

# Safety Signal lead / Safety Signal expert

Job ID REQ-10058572

8月 01, 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. Ensures optimal patient safety for assigned compounds by identifying new safety signals early using internal and external spontaneous reporting databases.

## About the Role

Major accountabilities:

- Lead the safety signal detection and triage activities for a challenging product portfolio.
- Identify new safety signals early based on review and comprehensive medical evaluation of technical hits in postmarketing spontaneous reporting databases analyzing single case reports as well as aggregate data available
- Provide expert evaluation of results of postmarketing signal detection activities at cross-

functional team meetings: Product Safety Team, SMT/SMB, Joint Safety Committees as appropriate.

- Collaborate productively with the safety leads for the respective products and, as a core
  member of the cross-functional SMT, provide expert input for postmarketing signal detection
  activities using internal and external spontaneous reporting databases.
- Provide expert input to MSRB presentations to safety team and Global Head of Safety Signal Detection.
- Perform database searches in external Health Authority databases (FAERS/ Vigibase), analyzing and reporting the results.
- Perform QC checks of Health Authority database searches done by colleagues.
- Provide relevant inputs for enhancements of current systems and processes
- Provide safety input as it relates to postmarketing signal detection activities to safety documents, as well as ad hoc Health Authority queries.
- Act as Subject Matter Expert (SME) for postmarketing Safety Signal Detection (including participation in initiatives) and provide guidance on methodology used for automated signal detection to safety leads and cross-functional SMT/SMB.
- Manage Eudravigilance database requests i.e. monitoring Eudravigilance for assigned products,
- Lead the training and mentoring of junior Safety Signal Colleagues and take an active part at the medical safety onboarding activities.
- Drive the development and update of Business Guidance documents and SOPs accordingly
- Contribute to the development of new approaches of automated signal detection in internal/ external databases

#### Key performance indicators:

- Timeliness and quality of safety analyses, interpretations, and presentations
- Compliance with internal and external regulations and procedures.
- Ability to work effectively within a metrics organization

Minimum Requirements: Medical Degree (MBBS or MD) required. Medical degree with specialization preferred.

#### Work Experience:

- Relevant experience (e.g., clinical, postdoctoral) after graduation.
- At least 4 years in drug development in a major pharmaceutical company, including 2 years in patient safety at an operational or medical position (or equivalent experience) is desirable.
- Experience in Quantitative Safety Signal Detection and Safety Signal Management related activities
- 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 safety assessments and regulatory reports involving safety information
- Experience with (safety or others) issue management.

#### Skills:

Aggregate review
Literature Review.
Pharmacovigilance.
Regulatory Compliance.

• Safety Science.

# Languages:

• English.

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部门 Development

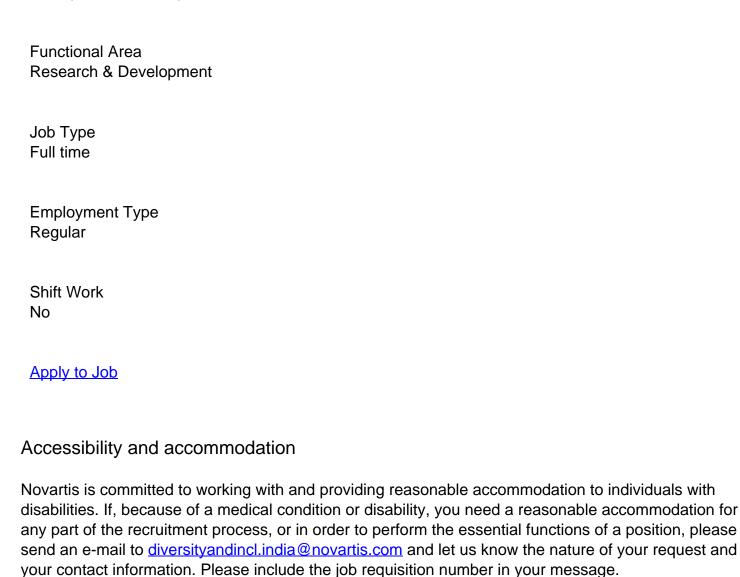
Business Unit Innovative Medicines

地点 India

站点 Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited



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