U NOVARTIS

Development QA Manager

Job ID REQ-10055113 Jul 03, 2025 Netherlands

Summary

#LI-Hybrid Location: Amsterdam, The Netherlands

The Development Quality Assurance Manager is responsible for assuring quality oversight of activities undertaken in all Novartis entities in a country to ensure they are conducted in compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines.

Operates in direct collaboration with local Development colleagues (Study and Site Operations, Patient Safety and Regulatory Affairs), Medical Affairs, Novartis Country Quality (NCQ) & Commercial teams for patient-facing projects, products and programs. Ensures implementation of the Novartis Quality Manual and Quality Management System in the country to achieve a high level of quality and compliance.

About the Role

Key responsibilities:

- Oversee implementation, maintenance, and monitoring of the local Quality System and Quality Plan to ensure compliance with Novartis global requirements and applicable local regulations.
- Ensure adequate training systems are in place for GCP, GPvP, and other relevant Development activities.
- Monitor local Quality System, processes, and Key Quality Indicators (KQIs) to proactively identify potential quality risks and collaborate with business partners to address them.
- Partner with local and global Development teams in the execution and follow-up of quality issues and audits related to clinical development and PV activities, ensuring robust corrective and preventive actions are implemented.
- Provide leadership and support for GCP and GPvP Health Authority (HA) inspections, ensuring timely submission of responses to local HA and completion of CAPAs.
- Execute QA activities required for the qualification and monitoring/governance of third party activities with a clinical/medical or PV component.

Essential Requirements:

- Typically more than 5 years experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area, preferably with a minimum of 3 years experience in clinical development.
- Dutch and English language

Diversity & Inclusion

Novartis is 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

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

Division Development **Business Unit** Universal Hierarchy Node Location Netherlands Site Amsterdam Company / Legal Entity NL08 (FCRS = NL008) Novartis Pharma NL **Functional Area** Quality Job Type Full time **Employment Type** Temporary (Fixed Term) Shift Work No Apply to Job

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