

QA Systems and Compliance Expert

Job ID

REQ-10080323

Jun 12, 2026

LOC_NL

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.

Role Requirements

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[Read our handbook \(PDF 30 MB\)](#)

Division

DIV_TO

Business Unit

Quality

Location

LOC_NL

Site

Baarle Nassau

Company / Legal Entity

NL42 (FCRS = NL042) IDB Holland BV

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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