# GCP/PV Auditor

Job ID
REQ-10015584
Juli 17, 2024
Mexiko

## 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 documents. Review and approve corrective action plans in support of the audit observations .

## About the Role

**Major accountabilities:**

- About the role:
  • 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 documents. Perform activities with a high degree of independence.
  • Assess the adequacy of responses (CAPA plans) to audit findings in agreement 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.
  • Execution of the risk based Unified Quality Audit Plan (UQAP).
  • Accuracy of findings and completion of audits and finalization of audit reports within established timelines, procedures and agreed upon standards/Key Performance Indicators (critical metrics). Effective analysis of audit metrics and causes of non-compliance.
  • Timely customer concern through accurate channels of issues and findings that impact NVS Good Clinical Practice/Pharmacovigilance and risk benefit evaluation capabilities. Timely, complete and accurate communication, consultation and support to business partners.
  • Effective facilitation and follow-up of HA inspections, as assigned. Effective collaboration on quality/compliance remediation and improvement initiatives; timely completion of projects. Timely review and feedback on policies, procedures and associated documents. Lead compliance investigations and initiatives passionate about inspection readiness and quality, process and compliance improvement as requested.

**Skills:**

- Audit Management.
- Auditing.
- Communication Skills.

- Compliance Audits.
- Compliance Risk.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Gmp Procedures.
- Inspection Readiness.
- Organizational Skills.
- People Management And Leadership.
- Qa (Quality Assurance).
- Regulatory Compliance.
- Risk Management.
- Self Awareness.
- Technological Expertise.

**Languages :**

- English.

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MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
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Quality
Job Type
Full time
Employment Type
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## GCP/PV Auditor

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