NOVARTIS

Global GMP Senior Quality Auditor

Job ID
REQ-10073874
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Испания

Сводка

In this role you will lead, support and report independent GMP audits according to the Novartis Quality System and the current GMP regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective action plans in support of the audit observations. The audits performed include internal and external targets of manufacturing sites, development centers, quality systems, contract manufacturers, laboratories, warehouses, country organizations, and suppliers.

The Global GMP Senior Quality Auditor also ensures alignment with strategic direction of the company and assist in driving implementation of the applicable actions and provides consultation to Novartis business units through risk based assessments.

About the Role

In this role you will be required to travel up to 60% of time. You can be based either in Spain (Madrid or Barcelona) or Slovenia (Ljubljiana).

Major accountabilities:

- Support the strategic development of an effective global risk-based audit strategy and program. Collect, collate, and incorporate input into the audit strategy and plan.
- Plan, lead, conduct, document, and follow-up of GMP audit according to the requirements specified in the respective Novartis Quality procedures as well as applicable regulations, standards, quality agreements, and guidance documents.
- For this role, auditors will be given more complex and higher-risk audits, such as sterile API, aseptic DP, and combination products. The ability to assess risk of these operations is critical to success. Provide technical guidance, mentoring, and training on audit activities.
- Provide regulatory guidance for timely remediation and recommendations regarding acceptability of the proposed filing.
- Prepare audit reports according to NVS requirements and timelines. Identify and report best practices and lessons learned to support development/training of GMP auditors. Mentor junior GMP staff as required .Act as GMP compliance consultant for GMP trainings, task forces, continuous improvement projects as needed.
- 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. Ensure adequate definition and recording of mitigation plans when applicable.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with the stakeholder QA representative and Auditee.
- Review and advise on relevant policies and procedures. Maintain current knowledge of regulations, standards, and guidance documents.

Essential requirements:

- 12+ years broad experience in Pharmaceutical or Medical Device Industry. 3 years auditing experience preferred, and excellent knowledge of regulatory requirements.
- **Strong knowledge of GMP regulations**, sound and practical judgement in the interpretation and application of regulations and standards.
- **Solid operational experience,** that should include QA/QC management and manufacturing, development or other relevant experience e.g. working at a regulatory health authority.
- **Strong experience in Sterile** and/or expertise in at least one of the following areas: DP Manufacturing, Laboratories activities, Medical Devices, API, Biologics, Microbiology, Computer System Validation, Quality Systems, Cell&Gene therapy, Radioligand therapy.
- Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Fluent English, written and spoken. Other languages are a plus.

Desirable requirements:

- Experience and/or interaction with local Health Authority and sporadically with other Health Authorities is 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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Quality
Место
Испания
Сайт
Barcelona Provincial
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Ljubljana, Словения
Alternative Location 2
Madrid Provincial, Испания
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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