

Senior Patient Safety Specialist

Job ID
REQ-10040783
Feb 17, 2025
China

Summary

To support management of Patient Safety operational processes at Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for vigilance of both marketed and investigational products (incl. drugs, food supplements and medical devices) from Novartis Group.

To mentor less experienced Patient Safety associates through Patient Safety processes, systems, and operations. To support the implementation of local projects/ initiatives under close collaboration with the CPSH and/or PSGM.

About the Role

Key responsibilities:

- Manage the collection, processing, documentation, reporting and follow-up of all adverse event reports for all Novartis products from Clinical Trials, Non-interventional Studies, Patient Oriented Program (POPs)s, Literature, Spontaneous Reports, and any other source of information.
- Transcribe, translate, and enter data from source documents into safety systems accurately and consistently with focus quality and on timeliness. When case processing activities are externalized, liaise with the respective External Service Providers to ensure Novartis Procedures' compliance.
- Manage reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN/SUSAR, PSUR, Biannual SUSAR Listing, DSUR) to Local Health Authorities (LHA) and/or clinical operations in cooperation with other Country Organization Departments.
- Develop, update, and implement local procedures to ensure compliance with Patient Safety global procedures and national requirements.
- Interact and collaborate with other departments (such as Medical Affairs, Marketing, Patient Engagement, etc.) to ensure that any projects/ initiatives involving safety data collection (POPs, DEAs, SM/SML, etc.) follow the Novartis vigilance requirements.
- Management and distribution of vigilance clauses to other departments (such as Legal, Procurement, etc.) to be included in local agreements if necessary.
- Advise the owners of local contracts/ agreements with impact in the vigilance system, about the vigilance provisions to be included, as required per Novartis procedures and/or applicable regulations.
- Ensure compliance with the commitments disposed in the contracts/ agreements. Ensure the applicable local contracts/ agreements are tracked in the respective Pharmacovigilance Agreement SharePoint. Ensure any significant departure from the standard vigilance templates are communicated and endorsed by the global PS Alliance group.
- Perform reconciliation with other departments (e.g., Medical Information, Quality Assurance, and Third-party contractors, as applicable) for potential AEs resulting from medical inquiries, quality related

complaints and other sources.

- Management and maintenance of all relevant local Patient Safety databases.
- Ensure that relevant local literature articles are screened as appropriate.
- Prepare and submit KPI reports on compliance in a timely manner including identification of root cause(s) for late reporting to LHA, development and implementation of corrective action(s) as needed.
- Develop and update training materials for vigilance and ensure training of Country Organization associates on relevant Patient Safety procedures for AE reporting, including field force and third-party contractors, as applicable.
- Ensure support to the internal audits, LHA inspections and implementation of the respective CAPA plan.
- Support the onboarding of new PS associates and mentor less experienced Patient Safety associates under close collaboration with the CPSH or PSGM.

Essential requirements

- Functional Breadth; Collaborating across boundaries; Operations Management and Execution.
- 2 years as Patient Safety Specialist (preferred)

Desirable requirements

- Knowledge of national and international regulations for pharmacovigilance; Knowledge of pharmacological and medical terminology
- Good communication and interpersonal skills; Quality and results oriente; Project management skills

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Combining

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Division

Development

Business Unit

Innovative Medicines

Location

China

Site

Shanghai (Shanghai)

Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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