(Senior) Group PV Head- Safety Physician/PV Physician

Job ID
REQ-10029468
Dec 03, 2024
China

Summary

• Act as the Qualified Delegate of the Local Qualified Person for Pharmacovigilance/ Local PV Responsible Person in Novartis Country Organization for assigned therapeutic areas/ products, including all pre and post approval pharmacovigilance activities as defined by local regulation and applicable legislation

About the Role

Key Responsibilities

- To be the accountable for specific operational vigilance process(es) at the Country Organization as assigned including local RMP, local signal detection, PSUR, and clinical trial related
- To mentor less experienced staff, maintaining a professional network of key contacts and role model Novartis values and behaviors
- Act as the Qualified Delegate of the Local Qualified Person for Pharmacovigilance/ Local PV Responsible Person in Novartis Country Organization for assigned therapeutic areas/ products, as defined by local regulation and applicable legislation, including:
  - To oversight the identification, assessment and control of drug safety risks and ensure the effective implementation of risk control measures
  - To be responsible for the management of drug safety information communication and ensure timely and effective communication
  - To ensure smooth communication channels within the Marketing Authorization Holders (MAHs) and with the drug regulatory authorities and the drug adverse reaction monitoring authorities
  - To be responsible for the review or sign-off of important pharmacovigilance documents
- Act as Qualified Delegate of the Country Patient Safety Head, functional (in terms of responsibility for PV system) for assigned therapeutic areas/ products
- Maintains the oversight, development, coordination, or verification in order to ensure that reporting/ submission/ distribution of safety reports/ updates/ information (e.g. SAE, SR, IN, SUSAR, PSUR, DSUR, GSC, SLC, changes in risk benefit, safety deliverables in CTA/ (s)NDA/ License Renewal/ Reimbursement dossier) is done according to the timeliness described into the respective procedures or as committed with line functions
- Work in close collaboration other local and global medical safety functions to ensure accurate evaluation of safety data
- Conduct local safety signal detection and escalate to global medical safety for potential safety signals identified from all local post-marketing sources per local regulatory requirements
- Lead local RMP and RMP China addendum creation and approval, based on local regulatory or LHA

requirement, if applicable
- Interact and exchange relevant safety information with LHA, other functional groups, third-party contractors, and PS associates, as applicable
- Represent PS in China Project Teams (CPT) clinical and submission sub-teams to contribute development strategy and programs from medical safety perspective, and a joint role with global safety leads/ SMTs for safety relevant issues or requests
- Represent PS in CTT and take safety lead responsibilities for Post Approval Commitment (PAC) studies, with the support by global safety lead if needed
- Support the activities with involvement of external experts (e.g. members of trial/ program specific data safety monitoring boards, ad-hoc support for LHA meetings, etc.). Prepares or review safety data for LHA review boards if needed
- Responsible for responses to inquiries from LHA on safety issues related, involve in the communication on safety topics related to responsible products with the LHA
- 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
- 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
- Ensure support for and close-out of audits, corrective action plan, investigation, and Health Authority inspections
- Other agreed tasks assigned by manager

Essential Requirements:

- Health Care Sciences Professional (Medical background, e.g. Medical Doctor is preferred) degree or equivalent training and experience
- At least 5 years experience in pharmacovigilance; or at least 2 years safety/PV physician, clinical physician, or medical affairs experience

Desirable Requirements:

- Project management skills
- Excellent communications and negotiation (networking) skills
- Safety Science, Medical Science
- AI technic
- Fluent in both written and spoken English
- Fluent in both written and spoken local language

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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