Pharmacovigilance QA Manager

Job ID
REQ-10064720

11月 07, 2025

Spain

摘要

Step into a critical quality role where your expertise ensures the safety and integrity of global healthcare. As the Manager, Pharmacovigilance QA, you ’ ll provide end-to-end quality assurance oversight for Pharmacovigilance (PV) and Device Vigilance (DV) activities across Novartis. You ’ ll be instrumental in maintaining compliance with both local and global regulatory standards, while upholding Novartis ’ commitment to excellence in patient safety. This is a unique opportunity to influence quality systems, support innovation, and make a meaningful impact on global health outcomes.

#Hybrid
Location: Barcelona, Spain

About the Role

Key Responsibilities:

- 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.

Essential Requirements:

- Relevant Degree in Life Sciences or related scientific discipline; higher degree desirable.
- Proficiency in English required - spoken & written, other languages is an asset.
- Demonstrated 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.

Commitment to Diversity & Inclusion:

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

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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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

地点
Spain

站点
Barcelona Gran V í a

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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