NOVARTIS

QA Compliance Specialist

Job ID
REQ-10083473
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Румыния
Available in: English

Сводка

#LI-Hybrid

Location: Târgu Mureș, Romania

This role is based in Târgu Mureș, Romania. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

The QA Compliance Specialist supports and strengthens GxP compliance, audit readiness, and quality management activities to ensure business operations, systems, site activities, and products comply with the Novartis Quality Manual, internal policies, cGxP requirements, data integrity standards, and applicable local and international regulations.

Contributes to internal audits, KPI and KQI monitoring, and the preparation and management of external audits, corporate audits, and Health Authority inspections, while providing specialized compliance support for the effective implementation of the Novartis Quality Management System.

About the Role

Major Accountabilities:

- Own and execute Quality Assurance activities across the company, ensuring compliance with GMP, GxP, Novartis Quality Manual requirements, internal procedures, HSE standards, and applicable regulatory expectations.
- Monitor and review quality-related activities, including systems, utilities, alarms, environmental monitoring trends, equipment status, deviations, non-conformities, and other indicators that may impact product quality or the quality system.
- Participate in internal and external audits and inspections, present and support the quality system, respond to audit findings, and escalate quality or compliance risks in line with company requirements.
- Review, verify, and approve documentation related to qualification, calibration, preventive maintenance, validation, evaluation, transport validation, storage qualification, equipment inventories, and annual planning for production, laboratory, technical, utility, and IT systems.
- Ensure compliance and validation of GxP-impacting computerized systems, including review and approval of validation deliverables such as risk assessments, validation plans, specifications, test protocols and results, SOPs, security, backup, archival, change control, incident management, periodic review, retirement, user access, and audit trail review documentation.
- Support the documentation system by reviewing and approving procedures for operation, sanitation, preventive maintenance, calibration, qualification, and validation, while assigning identification numbers for laboratory, technical equipment, and IT systems.
- Contribute to quality reporting, product quality reviews, deviation investigations, annual product analysis, GMP training, workplace-specific training, performance management activities, and the achievement of assigned quality objectives.
- Lead and support Operational Excellence and Continuous Improvement initiatives using Lean Manufacturing and Six Sigma principles, including cost reduction projects, KPI monitoring, root cause investigation support, visual management, best practice implementation, and productivity and quality improvements.

Obligatory Requirements:

- Degree or studies in a pharmaceutical or related scientific field, such as Pharmacy, Chemistry, Chemical Engineering, Medicine, or Biology.
- 3+ years experience in the pharmaceutical industry, preferably in a quality, GMP, validation, or compliance-related role.
- Strong knowledge of pharmaceutical product and material quality requirements, including international GMP standards and regulatory expectations.
- Solid understanding of quality assurance principles, quality standards, GMP requirements, and pharmaceutical compliance processes.
- Proficiency in MS Office and standard IT applications used to support quality, documentation, reporting, and compliance activities.
- Demonstrated competencies in collaboration, results orientation, operational excellence, continuous learning, resilience, and action-oriented execution.
- Strong technological competence, digital awareness, functional professional skills, and ability to identify and optimize work processes.
- Good level of English language skills, with the ability to understand and communicate professional and technical information.

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:

- Romania: RON 84,560 – 157,040.

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

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Primary location salary range
L84,560.00 - L157,040.00
Дивизион
Operations
Business Unit
Quality
Место
Румыния
Сайт
Targu Mures
Company / Legal Entity
RO03 (FCRS = RO003) Novartis Pharmaceuticals S.R.L
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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List of links present in page

1. https://www.novartis.com/careers/benefits-rewards
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://www.novartis.com/careers/benefits-rewards
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
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8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Targu-Mures/QA-Compliance-Specialist_REQ-10083473-1