Development Quality Assurance Manager

Job ID
REQ-10057894

7月 14, 2025

Taiwan

摘要

The Development Quality Assurance Manager is responsible for assuring quality oversight for activities undertaken in all Novartis entities in a country to assure compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines to assure the execution of high quality research and activities within a country(ies). Activities in scope include but may not be limited to assuring adequate systems are in place for the protection of patient safety, rights and well-being, data integrity, and quality oversight of Clinical and Pharmacovigilance activities as needed in both pre- and post- market settings in assigned country(ies) in all Novartis entities.
The Development Quality Assurance Manager is responsible for assuring the quality and compliance of Development, Global and local Medical Affairs (MA) & Commercial patient-facing projects, products and programs. Operates in direct collaboration with local Development colleagues (Study and Site Operations, Patient Safety and Regulatory Affairs), Medical Affairs and Novartis Country Quality (NCQ) to ensure compliance to Novartis entities requirements and relevant HA regulations and guidance. Ensures implementation of the Novartis Quality Manual and Quality Management System in assigned country(ies) to achieve a high level of quality and compliance.

About the Role

Major accountabilities:

- Local Quality System: Oversee implementation, maintenance, and monitoring of the local Quality System and written procedures to ensure GCP and Pharmacovigilance related processes and tasks are compliant with Novartis global requirements and applicable regulations and guidelines. This includes ensuring adherence to ICH GCP and GPvP guidance documents, Novartis written processes, acting as the QA subject matter expert for the approval of local GCP/PV procedures and supporting local IMP release process such that it is done according to global and local requirements.
- Quality Plan and Continuous Improvement: Support and monitor implementation of the local Quality Plan (QP) deliverables related to GCP and PV areas, ensuring alignment with the applicable global QP chapters where ever possible. Utilize lessons learned from audits, inspections, KQI reviews and day-to-day oversight of quality performance to recommend and initiate continuous improvement efforts.
- Training systems: Ensure adequate training systems are in place in assigned country(ies) for GCP, GPvP and other relevant Development activities in compliance with Novartis global and local requirements. Assure that relevant business areas are maintaining inspection-ready documentation to support reviews of training compliance.
- Quality Issue Management: Drive Clinical/PV QA investigation activities at the country level as appropriate and ensure implementation of robust CAPA plans where applicable. Take accountability for escalation of GCP/GPvP process non-compliance as needed.
- Risk Identification and Management: Monitor local Quality System, processes and Key Quality Indicators (KQIs) to proactively identify potential quality risk. Collaborate with business partners to ensure that risks are reviewed for root cause, impact, and recurrence and assure that relevant line function owners put in place mitigation plans to address. Ensure adequate and timely escalation of issues to relevant functions as needed.
- Inspection Management and Support: Provide leadership and/or support as needed for GCP and GPvP HA inspections of activities in assigned country(ies). Assure support prior to, during and post inspection for the country organization, investigational sites and/or external service providers, as applicable, in collaboration with the assigned inspection lead. Ensure that responses to local Health Authorities are submitted on-time, commitments are agreed internally and can be met and relevant CAPAs have been completed/closed according to agreed timelines.
- Audit Management: Partner with local and global Development teams, PS, NCQ and other internal stakeholders in the execution, where QA processes are subject to the audit, and follow-up of audits on clinical development and PV activities. Collaborate with the business, and auditees as appropriate to determine root cause for identified audit and inspection observations (any audits and inspections related to clinical/medical, PV related areas) and verify robust and sustainable corrective and preventive actions are implemented.
- CAPA management: Act as local approver for the documentation and management of local CAPAs to support appropriate review and closure of each corrective and preventive action. Assure local line functions take appropriate ownership of duties as required by the CAPA processes.
- ESP/Supplier Management: Responsible for the execution of QA activities required for the qualification/requalification of ESPs supporting activities with a clinical or PV component. Ensure the ESP selection, PV / QA agreements and oversight processes are properly

followed at the CO for ESPs supporting Development activities with a clinical/medical or PV component.

- Data integrity: Ensure that there is a process in place to maintain local quality and compliance with requirements for digital governance platforms and computerized systems with GCP and/or GPvP impact.
- Governance/Communication: Lead/co-lead local quality review board meetings (ex: Quality committee), and ensure any identified trends/risks related to PV or GCP are communicated and addressed in a timely manner. Ensure a process is in place to update local functions on the possible impact of changes to local and/or global requirements and regulations. Ensure there is an appropriate interface with internal/external stakeholders for any GCP/PV related activity (e.g. local Health Authority, clinical and PV related changes/initiatives). Partner with local NCQ team to ensure the analysis, assessment and resolution of issues with common interfaces (GCP/PV and GMP). Coordinate and analyze clinical and PV section of the AQMR. Ensure business continuity plan is maintained and resulting measures are implemented in GCP and GPvP areas.
- Investigational Medicinal Product (IMP): Ensure oversight of local IMP release as required.

Key performance indicators:

- GCP/PV risks proactively identified and effectively mitigated.
- CAPAs are holistic, on-time and prevent issue recurrence.
- The number and severity of GCP/PV issues identified during internal and external audits is minimized
- No regulatory delays are encountered due to inefficient local GCP/PV system
- Country(ies) are inspection ready at all times

Education (minimum/desirable): Degree in Life Sciences or related fields

Work Experience: 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. Experience in leading projects. GCP Inspection experience is preferred.

Languages:

- English fluent in speaking and writing.
- Mandarin is required to manage local regulatory inspection.

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部门
Development

Business Unit
Innovative Medicines

地点
Taiwan

站点
Taipei

Company / Legal Entity
TW03 (FCRS = TW003) Novartis (Taiwan) Co. Ltd

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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