GCP Compliance Head (Technology)

Job ID
REQ-10055331

7月 17, 2025

USA

摘要

This position will be located at East Hanover, NJ site and will not have the ability to be located remotely.
“Please note that this role would not provide relocation and only local candidates will be considered.”

The GCP Compliance Head (Technology) is accountable to ensure compliance against GCP for emerging technology and change of strategy in current GCO managed technology, including the use of artificial intelligence (AI) and machine learning in GCO operated clinical trials, and guarantee regulatory adherence in the use of computerized systems and in the collection of electronic data.
#LI-Onsite

Key Responsibilities:
- Accountability to ensure compliance against GCP for emerging technology and change of strategy in current GCO managed technology, including the use of AI and machine learning in GCO operated clinical trials, and guarantee regulatory adherence in the use of computerized systems and in the collection of electronic data.
- Build strong GCP Compliance support with expert knowledge in GxP relevant Enterprise IT systems including validation, user management, security, and electronic data for the data life cycle.

· Provide data analytics support to GCP Compliance enabling timely and robust GCP Compliance delivery.
· Contributor to the GCO self-assessment strategy development if relevant per scope.
· Bring and build GxP expertise in computerized systems in GCP Compliance and GCO.
· Contribute to the development of the GCO GCP Compliance vision under the leadership of the Head GCP Compliance, as member of the GCP Compliance Leadership Team, and ensure execution of the vision.
· Ensure compliance against GCP for emerging technology and change of strategy in current GCO managed technology, including the use of AI and machine learning in GCO operated clinical trials, and guarantee regulatory adherence in the use of computerized systems and in the collection of electronic data, working closely with the relevant functions within GCO, Development and the wider organization.
· Build strong GCP Compliance support with expert knowledge in GxP relevant Enterprise IT systems including validation, user management, security, and electronic data for the data life cycle.
· Provide data analytics support to GCP Compliance enabling timely and robust GCP Compliance delivery, in collaboration with Strategy Business Insights and Technology (SIT) in GCO and DDIT. ·
· Provide expert input supporting the GCP Compliance Community in all GCP Compliance pillars. ·
· Contribute to and execute the GCO self-assessment strategy development if in scope, as member of the GCP Compliance Leadership Team and ensure its delivery. Advise by using data mining and assessing relevant indicators/ metrics/thresholds on the selection of robust checks and controls and support the development of standardized methodologies, tools and repository. ·
· Monitor relevant indicators/ metrics/thresholds ensuring the detection of unreported issues, trends and early signals of risks associated with the use of GxP relevant computerized systems landscape including the use of AI and machine learning in GCO operated clinical trials.

About the Role

Requirements:

- Minimum: Advanced degree in science, engineering or relevant discipline. Desirable: Further education in Project management/Risk Management.
- 10+ years of industry experience, with experience in leadership positions (including line management, matrix leadership, stakeholders ’ management, collaboration fostering to increase performance). ·
- Advanced knowledge in GxP relevant IT systems include validation, user management, security, and electronic data for the data life cycle.
- · Advanced understanding of drug development with experience in clinical operations, with an in-depth knowledge of clinical research, international standards and regulatory requirements from Health Authorities. ·
- Strategic thinking and analytical skills; risk management and risk-based decision-making knowledge and mindset. ·
- Experienced in change management, intercultural experience, and ability to act in a complex and rapidly changing business environment. ·
- Strong interpersonal savviness, empathy, strong organizational awareness. ·
- Strong negotiation and influencing skills, able to naturally bridge scientific and business participants.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $185,500/yr and $344,500/yr; ***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.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

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

Alternative Location 1
Basel (City), Switzerland

Functional Area
Research & Development

Job Type
Full time

Employment Type

Regular

Shift Work
No

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