NOVARTIS

Globalni GMP revizor ekspert za kakovost / Senior Global GMP Quality Auditor

Job ID
REQ-10088228
Nov 11, 2026
LOC_SI

About the Role

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.

Rewards

At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and a minimum of 14 weeks paid parental leave.

Expected Annual Base Salary Range for role:

- Slovenia: EUR 46.900,00 - 87.100,00

The salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters. Further details will be provided during the application process.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

Read our brochure to learn more about our global total rewards offering: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.

Commitment to Diversity and Inclusion / EEO paragraph:

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: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Role Requirements

Primary location salary range
€46,900.00 - €87,100.00
Division
DIV_TO
Business Unit
Quality
Location
LOC_SI
Site
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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