Principal Scientist 2 - Preclinical Safety

Job ID
REQ-10006001
Jul 22, 2024
India

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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

Role Requirements

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

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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Biomedical Research
Business Unit
Pharma Research
Location
India
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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