NOVARTIS

JOB & COMPETENCY PROFILE

General

Job Title:	Drug Safety Specialist
Job Grade:	Professional
Department:	Drug Safety & Epidemiology
Reports to (Job Title):	Drug Safety Responsible

Job Purpose (State in one sentence the overall objective of the role)

To support management of DS&E operational processes at Country Pharma Organization (CPO) in ensuring compliance with Novartis global/local procedures, national and international regulations/ standards/guidelines for pharmacovigilance of Novartis marketed and investigational products.

Major Activities* (Describe main activities)

1. Manage collection, processing, documentation, reporting and follow-up of all serious adverse events (SAE) reports for all Novartis products from clinical trials, and all adverse events from Patient Oriented Programs, post-marketing studies (PMS), registries, and all Spontaneous Reports (SR).
2. Transcribe, translate and enter data of all Serious Adverse Events (from Clinical Trials,) and all adverse events (from Patient Oriented Programs, post-marketing studies (PMS), registries and all Spontaneous Reports) from source documents onto safety systems (e.g. Argus Affiliate, etc) accurately and consistently with emphasis on timeliness and quality.
3. Record and track receipts, submissions and distributions of SAEs, SRs, Investigator Notifications (IN), SUSARs, Periodic Safety Report Updates (PSUR) and Development Safety Update Report (DSUR) in cooperation with other CPO Departments.
4. 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 CPO Departments.
5. Work with other local/global PVO associates to ensure accurate evaluation of safety data.
6. Interact and exchange relevant safety information with LHA, PVO associates, other functional groups and third party contractor, if applicable.
7. Survey and monitor national pharmacovigilance regulations and provide update to global PVO organization.
8. Develop, update and implement local procedures to ensure compliance with PVO global procedures and national requirements.
9. Input, review and approval of program proposals for language, content and establishment of necessary controls on collection and reporting of adverse event information.
10. Perform reconciliation with other departments (e.g. Medical Information, Quality Assurance and third party contractor, if applicable) for potential AEs resulting from medical inquiries and quality related complaints.
11. Management and maintenance of all relevant PVO databases.
12. 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.
13. Develop and update training materials for pharmacovigilance and ensure training of CPO associates on relevant PVO procedures for AE reporting, including field force and third party contractor, if applicable.
14. Ensure support for and close-out of audits, corrective action plan, investigation and Health Authority inspections.
15. Ensure training and oversight of staff, as applicable.
16. Manage and maintain efficient PVO filing and archive system.

17. Review of all Phase IV Clinical Trial and PMS protocols safety sections and if a Contract Research Organisation (CRO) is conducting the trial, review the contract (SSW), train the CRO associates responsible from the trial
18. Acts as DSR Deputy: functional (in terms of responsibility for PV system) and operational (in terms of managing the DS&E Team).
19. Supports the Drug Safety Responsible in the local execution of the RMP for all Pharma, Sandoz and OTC products in Singapore

Key Performance Indicators (Indicate how performance for this role will be measured)

1. Organization and management of pharmacovigilance operations
2. CPO Accreditation on AE reporting compliance
3. Quality and timely reporting of KPI and safety reports/updates
4. Results of audits/inspections
5. Customer feedback

Job Dimensions (Indicate key facts and figures)

Number of associates:	None
Financial responsibility: (Budget, Cost, Sales, etc.)	Nil
Impact on the organization:	**Critical, a significant compliance failure could result in an enforced cessation of business.**

Ideal Background (State the preferred education and experience level)

Education (minimum/desirable):	A degree in medicine, pharmacy, health discipline or life sciences
Languages:	• Fluent in both written and spoken English • Good working knowledge of local language • Knowledge of other languages desirable
Experience/Professional requirement:	• Knowledge of national and international regulations for pharmacovigilance • Knowledge of pharmacological and medical terminology. • Excellent communications, interpersonal and negotiation skills • Quality and focus oriented • Computer knowledge • Additional educational requirements as may be mandated by national requirements

Interested candidates are requested to submit a detailed CV with current and expected salary, together with a photograph to:-

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