NOVARTIS

Global Program Safety Lead

Job ID
REQ-10074360
Июн. 03, 2026
Индия

Сводка

Successfully serves as scientific safety leader of the Medical Safety organization to improve patients' lives and impact on overall Novartis results through robust safety evaluation expertise and medical innovation. Ensures optimal patient safety for assigned compounds, is responsible for the integration, analysis, and interpretation of internal and external safety information from all sources through lifecycle management.

About the Role

Major Activities (Describe main activities)

- 1. 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).
- 2. Is responsible for safety issue management from formation of Global Program Team (GPT) through Life Cycle Management.
- 3. Develops and is responsible for key internal Novartis safety documents: reviews these documents regularly and updates as required (e.g. when significant new information received). Ensures that these, and all other project-related safety documents, are consistent in safety messages.
- 4. Owns the safety strategy and document it in the corresponding documents (e.g. dSPP, SSPT) and leads the production of the medical safety deliverables (e.g. DSUR, PSUR, RMP) for the assigned products.
- 5. 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. To this end, constitutes and runs the Safety Management Team (SMT). Ensures that this team appropriately and timely reviews all medical safety data from various sources (e.g. pre-clinical, clinical trial data post-marketing, literature) throughout the development and post-approval process.
- 6. Responsible for documentation/tracking/record keeping of the assigned compounds medical safety activities.
- 7. Is responsible for initial development and ongoing maintenance of safety information in Core Data Sheet (core global labeling), including addressing safety issues optimally in all project/product labeling indications.
- 8. 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. Prepares safety data for health authority review boards (together with the clinical and biostatistical functions). Attends Health Authority Meetings in person, as required.
- 9. Is responsible for responses to legal queries and Country Organization (CO) requests involving safety issues. Provides integrated safety input into all regulatory documents required during active development.
- 10. Ensures safety information is communicated/escalated to HPS/MPH, HMS HYD and/or EU Qualified Person in a timely fashion.
- 11. Facilitates involvement of external experts (e.g. authors of white papers, members of trial- specific data safety monitoring boards, ad-hoc support for HA meetings, etc.).
- 12. Prepares and presents safety issues to internal Novartis Boards and other meetings as required. Provides relevant input for SMT/SMB, GPT, GCT and CTT meetings as needed.
- 13. Initiates and maintains productive cross-functional Medical Safety collaborations with colleagues within PS and those from other functions, e.g. Clinical Development and Medical Affairs, Regulatory Affairs, Medical Information, Biostatistics, Quantitative Safety & Epidemiology, Clinical Pharmacology, QA, BD&L and NIBR, as well as externally with expert panels and other scientific contacts.
- 14. Provides expert medical input to trial and project level Drug Safety Monitoring Board/ Data Monitoring Committee and Safety Adjudication Committee activities for assigned projects/products, as required.
- 15. Performs tasks assigned as per applicable procedures (e.g., GOPs, SOPs, WIs), assigned to the role.
- 16. Keeps working instructions / SOPs / GOPs for the area of responsibility up to date with internal (e.g., QMs) and external (e.g., GVP modules) requirements, provides input to such procedural documents of other functions, and ensures implementation of such procedural documents in the area of responsibility.
- 17. Provides support as needed for licensing activities, regulatory authority inspections and for project /product recall activities.
- 18. Leads the day-to-day safety activities and provides guidance to junior personnel. Proactively engages in the development of competencies across the Medical Safety Function.

Performance Indicators (Indicate how performance for this job will be measured)

- 1. 2. Timeliness and quality of safety analysis, interpretations, presentations and communication.
- Compliance with internal SOPs/WPs and external regulations Job Dimensions (Indicate key facts and figures) Number of associates
- Ideal Background (State the preferred education and experience level) Education (minimum/desirable): Languages: 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) Fluent in spoken and written English. Understanding in another major language (e.g. French, German, Spanish) desirable
- 3 years clinical experience postdoctoral Experience/Professional requirement: Version: 6
- At least 5 years are in drug development in a major pharmaceutical company (of which 2 years in a global position), including 2 years in safety at an operational or medical position
- Experience in preparing or contributing to preparation of clinical safety assessments and regulatory re- ports/submissions involving safety information.
- Experience in leading cross-functional, multi-cultural teams
- Experience with (safety or others) issue management • Experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications

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.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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

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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