Patient Safety Specialist

Job ID
REQ-10055106
Jun 15, 2025
Taiwan

Summary

-Monitors and audits the company's drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

Major accountabilities:

- To support management of operational processes in ensuring compliance with Novartis global/local procedures, national and international regulations/standards/guidelines for pharmacovigilance of Novartis marketed and investigational products -Manage collection, processing, documentation, reporting and follow-up of all adverse events (AE) reports for all Novartis products from clinical trials, post-marketing studies (PMS), Patient Oriented Programs (POP), registries and all Spontaneous Reports (SR).
- Transcribe, translate (where required) and enter data of all Serious Adverse Events (from Clinical Trials,) and all adverse events (from POPs, PMS, registries and all SRs) from source documents onto safety systems accurately and consistently with emphasis on timeliness and quality.
- Record and track receipts, submissions and distributions of documents like SAEs, SRs, Investigator Notifications etc in cooperation with other departments -Manage reporting/submission/distribution of safety reports/updates/information to Local Health Authorities and/or clinical operations in cooperation with other Departments.
- Work with other local/global PV associates to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with LHA, PV associates, other functional groups and third party contractor, if applicable.
- Survey and monitor global/ regional/national (as applicable) pharmacovigilance regulations and provide update to global PVO organization.
- Develop, update and implement local procedures to ensure compliance with PVO global procedures and national requirements.
- Management and maintenance all relevant assigned PVO databases, if applicable.
- Develop and update training materials for pharmacovigilance -Ensure support for and close-out of audits, corrective action plan activities and Health Authority inspections.
- Provide timely, relevant information to trial coordinators, CRAs and other Novartis staff -Distribution of marketing samples (where applicable)

Key performance indicators:

- Adherence to Novartis policy and guidelines -Project and stakeholder feedback -Operational risk mitigation and audit/inspection findings -Quality and timely reporting of KPI and safety reports/updates -Results of audits/inspections

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Databases.
- Employee Training.
- Filing (Documents).
- Pharmacovigilance.
- Reporting.
- Safety Science.

Languages :

- English.

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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Division
Development
Business Unit
Innovative Medicines
Location
Taiwan
Site
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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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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