

Patient Safety Specialist (80%)

Job ID
REQ-10037375

1月 27, 2025

Switzerland

摘要

Support management of Patient Safety operational processes within the Country Organisation and ensure compliance with Novartis global/local procedures, national and international regulations/standards/guidelines for pharmacovigilance of Novartis group marketed and investigational products (drugs and devices). Provide training to other associates and third parties as appropriate. Support the assessment and implementation of local projects/initiatives in collaboration with other stakeholders.

About the Role

Key Responsibilities:

- Manage collection, processing, documentation, reporting and follow-up of all adverse event reports for all Novartis products from both marketed and investigational products. Transcribe, translate and enter data of all data from source documents into safety systems accurately and

consistently with emphasis on timeliness and quality. Where case processing activities are externalised, liaise with the respective External Service Providers to ensure Novartis Procedures' compliance.

- Manage reporting/submission/distribution of safety reports/ information to Local Health Authorities and/or clinical operations in cooperation with other Country Organisation Departments.
- Work with other local/global Patient Safety associates to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with the local health authority, Patient Safety associates, other functional groups and third-party contractors, as applicable.
- Survey and monitor national pharmacovigilance regulations, ensure implementation as per local requirements and provide updates to the global Patient Safety organisation when applicable.
- Develop, update and implement local procedures to ensure compliance with Patient Safety global procedures and national requirements.
- Perform reconciliation with other departments (e.g. Medical Information, Quality Assurance and third-party contractors, if applicable) for potential adverse events resulting from medical inquiries, quality related complaints and other sources.
- Management and maintenance of all relevant Patient Safety databases.
- Prepare and submit key performance indicator reports on compliance in a timely manner including identification of root cause(s) development and implementation of corrective action(s) as needed.
- Develop training materials for pharmacovigilance and ensure training of Country Organisation associates on relevant Patient Safety procedures for adverse event reporting, including third-party contractors, if applicable.
- Ensure support for and close-out of audits, corrective action plans, investigation and Health Authority inspections.
- Ensure training and oversight of staff and third-party contractors, as applicable, including the onboarding of new associates and mentor less experienced Patient Safety associates.
- Manage and maintain efficient Patient Safety filing and archive system.
- Review of all local Phase IV Clinical Trial and non-interventional study protocols safety sections and additional contracts with Contract Research Organisations (CRO) as applicable.
- Review, renewal and/or management of local pharmacovigilance contracts and local contracts that contain pharmacovigilance provisions.

What you will bring to the role:

- Health Care Sciences Professional (e.g. Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience.
- 2 years as Patient Safety Specialist or similar field (preferred)
- Fluent in both written and spoken English and German. French and/or Italian are desirable.
- Knowledge of national and international regulations for pharmacovigilance
- Knowledge of pharmacological and medical terminology.
- Excellent communications, interpersonal and negotiation skills
- Quality, focus and solution-oriented

Benefits and rewards:

Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally:

<https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Accessibility and accommodation:

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in any order to receive more detailed information about essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Switzerland

站点

Rotkreuz (Office-Based)

Company / Legal Entity

C018 (FCRS = CH018) Novartis Pharma Schweiz AG

Functional Area

Research & Development

Job Type

Part time

Employment Type

Regular

Shift Work

No

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