Senior Global Program Safety Team Lead

Job ID
REQ-10067167

11月 20, 2025

India

摘要

The Sr. GPSL-TL serves as strategic leader of the Medical Safety organization to improve patients ' lives and impact on overall Novartis results through robust safety risk management. This role requires an experienced and knowledgeable safety clinician responsible to predict safety risks and assess scientific information to guide the assigned teams on strategic considerations, effective risk management and overall positive impact in development programs.

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.

This is a management position requiring excellent collaboration skills and matrix leadership, who will work closely with the Head Patient Safety managing complex safety issues across several indications.

About the Role

Major accountabilities:

- Manages an efficient and successful disease area within the TA/DU Medical Safety organization, which provides robust medical and science-driven contribution to Benefit-Risk evaluation throughout product lifecycle to enable Novartis to provide impactful medicines to patients worldwide.
- Leads the day-to-day safety activities and provides guidance to assigned Medical Safety team members and mentee(s), as well as to the direct reports. Prepares objectives and evaluates related performance for the assigned team members.
- Provides expert safety input to the clinical development program, in particular for priority compounds; is an active member of the Global Program Team (GPT), Global Clinical Team (GCT) and Clinical Trial Team (CTT).
- Responsible for the review of PSURs together with QPPV office. Takes responsibility for MSRB presentations for his products/teams.
- Owns the safety strategy and documents it appropriately (e.g. dSPP, SSPT); leads the production of the medical safety deliverables (e.g. DSUR, PSUR, RMP) for the assigned products.
- 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.
- 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.
- 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.
- Prepares and presents safety issues to internal Novartis Boards and other meetings as required. Provides input to all relevant internal meetings with senior management (e.g., DevLT, TA LT, Medical Safety LT etc.) and other meetings as deemed necessary (e.g., GPT, SMT; GCT etc.)
- Initiates and maintains productive cross-functional Medical Safety collaborations with colleagues within PS&PV and those from other functions, e.g. Clinical Development and Medical Affairs, Regulatory Affairs, Medical Information, Biostatistics, Clinical Pharmacology, QA, BD&L and BR, as well as externally with expert panels and other scientific contacts.

Education:

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).

Work Experience:

- At least 7 years progressive experience in drug development in a major pharmaceutical company (of which 5 years in a global position), including 5 years in safety at a medical position. 5+ years clinical experience postdoctoral
- 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, multi- cultural 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 publications
- Strong leadership skills including coaching, motivating, and directing, and fostering teamwork
- Ability to develop and maintain effective working relationships with subordinates, superiors and peers
- Strong experience with medical writing and delivering high quality documents such as RMPs, PSURs

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: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Development

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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