

Global GCP/PV Senior Auditor

Job ID
REQ-10003761
Apr 24, 2024
Spain

Summary

Location: Spain/flexible (proximity to international airport is needed). How would you like to be a key part of the Global Auditing at Novartis, building upon and maintaining our exceptional standards? As Global Senior GCP/PV Auditor, you will be responsible for leading, supporting and reporting independent GCP and PV audits and approving follow-up CAPAs according to Novartis guidelines and GCP regulations. You will manage cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators). Furthermore, you will lead the preparation and management of external and corporate audits and Health Authority inspections.

About the Role

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.

Major accountabilities:

- Supporting the strategic development of an effective global risk-based audit strategy and programme; collecting, collating and incorporating input into audit strategy and plan
- Leading, planning, conducting, documenting and following-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. Performing activities with a high degree of independence
- Providing technical guidance, leadership, mentoring and training of other auditors on audit related activities
- Assessing the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP).
- Identifying and communicating quality and regulatory compliance issues to Quality Management through appropriate channels as well as recommending remediation
- Leading compliance investigations and initiatives focused on inspection readiness and quality, process and compliance improvement as requested
- Proactively researching local and global initiatives, trends and events that impact maintenance of compliance
- Maintaining current knowledge of regulations, standards, and guidance documents

Minimum Requirements:

- Bachelors/Masters in Natural Sciences, Biological Sciences or similar subject
- 7+ years of experience in GCP or PV – both would be advantageous but not essential
- Flexibility and willing to travel up to 60%
- Experience dealing with Health Authority inspections is key
- Strong knowledge of GCP, PV, GxP regulations
- Good knowledge of computer systems validation and 21CFR Part 11 requirements
- Ability to lead audit teams and operate successfully in various team capacities
- Fluency in English is essential – written and spoken. Additional languages are welcome

You'll receive:

Competitive salary, annual bonus, pension scheme, health insurance, flexible working arrangements, subsidized dining facilities, employee recognition scheme.

Why consider Novartis?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

Imagine what you could do at Novartis!

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>

Division

Operations

Business Unit

Pharmaceuticals

Location

Spain

Site

Barcelona Provincial

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Alternative Location 1

Mexico

Alternative Location 2

India

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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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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