Senior GCP/PV Auditor and Outsourcing

Job ID
REQ-10059651

8月 08, 2025

Spain

摘要

The Senior GCP/PV Auditor and Outsourcing is responsible to 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, stand-ards, 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.

The incumbent will be responsible for management, oversight of audits, where role includes management and oversight of outsourced audits, the number of direct reports will be reduced to allow for this additional responsibility. In addition, if required, develop, maintain, and man-age a standard process for the contracting and oversight of GCP/PV audits assigned to third party audit service providers.

About the Role

We pursue amazing talent across Spain! This position offers the possibility of being fully remote, with flexibility in location. We ' re excited to welcome you to our team whether you're based in **Madrid** or **Barcelona**.

Please note that **the role requires travel of up to 40% of the time.**

Major accountabilities:

- 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 CAPA Approver and CAPA Coordinator.
- 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.
- Review and advise on relevant global NVS policies and procedures.
- Proactively research local and global initiatives, trends and events that impact maintenance of compliance.
- Mentor junior GCP/PV staff as required.
- Complete any other requests from Global GxP Audit.
- Maintain current knowledge of regulations, standards, and guidance documents.
- Review and approve audit reports as required.
- Participate in the Lead Auditor program as requested.

Major Accountabilities for Management and Oversight of Outsourced Audits:

- 1. Assure third party auditors comply with Novartis requirements regarding adherence to the audit scope and agenda, audit conduct, and communication of audit results.
- 2. Provide strategic direction and operational support, to ensure audits assigned to third party auditors are completed in accordance with agreed upon timelines.
- 3. Create and/or maintain effective processes and procedures relating to the governance of the outsourcing audit program.
- 4. Ensure effective management and oversight of all third-party firms contracted to provide

GCP/PV auditing services, i.e., KPIs & KQI oversight and reporting.

- 5. Provide operational support to third-party auditors for all assigned outsourced audits. This includes the provision of audit related documentation and data for audit preparation activities in advance of the on-site audit conduct as well as providing ongoing support to contracted auditor(s), as needed, during the on-site portion of audit conduct.
- 6. Responsible for entry and review of draft audit reports; scheduling and chairing post audit TCs with appropriate business and QA stakeholders including escalations; issuance of final audit report; review and approval of the initial CAPA plan. This task may be delegated to the internal audit team as needed.

Obligatory requirements:

- Degree in natural/biological sciences or equivalent (or an equivalent mix of education and experience). Advance degree is desirable.
- Education: Degree in natural/biological sciences or equivalent (or an equivalent mix of educat ion and experience).
- 5 years GCP/GPvP/clinical /industry/health authority experience or equivalent; 1-2 years of GCP auditing experience preferred.
- **It is obligatory to be Certified Auditor.**
- Ability to manage and objectively evaluate compliance issues and 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.
- Thorough knowledge of applicable GCP, GPvP and GxP regulations, guidelines, policies and procedures.
- Experience with Health Authority inspections and interaction a plus.
- Good quality and compliance leadership and facilitation skills.
- Fluent English, written and spoken. Other languages are a plus.
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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

部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Provincial

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1
Madrid Provincial, Spain

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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