

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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