NOVARTIS

QA Systems and Compliance Expert

Job ID
REQ-10080323
Июн. 12, 2026
Нидерланды

Сводка

The QA Systems and Compliance Expert supports the maintenance, development, and continuous improvement of the Quality Management System and compliance status of the RLT Baarle-Nassau site. The role ensures implementation of applicable standards, procedures, and governance processes so that the site remains compliant with regulatory, GMP, data integrity, and Novartis Quality Manual requirements.

This position provides operational execution and governance oversight across quality systems, material and supplier management, CAPA, deviations, change control, inspection readiness, and continuous improvement. The role acts as a key support to the QA Systems & Compliance Manager, who is the operational manager of the position.

About the Role

Major Accountabilities:

- Maintain and continuously improve the site Quality Management System, ensuring all GxP activities comply with applicable regulatory, GMP, data integrity, eCompliance, and Novartis quality requirements.
- Manage the documentation lifecycle, including document review, updates, approval, archiving, gap assessments, and implementation of global Novartis procedures into the site quality system.
- Monitor, report, and support governance of quality KPIs and KQIs, including preparation of quality reports, quality plans, training plans, self-inspection planning, Quality Management Reviews, and Quality Review Boards.
- Plan and execute Product Quality Reviews / Annual Product Quality Reviews, ensuring appropriate CAPA identification, follow-up, and timely closure.
- Coordinate and support CAPA, deviation, incident, complaint, and change control processes, including effectiveness checks, investigations, routine and complex change approvals, and escalation of quality or cGMP issues where required.
- Maintain inspection readiness and support preparation, execution, and follow-up of internal audits, external audits, Health Authority inspections, and related responses.
- Provide quality oversight for suppliers, contract manufacturers, service providers, and externally supplied materials, including supplier qualification, quality agreements, audits, audit CAPA follow-up, quality risk assessments, and supplier-related changes.
- Support site and global projects, continuous improvement initiatives, data integrity activities, GMP training requirements, and implementation of quality system enhancements to improve overall site compliance performance.

Obligatory Requirements:

- Bachelor’s or Master’s degree in a scientific discipline, pharmacy, life sciences, biotechnology, chemistry, or a related field.
- Ideally **3–4 years of experience** in a GMP-regulated pharmaceutical, radiopharmaceutical, biotechnology, or medical device environment, preferably within Quality Assurance.
- Strong knowledge of GMP, GxP quality systems, documentation management, CAPA, deviations, change control, complaints, audits, inspection readiness, and data integrity requirements.
- Experience with supplier qualification, supplier quality oversight, quality agreements, audits, and external partner management is preferred.
- Initial experience in project management, continuous improvement, or cross-functional quality initiatives is recommended.
- Strong analytical, organizational, and problem-solving skills, with the ability to manage multiple priorities and ensure timely completion of quality system activities.
- Excellent communication and stakeholder management skills, with the ability to work effectively across functions and support governance meetings, inspections, audits, and escalations.
- Fluent English, both written and spoken, is required; Dutch is an asset.

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.

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Business Unit
Quality
Место
Нидерланды

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Company / Legal Entity
NL42 (FCRS = NL042) IDB Holland BV
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/about/strategy/people-and-culture
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Baarle-Nassau/QA-Systems-and-Compliance-Expert_REQ-10080323-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Baarle-Nassau/QA-Systems-and-Compliance-Expert_REQ-10080323-1