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GCP Compliance Manager (GCO)

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REQ-10037457
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Inde

Résumé

The GCP Compliance Manager (GCO) is accountable for the compliance oversight and control of regulated GCO activities focusing on GCO wide activities potentially having a high impact on GCO ability to deliver as per objectives, as per assignment. This role contributes to all compliance activities supporting the three pillars of GCP Compliance as per focus above, issue management, audits & inspections particularly system/process audits and global inspections supporting authorizations and GCO self-strategy delivery.
The GCP Compliance Manager (GCO) provides GxP expertise and may be referred in providing GCP Compliance support to other functions, compliance, process, training and risk groups. This role promotes a product quality culture within GCO supporting the GCP Compliance Head (GCO) focusing on quality and compliance being increased and sustained and on active risk management.

About the Role

Major accountabilities:

- Accountability for the compliance oversight and control of regulated GCO activities focusing on GCO wide activities potentially having a high impact on GCO ability to deliver as per objectives, as per assignment.
- Provide GxP expertise and may be referred in providing GCP Compliance support to other functions, compliance, process, training and risk groups.
- As per focus area and assignment, management of GCO wide systemic quality issues, deviations and quality events management.
- Management of the GCO audits and inspections landscape and coordination of system/process audits & global inspections supporting authorizations including inspection readiness.
- Delivery of the GCO self-assessment strategy related checks and controls.
- Coordination of GCO cross-functions risk assessments as per scope and as assigned.

Activities & Interfaces:

- Contribute to the execution of the GCO GCP Compliance strategy under the leadership of the GCP Compliance Head (GCO).
- Experience with Clinical Monitoring, Clinical Research, Clinical Study Reports, Clinical Trials, Collaboration, Data Analysis, Decision Making Skills, Health Sciences, Lifesciences, Regulatory Compliance.
- Drive the compliance oversight and control of regulated GCO activities focusing on GCO wide activities potentially having a high impact on GCO ability to deliver as per objectives, as per assignment, working closely with the relevant functions across GCO, involving and collaborating as required with GDD and the wider organization, such as Quality Assurance.
- Provide GxP expertise and may be referred in providing GCP Compliance support to other functions,

compliance, process, training and risk groups.

- Manage GCO wide systemic quality issues, deviations and quality events as per assignment, 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.
- Manage GCO audits and inspections landscape and coordinate as assigned system/process audits & global inspections supporting authorizations including the overall coordination and management of all phases, from preparation to CAPA & effectiveness checks completion. Manage and conduct of inspection readiness as per scope and assignment.
- Contribute to the maintenance of a centralized knowledge of audits/inspections related outcomes working closely with Training overseeing GCO Knowledge Management.
- Deliver the GCO self-assessment strategy related checks and controls as assigned and share insights within the GCP Compliance team based on experience and observed trends.
- Coordinate the GCO cross-functions risk assessments as per scope and as assigned, in collaboration with all GCO functions, working closely with Risk, Resilience & Insights and involving as needed the relevant parties.
- Contribute to the monitoring of relevant indicators/ metrics/thresholds ensuring the detection of unreported issues, trends and early signals of risks at GCO level.
- Participate in relevant GCO, PTC and GCP Compliance team meetings. May attend as needed or be delegated by the GCP Compliance Head (GCO) 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:

- Managing Crises.
- Compliance of regulated GCO activities, with increased oversight and control, focusing on GCO wide activities potentially having a high impact on GCO ability to deliver as per objectives.
- Increased capabilities through time with a strong support provided to GCO teams members, greater ability in partnering within and outside GCO and strong GxP expertise.
- 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 Excellence, Training & GCP Compliance objectives' achievement, ensuring delivery of assigned GCP Compliance objectives and targets.

Ideal Background

Education (minimum/desirable): Minimum: Advanced degree in science, engineering or relevant discipline.

Experience/Professional requirement:

- 8+ years industry experience specifically in clinical operations with an advanced knowledge 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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