Country Patient Safety Head

Job ID
REQ-10015875
Juil 17, 2024
Taiwan

Résumé

-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:

- Global and /or regional, cross-functional leadership of assigned pharmacovigilance processes across Novartis Divisions to ensure compliance with worldwide regulations with maximum efficiency -Globally responsible for compliance, quality, efficiency and management of Post Marketing and Clinical Trial adverse event handling -Lead management of activities /interfaces with other Global Line Functions management, Investigator Sites, Novartis affiliates and Novartis Sectors management to ensure timeliness, consistency and quality of safety information and to achieve a common understanding of other departmental needs.
- Build high performance safety teams with challenging clear objectives in alignment with Global functional objectives to facilitate implementation of strategic initiatives.
- Accountable for delivery of continuous operations (quality and compliance) goals.
- Optimize operational efficiency and clinical trial effectiveness by ensuring speedy follow-up for key safety information -Manage direct reports.
- Responsible for ensuring recruitment, development of top safety talent and retention of high performing associates to maintain stable pharmacovigilance operations.
- Ensure regular performance evaluations, development and succession planning -Manage audits and inspections.
- Takes complete responsibility for timely implementation of necessary corrective and preventive actions (CAPA commitments).
- Maintain inspection readiness at all times to minimize findings -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:

- 2+ years experience in People Leadership.
- Critical Negotiations.
- People Challenges.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Clinical Trial.
- Databases.
- Employee Training.
- Pharmacovigilance.
- Project Management.
- Reporting.
- Safety Science.
- Team Management.

Languages :

- English.
- Mandarin

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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TW03 (FCRS = TW003) Novartis (Taiwan) Co. Ltd
Functional Area
Recherche & Développement

Job Type
Full time
Employment Type
Regular
Shift Work
No
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