Good Clinical Practices and Pharmacovigilance Sr. Auditor

Job ID
REQ-10025384
Nov 05, 2024
Messico

Sommario

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 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

Major accountabilities:

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.

2. 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.

3. Provide technical guidance, leadership, mentoring and training of other auditors on audit related activities.

4. Prepare audit reports according to NVS requirements and timelines.

5. 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.

6. Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP).

7. Identify and communicate quality and regulatory compliance issues to Quality Management through appropriate channels as well as recommend remediation.

8. Lead compliance investigations and initiatives focused on inspection readiness and quality, process and compliance improvement as requested.

9. Support Mock Pre-Approval Inspections (PAIs) and Health Authority (HA) inspections as needed. 10.

Review and advise on relevant global NVS policies and procedures.

11. Proactively research local and global initiatives, trends and events that impact maintenance of compliance.

12. Mentor junior GCP/PV staff as required.

13. Complete any other requests from Global GxP Audit.

14. Maintain current knowledge of regulations, standards, and guidance documents.

15. Review and approve audit reports as required.

16. Participate in the Lead Auditor program as requested.

Key performance indicators:

- Execution of the risk based Unified Quality Audit Plan (UQAP).
- Assigned audits led appropriately, delivered on time and according to Global GxP Audit quality standards.
- Accuracy of findings and completion of audits and finalization of audit reports within established timelines, procedures and agreed upon standards/Key Performance In- dicators (KPIs). Effective analysis of audit metrics and causes of non-compliance.
- Timely escalation through proper 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 initia- tives; timely completion of projects.
- Timely review and feedback on policies, procedures and associated documents.

Job Dimensions

Financial responsibility:

- According to Novartis rules

Additional Actions

- Deputize for Regional Audit Head as required
- Attend relevant QA Audit & IM, Quality Management and quality related meetings
- Cross train if not proficient in both disciplines (GCP/PV)
- Review audit reports, when required etc.
- Review procedural documents
- Prepare and conduct GCP/PV and audit related training
- Deliver presentations to QA and business partners
- Issue escalation where appropriate

Impact on the organisation:

- Assist in developing a robust, effective and compliant GCP/PV audit plan for NVS.
- Participate in discussions with management regarding the program and its effectiveness
- Timely execution of comprehensive and targeted audits and timely communication of audit results to appropriate NVS management is crucial to prevent GCP/PV compliance related incidents and regulatory enforcements.

- Add value to NVS business by supporting Global GxP Audit and other business partners to operate in compliance with global regulations, standards, and guidance documents and to initiate quality improvement measures. Both items help to minimize any adverse regulatory impact.
- Alerts the Global GxP Audit team to potential non- compliance issues.

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

Divisione
Operations
Business Unit
Innovative Medicines
Posizione
Messico
Sito
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Accessibility and accommodation

Novartis is committed to work with and provide 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 tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Job ID
REQ-10025384

Good Clinical Practices and Pharmacovigilance Sr. Auditor

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10025384-good-clinical-practices-and-pharmacovigilance-sr-auditor*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/INSURGENTES/Global-Audit-and-Compliance-Professional_REQ-10025384-1
5. mailto:tas.mexico@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/INSURGENTES/Global-Audit-and-Compliance-Professional_REQ-10025384-1