NOVARTIS

Senior Medical Safety Lead

Job ID
REQ-10076935
апр 30, 2026
Индия

Сводка

-Responsible for the 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

Key Responsibilities:

- 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. May deputize for the GPSL (in agreement with the project's GPSL) or function as a GPSL for products to which no GPSL are assigned.
- Performs medical assessment and related activities for single cases whenever required, including collecting additional follow-up information as necessary, medical evaluation of quality defects, review of line listings of single cases, literature review 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 Senior Medical Safety Leads as required according to business needs.
- 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.
- 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 input to responses for legal queries and Country Organization requests involving safety issues.
- Provides pharmacovigilance inputs to initial development and subsequent updates of core data sheet (CDS) and its related documents. May review and author submission documents (e.g. summary of clinical safety, clinical overview).
- Plays a significant role in the development and maintenance of Safety Profiling Plans (SPP) and Risk Management Plans (RMP) including the coordination with other line functions for associated activities such as updates, and the ongoing tracking of commitments and effectiveness measures.
- Provides guidance as appropriate to Clinical/PV Safety Operations for the coding and causality/expectedness assessment of adverse event reports.
- Provides expert evaluation on the clinical context of adverse event reports, assessment of the medical conditions, and the implications on Novartis products.
- Collaborates productively on clinical safety tasks with colleagues from Clinical Development, Regulatory Affairs, Medical Affairs, Medical Information, Statistics, Safety Data Management, Epidemiology and other related departments.
- Provides safety inputs for clinical and regulatory deliverables including clinical study protocols, clinical study reports, investigator brochure, submission documents. Provides relevant inputs for Global Program/Brand Team (GPT/GBT), Global Clinical Team (GCT)

Minimum Requirements:

- At least 6 years in drug development in a major pharmaceutical company,
- including 4 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
- 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

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Business Unit
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Место
Индия
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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type

Regular
Shift Work
No

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com 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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