

GCP Compliance Specialist/Manager (Technology)

Job ID
REQ-10064514

10月 23, 2025

India

摘要

The GCP Compliance Specialist (Technology) is accountable to manage delegated activities supporting GCO projects and teams in ensuring compliance against GCP for emerging technology and change of strategy in current GCO managed technology, including awareness of the use of artificial intelligence (AI) and machine learning in GCO operated clinical trials, with the aim to guarantee regulatory adherence in the use of computerized systems and in the collection of electronic data.

The GCP Compliance Specialist (Technology) provides data analytics and reporting support, knowledge in GxP relevant Enterprise IT systems in the frame of GCP Compliance activities and supports the delivery of the GCP Compliance Technology roadmap. This role promotes a product quality culture within GCO supporting the GCP Compliance Head (Technology), focusing on quality and compliance being increased and sustained.

About the Role

Major accountabilities:

- Contribute to the compliance against GCP for emerging technology and change of strategy in current GCO managed technology via assigned activities.
- Support the delivery of the GCP Compliance Technology roadmap via assigned activities.
- Provide data analytics and reporting support in the frame of GCP Compliance activities.
- Provide day-to-day technical support with knowledge in GxP relevant Enterprise IT systems to GCP Compliance teams and GCO teams.
- Support the monitoring of relevant indicators/metrics/thresholds if relevant per scope.

Key performance indicators:

- Compliance against GCP for emerging technology and current GCO managed technology in case of change.
- Increased technical capabilities in GxP computerized systems including artificial intelligence (AI) through time, with support provided to GCP Compliance teams and GCO teams and greater ability in partnering within and outside GCO.
- Timely delivery of GCP Compliance Technology roadmap assigned activities.
- Support Process, Training & GCP Compliance objectives ' achievement, ensuring the delivery of GCP Compliance objectives and targets.

Minimum Requirements:

Education: Minimum: Bachelor ' s degree in science, B.Pharm, M.Pharm, Computer Science engineering or relevant discipline.

Language: Proficiency in English.

Experience/Professional requirement:

- 5+ years of industry experience, preferably in major Pharmaceuticals company and in particular technical expertise in computerized systems used in clinical operations with an understanding of clinical research international standards and regulatory requirements from Health Authorities.
- Organizational skills, associated with an aptitude in critical thinking, quality management and continuous improvement.
- Ability in partnering with a proactive and customer focused solution- oriented mindset.
- Experienced in change management, intercultural experience, and ability to act in a complex and rapidly changing business environment.
- Skills to facilitate contribution of team members as individuals and members of a cohesive team.
- Ability to work in a matrix cross-functional environment.
- Written and verbal communication skills.
- Self-awareness, willingness to further develop own strengths and explore opportunities for improvement.

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Development

Business Unit
Innovative Medicines

地点
India

站点
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

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