Patient Safety Manager

Job ID
REQ-10054061

6月 13, 2025

Spain

摘要

LOCATION: Barcelona, Spain
ROLE TYPE: Hybrid working. #LI-Hybrid

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

They also support the Country Patient Safety Head (CPSH) in the implementation of Patient Safety (PS) strategy at country level.

About the Role

Major accountabilities:

- To be the accountable for specific operational vigilance process(es) at the Country Organization
- Ensure oversight and compliance in terms of reporting/submission/distribution of safety reports/updates/information to Local Health Authorities (LHA) according to regulatory requirements and Novartis procedures.
- Interact and exchange relevant safety information with Health Authorities, other functional groups, third-party contractors, and PS associates.
- Ensure local PS-related Risk Management Plan (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.
- Provide scientific expertise during review of all Phase IV Clinical Trial and Non-Interventional Studies (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.
- Ensure timely preparation and submission of KPI reports on Adverse Event (AE) reporting or AE follow-up 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.
- Ensure support for and close-out of audits, corrective action plan, investigation, and Health Authority inspections.

Key performance indicators:

- Organisation, quality management and efficiency of vigilance processes
- Country Organization AE reporting compliance
- Internal and external customer satisfaction
- Compliance with RMP commitments

Minimum Requirements:

For this role we are searching for applicants with experience of case processing from Pharmacovigilance (PV) perspective at a local level.

They will also require the following:

- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience
- Project management skills
- Excellent communications and negotiation (networking) skills
- Quality focused and results oriented
- 2 years ' experience in pharmacovigilance or equivalent field

Languages :

Fluency in both Spanish and English are essential for this position

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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