Patient Safety Specialist

Job ID
REQ-10019782
Aoû 26, 2024
République arabe d'Egypte

Résumé

Location: Cairo, Egypt #LI-Hybrid

About the Role:

As a Patient Safety Specialist, you will be responsible for monitoring and auditing the company's drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participating in the resolution of any legal liability and in complying with government regulations. Ensuring accurate receipt, maintenance and assessment against product labeling. Reporting events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May be providing trending and safety signal detection and assessment. Supporting all clinical trial activity and post marketing.

This role reports directly into the POP Governance/Patient Safety Manager.

About the Role

Key Responsibilities:

- Support in the 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.
- Collaborate 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. Manage and maintain 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)

Essential Requirements:

- Pharmacist or MD is a must.
- 1-2 years of relevant experience (e.g., Patient Safety, Medical Affairs, QA, PSP, Regulatory).
- A proven experience contributing to different projects if experience is in Commercial.
- Proficient in English Language.
- Advanced proficiency in Microsoft Office (e.g. MS Word, MS PowerPoint, MS Excel, MS Outlook).

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:

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

Novartis is a proud member of the *ILO Global Business and Disability Network* and the *Valuable 500,* promoting the inclusion of people with disabilities in workplaces around the world. We also collaborate with international partners, such as *Disability: IN*, *Purple Space,* and *Business Disability Forum* to identify and develop best practice solutions to enable people with disabilities to participate as equal members of our organization.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

Skills:

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

Languages :

- Arabic.
- 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

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Innovative Medicines
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Amiria
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Functional Area
Recherche & Développement
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Employment Type
Regular
Shift Work
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