Senior Auditor Good Clinical Practices and Pharmacovigilance

Job ID
REQ-10052696
Jun 30, 2025
Canada

Summary

Lead, support and report independent GCP/PV audits according to the NVS Quality System and the current GCP/PV regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective ac-tion plans in support of the audit observations.

Ensure alignment with strategic direction of the company and assist in driving im-plementation 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

Location:Montreal#LI-Hybrid

Permanent position:

Key Responsibilities:

1) 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.

2) Provide technical guidance, leadership, mentoring and training of other auditors on audit related activities. Prepare audit reports according to NVS requirements and timelines.

3) 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)..

4) 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.

5) Support Mock Pre-Approval Inspections (PAIs) and Health Authority (HA) inspections as needed. Review and advise on relevant global NVS policies and procedures.

6) Proactively research local and global initiatives, trends and events that impact maintenance of compliance. Mentor junior GCP/PV staff as required.

7) Complete any other requests from Global GxP Audit. Maintain current knowledge of regulations, standards, and guidance documents.

8) Review and approve audit reports as required. Participate in the Lead Auditor program as requested.

Essential Requirements:

1) Degree in natural/biological sciences or equivalent (or an equivalent mix of education and experience). Advance degree desirable

2) English fluency at operational and functional level (as first or second language; second language a plus)

3) 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; Experience with Health Authority inspections and in-teraction; Extensive knowledge of applicable GCP, PV and GxP regulations, guidelines, policies and procedures;

4) Willingness to travel approximately 60% of the time.

5) Excellent computer skills, including Excel, Word, etc;

Desirable Requirements:

1) Auditor certification desired. Good knowledge of computer systems validation and 21CFR Part 11 requirements;

2) Ability to independently manage and objectively evaluate complex compliance issues with minimal super-vision. Excellent quality and compliance leadership and facilitation skills. Excellent verbal and written communication, organiza-tional and interpersonal skills. Ability to lead audit teams and operate successfully in various team capacities. Excellent leadership and facilitation skills. Ability to operate successfully in various cultural environments; Ability to deputize for Regional Audit Head as required.

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Division
Operations
Business Unit
Innovative Medicines
Location
Canada

Site
Montreal
Company / Legal Entity
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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
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