NOVARTIS

GCP Compliance Manager (Asia Hub) - Clinical Quality

Job ID
REQ-10050461
Ιουλ 11, 2025
China

Περίληψη

The GCP Compliance Manager (Asia Hub) is accountable for the compliance oversight and control of regulated GCO activities focusing on Asia 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 (Asia Hub) is the single point of contact for Asia 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 (Asia hub), focusing on quality and compliance being increased and sustained and on active risk management.

About the Role

Key responsibilities:

- Contribute to the execution of the GCO GCP Compliance strategy under the leadership of the GCP Compliance Head (Asia hub).
- Drive the compliance oversight and control of regulated GCO activities focusing on Asia 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 Asia Hub & Country team members as per country assignment for GCP Compliance.
- Manage and provide day-to-day support to the Asia 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 (Asia 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:

- 8+ years industry experience specifically in clinical operations and clinical site management with a strong understanding of clinical research international standards and regulatory requirements from Health Authorities. Audits and inspections experience highly desirable
- Advanced degree in science, engineering or relevant discipline.
- Proficiency in English
- Organizational and analytical skills associated with an aptitude in quality management and continuous improvement.
- Ability to work effectively in a matrix cross-functional environment.

Desirable requirements:

- Critical thinking ability and risk management and risk-based knowledge and mindset.
- Ability in partnering with a proactive and solution-oriented mindset.
- Strong skills to facilitate/optimize contribution of team members as individuals and members of a cohesive team.
- Strong capacity for working independently with minimal guidance.
- Ability to make & communicate difficult decisions, associated with strong written and verbal communication skills.
- Self-awareness, willingness to further develop own strengths and explore opportunities for improvement.

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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Τομέας
Development
Business Unit
Innovative Medicines
Τοποθεσία
China

Τοποθεσία
Beijing (Beijing)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Alternative Location 1
Shanghai (Shanghai), China
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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