# GCP/PV Auditor

Job ID
REQ-10024686

10月 14, 2024

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.

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 efinition 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 educat ion 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

**You ’ ll receive:**You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards 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.

**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

**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

**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

Apply to Job

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

Job ID
REQ-10024686

## GCP/PV Auditor

Apply to Job

---

**Source URL:**
*https://www.novartis.com.cn/careers/career-search/job/details/req-10024686-gcppv-auditor*

**List of links present in page**

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Provincial/GCP-PV-AuditorREQ-10024686-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Provincial/GCP-PV-AuditorREQ-10024686-1