GCP Compliance Manager

Job ID
REQ-10052995

6月 24, 2025

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摘要

The GCP Compliance Manager (EMEA Hub) is accountable for the compliance oversight and control of regulated GCO activities focusing on EMEA Hub & Country level delivery including country trial level conduct as per country assignment. This role contributes to all compliance activities supporting the three pillars of GCP Compliance, issue management, audits & inspections as per country assignment and GCO self-strategy delivery.
The GCP Compliance Manager (EMEA Hub) is the single point of contact for EMEA Hub & Country team members, providing day-to-day support and ongoing quality oversight. This role promotes a product quality culture within GCO supporting the GCP Compliance Head (EMEA hub), focusing on quality and compliance being increased and sustained and on active risk management.

About the Role

Major Accountabilities:

- Accountable for the compliance oversight and control of regulated GCO activities focusing on EMEA

Hub & Country level delivery including country trial level conduct as per country assignment.
- Single point of contact for EMEA Hub & Country team members for GCP Compliance.
- As per focus area and assignment, management and day-to-day support provided in program/trial level quality issues, deviations and quality events management.
- Coordination and support to program/trial delivery teams for audits and inspections based on trials' selection and audit/inspection scope.
- Delivery of the GCO self-assessment strategy related checks and controls.
- Support cross-functions risk assessments if program/trial/country level in scope and contribute to the monitoring of relevant indicators/metrics/thresholds.

Activities & Interfaces
- Contribute to the execution of the GCO GCP Compliance strategy under the leadership of the GCP Compliance Head (EMEA hub).
- Drive the compliance oversight and control of regulated GCO activities focusing on EMEA Hub & Country level delivery including country trial level conduct as per country assignment, working closely with the Hub & Country teams members, the relevant functions across GCO, involving and collaborating as required with GDD and the wider organization, such as Quality Assurance.
- Be the single point of contact for for EMEA Hub & Country team members as per country assignment for GCP Compliance.

- Manage and provide day-to-day support to the EMEA Hub & Country team members in Hub & Country level quality issues, deviations and quality events management, providing expertise in investigation, RCA and CAPA development. - Involve and collaborate as needed with the relevant functions across GCO, GDD and the wider organization, such as Quality Assurance.
- Coordinate and support Hub & Country related audits & inspections (e.g. Clinical Development Audit, Investigator Site Inspection) as per selection and scope, from preparation to CAPA & effectiveness checks completion, working closely with Quality Assurance. Support and conduct of inspection readiness as per scope.
- Deliver the GCO self-assessment strategy related checks and controls as assigned and share insights within the GCP Compliance team based on the day-to-day support provided.
- Support cross-functions risk assessments if program/trial/country level in scope, working with Hub & Country Teams and the relevant GCO functions.
- Contribute to the monitoring relevant indicators/ metrics/thresholds ensuring the detection of unreported issues, trends and early signals of risks at Hub & Country level.
- Participate in relevant GCO, PTC, GCP Compliance team meetings. May attend as needed or be delegated by the GCP Compliance Head (EMEA hub) to participate in relevant boards, committees and escalation meetings (e.g. GCO Quality Review Board; Issues Management & Escalations Triaging Meetings).
- Contribute to build a network of managers and other relevant stakeholders with other functions, compliance, process, training and risk groups across GCO, in GDD and within the wider organization, such as Quality Assurance.
- Promote a compliance culture within GCO, advocating the adherence to highest standards and ethical integrity.

Essential Requirements:

- Minimum 8-10 years of experience in related scope in the pharmaceutical industry.

- Influencing capabilities in matrix environment.

- C ollaboration skills cross country and cross function.
- A ccountability for and deliver on agreed objectives.
- E xperience as clinical research associate and / or clinical project manager.
- E xperience of GCP audits.
- E xperience in leading / coordinating cross functional project management.
- E xperience in root cause analysis and CAPA development.
- Fluency in English is required.

This position requests presence in the office for at least 50% of time.

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部门
Development

Business Unit
Innovative Medicines

地点
T ü rkiye

站点
Istanbul Ata ş ehir

Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sa ğ l ı k, G ı da ve Tar ı m Ü r ü nleri San. Ve Tic. A. Ş .

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work

No

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