Senior GCP/PV Auditor

Job ID
REQ-10010471

12月 03, 2024

India

摘要

Lead, support, and report independent GCP/PV audits according to the Novartis Quality Systems and the current GCP/PV regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective action plans in support of the audit observations. Ensure alignment with the company's strategic direction and assist in driving the implementation of the applicable actions. Provide consultation to NVS business units through risk-based assessments. Act as SME for assigned areas of responsibility.

About the Role

Sr. GCP/PV Auditor

Location - Mumbai #LI Hybrid

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Key Responsibilities:

- Support the strategic development of an effective global risk-based audit strategy and program; 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 audit findings and support immediate follow-up measures according to the Novartis requirements on Management Escalations and other relevant procedures. Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with the 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 remediations. Lead compliance investigations and initiatives focused on inspection readiness and quality, process, and compliance improvement as requested.
- Support mock pre-approval inspections (PAIs) and HA inspections as needed. Proactively research local and global initiatives, trends, and events that impact the maintenance of compliance. Mentor GCP/PV staff as required. Complete any other request from global GCP Audit. Review and approve audit reports as required and also participate in the Lead Auditor program.

Essential Requirements:

- 15+ years of proven experience in GCP/GPvP/clinical/industry/health authority experience or equivalent.
- 8+ years of GCP/PV auditing experience preferred and willingness to travel up to 60% of the time.
- Ability to lead and objectively evaluate compliance issues. Ability to address a variety of tasks within the same timeframe while maintaining oversight; maintain a moderate degree of independence with respect to decision-making and problem-solving.

- Experience with Health Authority inspections and interactions preferred. Good quality and compliance leadership and facilitation skills.
- Excellent verbal and written communication, organizational, and interpersonal skills. Excellent computer skills including Excel, MS Office, etc.
- Extensive knowledge of applicable GCP, PV, and GxP regulations, guidelines, policies, and procedures. Good knowledge of CSV and 21 CFR Part 11, ability to lead audit teams, and operate successfully in various team capacities.
- Excellent leadership and facilitation skills, Auditor certification desirable.

Desirable Requirements:

- Graduate in natural/biological sciences or equivalent, or an equivalent mix of education and experience

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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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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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