Global GCP/PV Auditor

Job ID
REQ-10058506

7月 22, 2025

Spain

摘要

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.

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 60% of the 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).
- 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 efinition and recording of mitigation plans when applicable.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with CAPA Approver and CAPA Coordinator.
- Maintain current knowledge of regulations, standards, and guidance documents.

Minimum Requirements:

- 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.
- 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.

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

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部门
Operations

Business Unit
Other

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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