regulatory compliance.
As a Principal Scientist-2, you will join our PCS team in India to discuss strategies and deliver non-clinical safety deliverables for the products you are globally responsible for. This role also involves development and review of nonclinical scientific submission components (eCTD module 2.4 and 2.6) and other lifecycle management regulatory documents for multiple projects.

About the Role

Key Responsibilities**:**

- Strategy and delivery of PCS deliverables for products under development and in-market.
- Independently provide PCS inputs in PSURs, DSURs, annual reports, registrations, renewals and label updates for the delegated products.Addresses regulatory queries on delegated products.
- Conducts literature searches and analyzes relevant non-clinical safety data and decide benefit-risk of new nonclinical information in collaboration with patient safety experts.
- Contribute to the objectives and deliverables of (Global Project Team) in cross-functional collaboration with other GPT representatives.
- Evaluates the toxicological profiles of impurities, degradants and assess the specification limits based on ICH guidelines.
- Provides to nonclinical scientific writing support fo regulatory submission documents such as, IB, IND/CTA, NDA/BLA/MAA and Health Authority briefing books.
- Organizes nonclinical scientific activities and timelines in collaboration with authors for planned submission to meet strategic objectives of nonclinical submission deliverables.
- Develop expertise in internal Document management system to facilitate timely completion of projects and meet compliance requirement.
- Act as a nonclinical scientific liaison to Submissions & Documentation (S&D) vendor supporting nonclinical submission document management.
- Ensure that all the activities and deliverables are compliant with Novartis animal welfare policies, in-house standard operating procedures, Novartis expert recommendations (where feasible) and all relevant international regulatory guidelines/regulations.
- Be a team player and support local implementation of Preclinical safety strategies and independently contribute to multidisciplinary project/program goals within the Preclinical safety team. Communication skill is critical to this role in forming strong working relationships with team members and across functional disciplines.

Essential Requirements:

- PhD in life sciences with 6+ years experiences in drug discovery, drug development and/or life cycle management studies with an exceptional understanding of nonclinical submission writing
- In-depth knowledge of toxicology and preclinical safety assessment, understanding of drug metabolism and pharmacokinetics / pharmacodynamics, experience working in project teams, and knowledge of drug development and regulatory environment
- Understanding of GLP principles in nonclinical studies and submission writing.
- Proficient with full range of techniques used in job and core areas. Working knowledge of tools and processes used in drug design and development.
- Extensive library research skills and knowledge of problems-solving techniques; publication and presentation experience preferred.
- Excellent communicators, strong team players and have a high level of logistical/planning ability.Strong written and verbal capabilities in English preferred.
- Registration and certification with one of the International Toxicology registers.

Desirable Requirement:

- Animal Models ,Communication Skills, Data Analysis.
- Ethics ,Laboratory, Problem Solving.
- Regulatory Compliance.
- Research.
- Risk Assessment.
- Toxicology.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Employment Type
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Shift Work
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