GCP Compliance Manager -Americas Hub (Remote Position)

Job ID
REQ-10049006

5月 01, 2025

USA

摘要

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

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.
#LI-Remote

About the Role

Key Responsibilities:

- Americas Hub & Country level delivery including country trial level conduct as per country assignment.
- Single point of contact for Americas 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.

Role Requirements:

- Bachelor's degree in science, engineering or relevant discipline.

- Advanced degree preferred
- 8+ years industry experience specifically in clinical operations or clinical site 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 a proficiency 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 optimally in a matrix cross-functional environment.
- Strong capacity for working independently with minimal guidance.

Desirable Requirements:
- 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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: $145,600 and $270,400/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market
may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level,

knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Innovative Medicines

地点
USA

状态
Remote, US

站点
Remote Position (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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REQ-10049006

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