Patient Safety Manager

Job ID
REQ-10058061

7月 21, 2025

Taiwan

摘要

To manage the Patient Safety operational processes at the Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for the vigilance of Novartis group approved, marketed and investigational products (incl. drugs, food supplements and medical devices). To support the CPSH in the implementation of PS strategy at country level.

About the Role

Major accountabilities:

- To be the accountable for specific operational vigilance process(es) at the Country Organization
- To mentor less experienced staff, maintaining a professional network of key contacts and role model Novartis values and behaviors.

- Act as deputy of the Country Patient Safety Head, and operationally (in terms of management of the PS Team)
- Ensure oversight and compliance in terms of reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN, SUSAR, PSUR, changes in risk-benefit profile) to TFDA according to regulatory requirements and Novartis procedures.
- Work in close collaboration other local and global medical safety functions to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with TFDA, other functional groups, third-party contractors, and PS associates, as applicable.
- Monitor national pharmacovigilance regulations and provide update to global PS organization.
- Set up, update, and implement local procedures to ensure compliance with PS global procedures and national requirements.
- Ensure local PS-related RMP commitments are executed and properly documented
- Provide scientific expertise during review of all Phase IV Clinical Trial and NIS protocols safety sections including Research Collaborations and if a Contract Research Organization (CRO) is conducting the trial or study, review safety relevant sections of the contract.
- Act as a key partner who provides input, during the process of establishing local programs (ex. POPs, DEAs; SM/SML, etc.): comments on proposals for vigilance language, content, and establishment of necessary controls on collection and reporting of adverse event information.
- Ensure that relevant local literature articles are screened as appropriate.
- Supervision of management and maintenance all relevant PS databases.
- Ensure timely preparation and submission of KPI reports on AE reporting or AE follow-up including identification of root cause(s) e.g., for late reporting to HA, missed or delayed follow-up attempt, development and implementation of corrective and preventative action(s) as needed.
- Support in developing and updating training materials for pharmacovigilance and ensure training of Country Organization associates on relevant PS procedures for AE reporting, including field force and third-party contractor, if applicable.
- Ensure support for and close-out of audits, corrective action plan, investigation, and Health Authority inspections.
- Other agreed tasks assigned by manager.

Key performance indicators:

- Organisation, quality management and efficiency of vigilance processes
- Country Organization AE reporting compliance
- Results of business review, quality review, audits and inspections
- Internal and external customer satisfaction
- Compliance with VA requirements
- Compliance with RMP commitments
- Efficiency in transfer of activities during acquisitions and divestments

Minimum Requirements:

Work Experience:

- At least 2 years experience in pharmacovigilance industry
- Strong knowledge of PV regulations and guidelines(eg. ICH, GPvP)

- Experience in health authority inspections or internal PV audit
- Hands-on experience in authoring and maintaining Risk Management Plans(RMPs)
- Demonstrated ability to work with clinical, regulatory, medical affairs , quality teams and commercial
- Experience leading safety-related projects or initiatives
- Ability to mentor junior staff or manage a small team is a plus
- Strong written and verbal communication in English

Skills:

- Excellent communications and negotiation (networking) skills
- Quality focused and results oriented
- In-depth knowledge of adverse event (AE) reporting, signal detection, and benefit-risk evaluation
- Ability to align safety operations with broader organizational goals and contribute to innovation and transformation strategies
- Experience applying AI or machine learning tools in pharmacovigilance workflows (e.g., automation, Microsoft Automate) is a plus

Languages :

- Fluent in both written and spoken English
- Fluent in both written and spoken Chinese

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部门
Development

Business Unit
Innovative Medicines

地点
Taiwan

站点
Taipei

Company / Legal Entity
TW03 (FCRS = TW003) Novartis (Taiwan) Co. Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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