Senior Global Program Safety Team Lead

Job ID
REQ-10067167

11月 18, 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.
- Enhances scientific and clinical experience of Medical Safety physicians / scientists through continuous training and coaching. Prepares safety objectives and evaluates and manages performance of the Medical Safety associates within the TA/DU. Identifies talents and high potential associates and is able to defend and discuss in front of leadership team. Together with associates identifies carrier development opportunities and support associates in the carrier path.
- 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
- Mentors junior PS&PV personnel. Proactively engages in the development of competencies across the Medical Safety Function.
  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).
- When necessary, takes responsibility for the strategic reviews of documents for ISRC and C-ISRC. Responsible for the review of PSURs together with QPPV office. Takes responsibility for MSRB presentations for his products/teams.
  Responsible for regular review and updates of key internal Novartis safety documents, either as individual contributor or as manager of the Safety Team. Ensures that all project-related safety documents are consistent in safety messages.
- 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.
- Responsibilities, whether as individual contributor or Team Lead (depending on the team size, complexity, and project needs), include:

a. 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. Ensures that the 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.
b. Documentation/tracking/record keeping of medical safety activities for the assigned compounds.
c. 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.
d. 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.
e. Responses to legal queries and Country Organization (CO) requests involving safety issues. Provides integrated safety input into all regulatory documents required during active development.

- Ensures safety information is communicated/escalated to senior management in a timely

fashion.
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.).

- 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.
- 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.
  Performs tasks assigned as per applicable procedures (e.g., GOPs, SOPs, WIs), assigned to the role.
- 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.
- Provides support as needed for licensing activities, regulatory authority inspections and for project /product recall activities. Deputizes for Head Patient Safety (HPS) as required.

Key performance indicators:

Timeliness and quality of safety analysis, interpretations, presentations and communication in all the assigned programs Strategic input and guidance in the assigned programs Compliance with internal SOPs/WPs and external regulations

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 negotiation and conflict management skills
- Excellent written and verbal communication skills
- Strong experience with medical writing and delivering high quality documents such as RMPs, PSURs
- Proven administrative skills including the ability to set and achieve goals, and develop departmental strategies
- Good project management and time management skills, required
- Strong knowledge of global regulatory requirements for safety reporting and labeling
- Previous people management experience preferred

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

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部门
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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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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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