

Patient Safety Group Manager

Job ID
REQ-10061108
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Сводка

To lead Patient Safety operational processes at the Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for vigilance of Novartis group approved, marketed and investigational products (incl. drugs, food supplements and medical devices).

About the Role

Key responsibilities:

- Manage a team of PS Associates (such as PS Specialists, PS Senior Specialists and/or PS Managers) in line with the country PS organizational structure and PS strategy in place.
- Act as qualified delegate of the Local Qualified Person for Pharmacovigilance/ Local PV Responsible Person in Novartis Country Organization, as defined by local regulation and applicable legislation, in terms of ensuring compliance of adverse drug reactions monitoring and submission.
- Act as qualified delegate of the Country Patient Safety Head in terms of operational vigilance processes.
- Ensure robust oversight and compliance in terms of reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN, SUSAR, PSUR, DSUR, changes in risk-benefit profile) to Local Health Authorities (LHA) according to regulatory requirements and Novartis procedures.
- Work in close collaboration with other local and global medical safety functions to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with Health Authorities, other functional groups, third-party contractors, and PS associates, as applicable.
- Monitor national pharmacovigilance regulations and provide update to global PS organization.
- Set up, update, and implement local procedures to ensure compliance with PS global procedures and national requirements.
- Ensure local PS-related RMP commitments are executed and properly documented
- Provide scientific expertise during review of all Phase IV Clinical Trial and NIS protocols safety sections including Research Collaborations and if a Contract Research Organization (CRO) is conducting the trial or study, review safety relevant sections of the contract.
- Act as a key partner who provides input, during the process of establishing local programs (ex. POPs, DEAs; SM/SML, etc.): comments on proposals for vigilance language, content, and establishment of necessary controls on collection and reporting of adverse event information.
- Ensure that relevant local literature articles are screened, as appropriate.
- Supervision of management and maintenance of all relevant PS databases.
- Ensure timely preparation and submission of KPI reports on AE reporting and AE follow-up attempts including identification of root cause(s) e.g., for late reporting to HA, missed or delayed follow-up attempt, development and implementation of corrective and preventative action(s) as needed.
- Support in developing and updating training materials for pharmacovigilance and ensure training of Country Organization associates on relevant PS procedures for AE reporting, including field force and third-party contractor, if applicable.
- Ensure support for and close-out of audits, corrective action plan, investigation, and Health Authority inspections.
- Ensure selection, and recruitment of qualified PS team members and their further professional development.
- Ensure training and oversight of commissioned staff, as applicable.
- Contribute to the preparation and update of the local Pharmacovigilance System Master File as per regulation and related procedures.
- Other agreed tasks assigned by manager.

Essential requirements:

- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience
- Fluent in both written and spoken English
- Fluent in both written and spoken local language
- Knowledge of other languages (desirable)
- Leadership and (people-)management skills
- Excellent communications and negotiation (networking) skills
- Quality and results oriented
- Business mindset
- Computer skills
- 3 years' experience in pharmacovigilance or equivalent field

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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Business Unit
Development
Место
Китай
Сайт
Beijing (Beijing)
Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
Alternative Location 1
Shanghai (Shanghai), Китай
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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