

GCP/PV Auditor

Job ID
REQ-10024686
Oct 14, 2024
Spain

Summary

In this role you will lead, support and report independent GCP/PV audits and approve follow-up corrective and preventive activities according to the Novartis Quality Systems and Standards, Good Clinical Practice(GCP)/Good Pharmacovigilance Practice(GPvP) and the current GCP/PV regulations. You will provide GCP/PV related quality guidance and assist in the identification and implementation of quality assurance training needs for Global GxP Audit and other business partners.

The audits performed on behalf of Global GxP Audit include all audit types across GCP and PV disciplines including internal and external targets.

How would you like to be a key part of the Global Auditing at Novartis, building upon and maintaining our exceptional standards? We pursue amazing talent across Spain! This position comes with a flexible location and we are ready to hire this role in the city of preference (within Spain) of the successful candidate.

About the Role

In this role you will be required to travel up to 60% of time.

Major accountabilities:

- Plan, lead, conduct, document, report and follow-up of GCP/PV audits according to the requirements specified in the respective Novartis procedures as well as applicable regulations, standards, quality agreements, and guidance documented.
- For this entry-level global auditor role, audits will typically be limited to low risk GCP/PV activities such as Investigator site audits, single service vendors, systems/process, Patient Oriented Programs, etc). Auditor may assist in supporting complex audits (Country Organizations, multiservice vendors, high risk vendors, etc).
- Provide technical guidance and training on audit activities.
- 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. Ensure adequate definition and recording of mitigation plans when applicable.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP).
- Maintain current knowledge of regulations, standards, and guidance documents.

Minimum Requirements:

- Education: Degree in natural/biological sciences or equivalent (or an equivalent mix of education and

experience).

- 5 years GCP/GPvP/clinical /industry/health authority experience or equivalent (1-2 years of GCP/PV auditing experience is preferred)
- Thorough knowledge of applicable GCP, GPvP and GxP regulations, guidelines, policies and procedures.
- Ability to manage 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.
- Fluent English, at operational and functional level

Desirable requirements:

- Experience with Health Authority inspections and interaction a plus.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

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Commitment to Diversity and Inclusion:

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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>

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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>

Division

Operations

Business Unit

Innovative Medicines

Location

Spain

Site

Barcelona Provincial

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, 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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