Senior GCP/PV Auditor

Job ID
REQ-10051674

5月 12, 2025

India

摘要

About the Role:

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Senior GCP/PV Auditor

Location - Mumbai #LI Hybrid

About the Role:

Lead, support and report independent GCP/PV audits according to the NVS Quality Sys-tem and the current GCP/PV regulations to assess compliance with applicable regula-tions, standards, and guidance documents. Review and approve corrective action plans in support of the audit

observations.

Ensure alignment with strategic direction of the company and assist in driving implementation of the applicable actions. Provide consultation to NVS business units through risk based assessments. Act as SME for assigned areas of responsibility.

Key Responsibilities:

- Support the strategic development of an effective global risk-based audit strategy and programme; collect, collate and incorporate input into audit strategy and plan.
- Lead, plan, conduct, document and follow-up of global quality regulatory compliance audits and assessments of GCP/GPvP according to the requirements specified in the respective Novartis Quality Module as well as applicable regulations, standards, quality agreements, and guidance documents. Perform activities with a high degree of independence.
- Provide technical guidance, leadership, mentoring and training of other auditors on audit related activities.Prepare audit reports according to NVS requirements and timelines.
- Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures according to NVS requirements on Management Escalations and other relevant procedures.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP)..
- Identify and communicate quality and regulatory compliance issues to Quality Management through appropriate channels as well as recommend remediation.
- Lead compliance investigations and initiatives focused on inspection readiness and quality, process and compliance improvement as requested.
- Support Mock Pre-Approval Inspections (PAIs) and Health Authority (HA) inspections as needed.
- Proactively research local and global initiatives, trends and events that impact maintenance of compliance.Complete any other requests from Global GxP Audit. Review and approve audit reports as required.

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- 7+ years of GCP/PV/Pharmaceutical.
- Industry/Health Authority experience or equivalent.
- 3 years of GCP/PV auditing experience; 5 years preferred; experienced in both GCP and PV auditing is ideal.
- Willingness to travel approximately 60% of the time.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Ability to address a variety of tasks within the same timeframe while maintaining oversight; ability to maintain a high degree of independence with respect to decision making and problem solving.

- Experience with Health Authority inspections and interaction.
- Excellent quality and compliance leadership and facilitation skills.
- Excellent verbal and written communication, organizational and interpersonal skills.

Desirable Requirements:

- Good knowledge of computer systems validation and 21CFR Part 11 requirements.
- Ability to lead audit teams and operate successfully in various team capacities.

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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

部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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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