R&D Quality Specialist

Job ID
REQ-10039114
Feb 04, 2025
Colombia

Summary

The Development Quality Assurance Specialist assists with 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. Activities in scope include but may not be limited to assuring adequate systems are in place for the protection of patient safety, rights and wellbeing, 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 Specialist is responsible for assisting in 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: Assist in the 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 the implementation of the local Quality Plan (QP) deliverables related to GCP and PV areas, ensuring alignment with the applicable global QP chapters wherever 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: Ensuring that 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: Support and facilitate 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: Support monitoring 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 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: Support 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: Support the processes 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: Support the 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. Partner with local NCQ team to ensure the analysis, assessment and resolution of issues with common interfaces (GCP/PV and GMP). Support the coordination and analysis of the clinical and PV section of the AQMR. Support the maintenance of the business continuity plan and the resulting measures that are implemented in GCP and GPvP areas.
- Investigational Medicinal Product (IMP): Ensure oversight of local IMP release.

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
- Quality issues and gaps, when not properly identified and addressed, can lead to regulatory actions resulting in delays in product development, cessation of development activities, and may pose a risk to patients. All of these issue can have a major impact on the Novartis reputation.

Minimum Requirements

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

- **Work Experience:** Typically a minimum of 5 years' experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance, clinical development or a directly related area

Skills:

- Agility.
- Audit Management.
- Business Partnering.
- Continuous Learning.
- Health Authorities.
- Influencing Skills.
- Knowledge of CAPA.
- Quality Management Systems (QMS).
- Risk Management.
- Root Cause Analysis (RCA).
- Self Awareness.
- Standard Operating Procedure (SOP
- Technological Expertise.

Languages :

- English fluent in speaking and writing

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
Colombia
Site
Bogota (Pharmaceuticals / GDD / NTO / CTS)
Company / Legal Entity
CO01 (FCRS = CO001) Novartis de Colombia S.A
Functional Area
Quality
Job Type
Full time
Employment Type

Regular
Shift Work
No
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