Manager, Pharmacovigilance QA

Job ID
REQ-10057681

8月 26, 2025

USA

摘要

The 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

This position will be located in East Hannover, NJ and has the ability to work remotely the majority of the time, with the ability to be on-site during inspection time.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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 the 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:

- Agility.
- Analytical Development.
- Audit Management.
- Auditing.
- Business Partnering.
- Change Control.
- Continuous Learning.
- Health Authorities.
- Influencing Skills.
- Knowledge Of Capa.
- QA (Quality Assurance).
- Quality Management.
- Risk Management.
- Root Cause Analysis (RCA).
- Self-Awareness.
- Six Sigma.
- Sop (Standard Operating Procedure).
- Technological Expertise.

Languages:

- Excellent communication skills with good written and verbal command of English. Fluency in at least one other language is a plus.

Novartis Compensation and Benefit Summary:

The pay range for this position at commencement of employment is expected to be between $98,700 and $183,300/year; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities.*** The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Company will not sponsor visas for this position.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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