Patient Safety Group Manager

Job ID
REQ-10061108

11月 30, 2025

China

摘要

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

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

部门
Development

Business Unit
Development

地点
China

站点
Beijing (Beijing)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Alternative Location 1
Shanghai (Shanghai), China

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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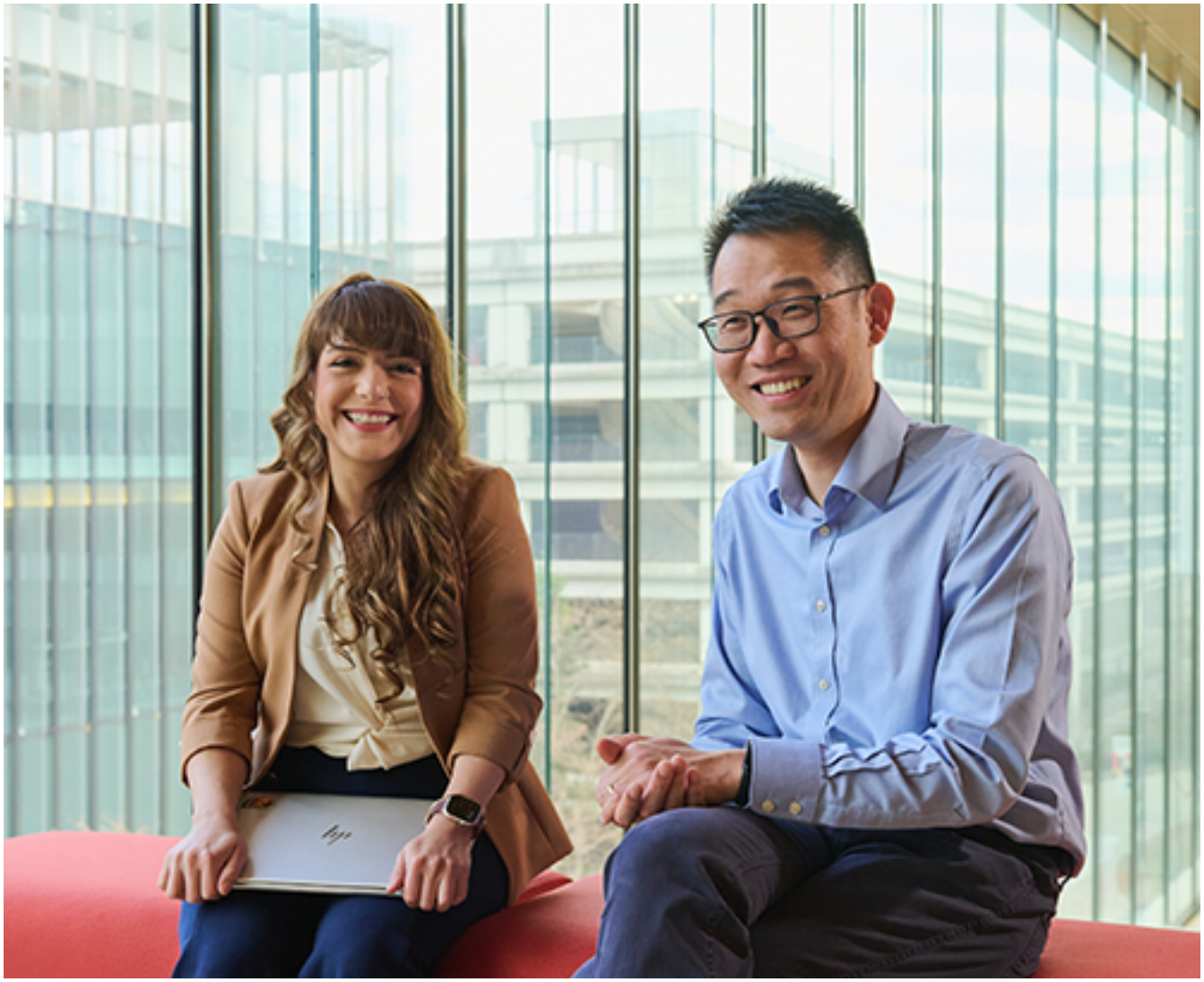
Accessibility and accommodation

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

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



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