Senior Patient Safety Specialist

Job ID
REQ-10053842

7月 11, 2025

China

摘要

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.
- Advice 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 Thirdparty 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 rootcause(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 associateson 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
- Other agreed tasks assigned by manager.

Essential requirements：

- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience.

- Fluent in both written and spoken English
- Fluent in both written and spoken local language
- Knowledge of national and international regulations for pharmacology
- Knowledge of pharmacological and medical terminology
- Project management skills
- Computer skills
- 2 years as Patient Safety Specialist (preferred)

Desirable requirements：

- Good communication and interpersonal skills
- Quality and results oriented

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
Development

Business Unit
Innovative Medicines

地点
China

站点
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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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.china@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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