NOVARTIS

Associate Director, PV QA - Data & Digital

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REQ-10076730
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Испания

Сводка

The Associate Director, Pharmacovigilance QA - Data & Digital leads PVQA Data and Digital strategy and initiatives to support quality assurance oversight 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:

- Lead PV QA Data and Digital strategy and initiatives to drive operational excellence, and insight-driven decision-making to maintain or improve quality performance and compliance of Novartis PV activities including ICSR management, aggregate reporting, medical safety, risk management, Health Authority reporting, PV IT systems and device vigilance.
- Act as a quality Artificial Intelligence (AI) champion and Innovation Lead representing PVQA across RDQ, Quality, and PS&PV Data & Digital related networks and initiatives, to influence strategy and ensure alignment.
- By championing capability building in AI, automation, and compliant change management. proactively propose potential quality improvement measures and develop strategies aimed at simplifying processes and improving quality of outputs while ensuring compliance with regulatory requirements; share best practice and lessons learned.
- Lead and/or support due diligence (DD) activities for potential product and/or company acquisitions when applicable.
- Lead and/or support transition and integration related activities of PV and Device Vigilance systems resulting from mergers, acquisitions, and/or divestments.
- Support maintenance of the Pharmacovigilance System Master File (PSMF).
- Ensure lessons learned and best practices are shared across the business to help close learning gaps.
- Provide expertise and support PS and PV and other groups/business partners involved in PV and DV activities with identification and compliance of Quality Issue investigations, act as functional QA in the QMS and ensure timely escalation of applicable Quality Issues to management; provide assistance in the remediation of PV system issues; ensure follow-up and monitoring of completeness of CAPAs in alignment with PV QA team.
- Support Health Authority Inspections, including inspection readiness activities, conduct and follow-up.
- Expertly guide (co-lead, if applicable) the development of robust and sustainable corrective and preventative action plans (CAPA) for complex issues 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. Lead initiatives geared towards remediation of compliance concerns; determine effectiveness of remediation activities; provide ongoing project support and governance.
- Lead and execute deliverables of the Development Quality Plan.
- Deputize for the Team Head as needed.
- Ensure effective quality oversight, management, and support of global PV operational vendors. Drive vendor quality awareness and improvement measures.

Essential Experience:

- Degree in Life Sciences or related scientific discipline. BA/BS or equivalent; PharmD, PhD or other higher degree desirable.
- Five plus years PV/PV quality and related pharmaceutical industry and/or Health Authority experience, with demonstrated involvement in digital, data, or technology-enabled transformation initiatives.
- Demonstrated ability to translate quality and compliance requirements into data- or technology-enabled solutions, and to engage effectively with IT, Data & Digital, and Quality stakeholders.
- Experience with compliant development, implementation, and change management of pharmacovigilance relevant AI applications is an asset.
- PV auditing or inspection experience and Health Authority interactions an advantage.
- Experience in compliance oversight and/or procedure governance a plus.
- Ability to travel up to 15%.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision; excellent problem solving, decision making and prioritization skills.
- Quality mindset and excellent quality and compliance leadership and facilitation skills.
- Extensive knowledge of PV regulations, guidelines, and policies; awareness of GCP and Part 11 requirements.

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.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Quality
Место
Испания
Сайт
Barcelona Gran Vía

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Job ID
REQ-10076730

Associate Director, PV QA - Data & Digital

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