Manager, Pharmacovigilance QA

Job ID
REQ-10064966

10月 24, 2025

India

摘要

Manager, Pharmacovigilance QA, provides quality assurance oversight and support of end-to-end Pharmacovigilance (PV) and Device Vigilance (DV) activities within Novartis to ensure compliance with applicable local and global regulatory requirements and Novartis procedures and quality standards.

About the Role

Major accountabilities:

- Support initiatives to maintain or improve quality performance and compliance of Novartis PV activities including case processing, medical safety, risk management, Health Authority reporting, PV IT systems and device vigilance. Champion the quality mindset.
- Support initiatives focused on quality, process, and compliance improvement. Through close collaboration with business partners, identify opportunities and develop strategies aimed at

simplifying processes and improving quality while ensuring compliance with applicable regulatory requirements.
- Provide quality support of transition and integration-related activities for PV and Device Vigilance systems resulting from mergers, acquisitions, and/or divestments.
- Support maintenance of the Pharmacovigilance System Master File (PSMF).
- Support training initiatives as assigned.
- Provide quality support to PS&PV and other groups/business partners involved in PV and DV activities; assist with issue identification and root cause investigations; sign-off investigation reports.
- Support Health Authority Inspections, including inspection readiness activities, conduct, and follow-up.
- Guide the development of robust and sustainable corrective and preventative action plans (CAPA) in collaboration with the responsible groups performing PV and DV activities. Monitor status of corrective and preventative actions to ensure the issues are adequately addressed, completed, and appropriately documented.
- Ensure quality and regulatory compliance issues are promptly communicated to appropriate management. Support initiatives geared towards remediation of compliance concerns; determine effectiveness of remediation activities; provide ongoing project support and governance.
- Support activities to ensure effective quality oversight, management, and support of global PV operational vendors. Support vendor quality awareness and improvement measures.

Key performance indicators:

- Effective coordination, facilitation, and follow-up of HA inspections
- DD, transition and integration activities completed in accordance with specified timelines
- Successful management of the PV-related actions of the GDD Quality Plan
- Timely escalation through proper channels of issues and findings that impact Novartis' PV, Patient Safety, and risk benefit evaluation capabilities
- Effective collaboration on quality, compliance, remediation, and improvement initiatives
- Timely review and feedback on policies, guidelines, and procedures
- Timely and effective communication, consultation, and support to business partners

Minimum Requirements:
Work Experience:

- A minimum of two years PV/PV quality and related pharmaceutical industry and/or Health Authority experience; Device vigilance experience a plus.
- PV auditing or inspection experience and Health Authority interactions a plus.
- Experience in maintenance of PV and/or device Quality Management Systems a plus.
- Ability to manage and objectively evaluate compliance issues with limited supervision; good problem solving, decision making and prioritization skills.
- Quality mindset.
- Good knowledge of PV regulations, guidelines, and policies; awareness of GCP and Part 11 requirements a plus.
- Ability to operate cross-functionally and in diverse cultural environments.

Skills:

Defining, maintaining, and sustaining adequate PV quality systems and standards is crucial and will help to establish improved business processes with increasing efficiency and effectiveness, thus contributing to the overall success of Novartis PV and DV management and compliance.

- Agility
- Analytical Development.
- Business Partnering.
- Change Control.
- Continuous Learning.
- Influencing Skills.
- Knowledge Of CAPA
- Quality Management
- Risk Management
- Root Cause Analysis (RCA).
- Self Awareness
- SOP (Standard Operating Procedure).
- Technological Expertise.

Languages:

- Excellent communication skills with good written and verbal command of English and fluency in at least one other language

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Telangana

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Barcelona Gran V í a, Spain

Functional Area
Quality

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.india@novartis.com and let us know the nature of your request and

your contact information. Please include the job requisition number in your message.

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