Medical Safety Lead

Job ID
REQ-10058870

7月 30, 2025

USA

摘要

This position will be located at East Hanover, NJ site and will not have the ability to be located remotely. “Please note that this role would not provide relocation and only local candidates will be considered.”

Title: Medical Safety Lead
In close collaboration with the Global Program Safety Lead (GPSL) provides robust safety evaluation expertise and medical innovation in order to improve patients’ lives and impact on overall Novartis results. As a member of the Medical Safety organization, prioritizes the safety of patients, ensures optimal patient safety for assigned compounds and shares responsibility for the integration, analysis, and evaluation of internal and external safety information through product lifecycle management, and evaluation of internal and external safety information through product lifecycle management.
#LI-Onsite

1. Monitors the clinical safety of projects/products including activities such as literature review, evaluation of individual cases or signal detection, and responds to safety-related questions appropriately.
2.Performs medical assessment and related activities for single cases whenever required, including

collecting additional follow-up information as necessary, medical evaluation of product quality defects with adverse events, review of line listings of single cases, and preparation of investigator notifications and periodic medical assessments for ethics committees. Of note: medical review of single case reports may need to be performed by Medical Safety Leads as required according to business needs.
3.Identifies safety signals based on the review of solicited or unsolicited single cases. Performs signal detection, monitoring and evaluation of all safety signals based on single cases and aggregate data using proper signal detection tools.
4.Provides inputs into responses to inquiries from regulatory authorities or health care professionals on safety issues. Prepares safety data for Health Authority review boards. Provides inputs to responses for legal queries and Country Organization requests involving safety issues.
5.May support the GPSL and the Senior Medical Safety Lead in submission activities as required by providing pharmacovigilance inputs to initial development and updates of core data sheet (CDS) and its related documents. In this context, the Medical Safety Lead may deputize for the Senior Medical Safety Lead for the preparation of safety documents (e.g. summary of clinical safety, clinical overview) for review by GPSL.
6.Prepares medical input to aggregate clinical safety regulatory reports.
7.Provides inputs and collaborates on preparation of Safety Profiling Plan (SPP) and Risk Management Plan (RMP) updates.
8.Provides guidance as appropriate to Clinical and Pharmacovigilance Operations for the coding and causality/expectedness assessment of adverse event reports.
9.Provides expert evaluation on the clinical context of adverse event reports, assessment of the medical conditions, and the implications on Novartis products.
10.Collaborates productively on clinical safety tasks with colleagues from Clinical Development, RegulatoryAffairs, Medical Affairs, Medical Information, Statistics, Safety Data Management, Epidemiology and other related departments.

About the Role

Requirements:

- Bachelor of Science in Pharmacy / Bachelor of Science in Nursing / PharmD / PhD in relevant field or Medical Degree (MBBS or MD) required. Medical degree with specialization preferred. Medical degree is essential for associates performing medical review of single case reports whenever business needs require this activity.
- Relevant experience (e.g., clinical, postdoctoral) after graduation.
- At least 4 years in drug development in a major pharmaceutical company, including 2 years in patient safety at an operational or medical position (or equivalent experience) is desirable.
- Experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications.
- Proven ability to analyze, interpret, discuss, and present safety information both in writing and orally
- Experience in preparing or contributing to preparation of clinical safety. assessments and regulatory reports involving safety information
- Experience with (safety or others) issue management.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $168,000/yr and $312,000/yr; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, 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

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.

部门
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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Job ID
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Medical Safety Lead

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