Global Program Safety Lead

Job ID
REQ-10059289

8月 08, 2025

USA

摘要

Designs & develops safety surveillance strategy for products and approval. Responsible for the company ' s drug surveillance program including the necessary follow-up, risk assessment, and relatedness to product on adverse reaction reports, oversight of safety in clinical trials and post marketing programs. Participates in the resolution of any legal liability and complying with governmental regulations. Provides and contributes trending and safety signal detection and risk management assessment for the products ' life cycle. Provides safety support to the clinical development teams.

About the Role

#LI-Hybrid

Two roles available

Key Responsibilities:

- Provides expert safety input to the clinical development program for assigned projects/products and be an active member of the Global Program Team (GPT), Global Clinical Team (GCT) and Clinical Trial Team (CTT) -Is responsible for safety issue management from formation of Global Program Team (GPT) through Life Cycle Management.
- Is responsible for overall signal detection, monitoring, evaluation, interpretation and appropriate management of safety information, based on information from all relevant line functions, post-marketing data, and other sources.
- Responsible for documentation/tracking/record keeping of the assigned compounds medical safety activities.
- Is responsible for responses to inquiries from regulatory authorities or health care professionals on safety issues.
- Leads the preparation of the safety strategy for health authority responses and strategy, in collaboration with other project team members -Contributes to and often leads the development of departmental and functional/business unit goals and objectives.
- Distribution of marketing samples (where applicable)

Key Performance Indicators:

- Timeliness and quality of safety analyses, interpretations, and presentations -Compliance with internal and external regulations & procedures -Compliance, consistency and quality of safety deliverables

Essential Requirements:

- Medical Degree or equivalent (preferred), PhD, PharmD or equivalent graduate level health care professional degree required. Specialty Board certification desirable. Useful additional degrees: Post graduate degree in Pharmaceutical Medicine; Master of Public Health in Epidemiology (or equivalent)
- 5 years clinical experience postdoctoral
- At least 5 years progressive experience in drug development in a major pharmaceutical company, including 3 years in safety at a medical position
- Expertise in preparing or contributing to preparation of clinical safety assessments and regulatory reports/submissions involving safety information - to include NDA submission documents
- Strong experience in leading cross-functional, multicultural teams
- Strong experience with (safety or others) issue management
- Strong experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publication
- Strong leadership skills including coaching, motivating, and directing, and fostering teamwork. Ability to develop and maintain effective working relationships with subordinates, superiors and peers

The salary for this position is expected to range between $204,400 and $379,600 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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.

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Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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