Medical Safety Lead

Job ID
REQ-10059244

8月 21, 2025

India

摘要

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

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.

- 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.

- 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 inputs to responses for legal queries and Country Organization requests involving safety issues.

- 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.

- Prepares medical input to aggregate clinical safety regulatory reports.

- Provides inputs and collaborates on preparation of Safety Profiling Plan (SPP) and Risk Management Plan (RMP) updates. Provides guidance as appropriate to Clinical and Pharmacovigilance 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, and investigator brochure. Provides relevant inputs for Global Program/Brand Team (GPT/GBT), Global Clinical Team (GCT), and Clinical Trial Team (CTT) meetings as needed. Provides support as needed for licensing activities, regulatory authority inspections and for project/product recall activities.

Role Requirements:

- **PharmD / M Pharm 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 8 years in drug development in a major pharmaceutical company, including 8 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.**

Skills:

- **Clinical Trials.**
- **Functional Teams.**
- **Literature Review.**
- **Management Skills.**
- **Medical Information.**
- **Medical Records.**
- **Medical Strategy.**
- **Pharmacovigilance.**
- **Regulatory Compliance.**
- **Risk Management.**
- **Safety Science.**

Languages:

- **English.**

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
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

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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.

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

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