

Development QA Manager

Job ID
REQ-10055113

8月 12, 2025

Netherlands

摘要

#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>

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部门
Development

Business Unit
Universal Hierarchy Node

地点
Netherlands

站点
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

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