Clinical Trials and Pharmacovigilance QA Manager

Job ID
REQ-10018211

9月 03, 2024

Malaysia

摘要

The Clinical Trials and Pharmacovigilance QA Manager will be responsible for assuring quality oversight for activities undertaken in assigned country(ies) to assure compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines, to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.

About the Role

Your Responsibilities:

Your responsibilities include, but not limited to:

- 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.

- 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 wherever possible.
- 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.
- 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.
- 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.
- 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.
- 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.

What you ' ll bring to the role:

- Degree in Life Sciences or related fields
- English fluent in speaking and writing.
- 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
- Critical Negotiations.
- Project Management.
- Collaborating across boundaries.
- Experience in leading projects

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us!

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部门
Development

Business Unit
Innovative Medicines

地点
Malaysia

站点
Selangor

Company / Legal Entity
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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