NOVARTIS

Manager, Pharmacovigilance Quality Assurance

Job ID
REQ-10078594
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Германия

Сводка

The Manager, Pharmacovigilance (PV) QA, provides quality assurance oversight and support of end-to-end 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.

Minimum Requirements:

- 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.
- Experience in maintenance of PV and/or device Quality Management Systems
- 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.
- Ability to operate cross-functionally and in diverse cultural environments.

Languages:

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

Adjustments for Applicants with Disabilities:

The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Дивизион
Development
Business Unit
Quality
Место
Германия
Сайт
Munich (Novartis Business Services GmbH)
Company / Legal Entity

DE61 (FCRS = DE061) Novartis Business Services GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability. The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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