NOVARTIS

GCP Compliance Manager, Program & Study

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Индия

Сводка

The GCP Compliance Manager (Program & Study) is accountable for the compliance oversight and control of regulated GCO activities focusing on program/trial level delivery as per program(s)/trial(s) assignment. This role contributes to all compliance activities supporting the three pillars of GCP Compliance, issue management, audits & inspections as per program/trials' selection and GCO self-strategy delivery.
The GCP Compliance Manager (Program & Study) is the single point of contact for Clinical Trial Teams for GCP Compliance, providing day-to-day support and ongoing quality oversight. This role promotes a product quality culture within GCO supporting the GCP Compliance Head (Program & Study), focusing on quality and compliance being increased and sustained and on active risk management.

About the Role

Activities & Interfaces

- Contribute to the execution of the GCO GCP Compliance strategy under the leadership of the GCP Compliance Head (Program & Study).
- Drive the compliance oversight and control of regulated GCO activities focusing on program/trial level delivery as per program(s)/trial(s) assignment, working closely with the Clinical Trial Teams and the relevant functions across GCO, involving and collaborating as required with GDD and the wider organization
- Be the single point of contact for Clinical Trial Teams per program(s)/trial(s) assignment for GCP Compliance
- Manage and provide day-to-day support to the Clinical Trial Teams in program/trial 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, including Quality Assurance
- Coordinate and support audits and inspections based on program(s)/trial(s)' selection and audit/inspection 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(s) or trial(s) identified working with Clinical Trial Teams and the relevant GCO functions.
- Contribute to the monitoring of relevant indicators/ metrics/thresholds ensuring the detection of unreported issues, trends and early signals of risks at program/trial delivery level
- Participate in relevant GCO, PCT, GCP Compliance team meetings. May attend as needed or be delegated by the GCP Compliance Head (Program & Study) 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.

Key performance indicators: -

- Key Performance Indicators• Compliance of regulated GCO activities, with increased oversight and control, focusing on program/trial level delivery as per program(s)/trial(s) assignment
- Increased capabilities through time with a strong support provided to Clinical Trial Teams and greater ability in partnering within and outside GCO.• Timely delivery of the GCO self-assessment strategy related checks and controls
- Contribution in potential impact mitigations when possible related to the product quality and compliance supporting GCO deliverables targets for quality.• Support Process, Training & GCP Compliance objectives' achievement, ensuring delivery of assigned GCP Compliance objectives and targets.

Minimum Requirements

Minimum: Advanced degree in science, engineering or relevant discipline.

Professional Requirements

• 8+ years indonal requirements:ustry experience specifically in clinical operations and trial management with a strong understanding of clinical research international standards and regulatory requirements from Health Authorities. Audits and inspections experience highly desirable.

• Organizational and analytical skills associated with an aptitude in quality management and continuous improvement.

• 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.

• Ability to work effectively in a matrix cross-functional environment.

• 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.

Languages :

- English

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Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Дивизион
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Business Unit
Development
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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