NOVARTIS

# Qualified Person

Job ID
REQ-10072955
апр 07, 2026
Нидерланды

### Сводка

Ensuring the quality of products and compliance with regulatory requirements and cGMP.
Responsible for the quality oversight for the operational activities, assurance of compliance to the Dutch Law and other applicable regulations and maintaining and effective implementation, monitoring, and maintenance of a GMP-compliant system.
Responsible for the timely release of the radiopharmaceutical products to ensure a reliable supply chain. Release of batch analysis in accordance with the relevant requirements and the European Union pharmaceutical regulation (Directive 2001/83/EC for medicinal products for human use) in line with the market authorisation.

### About the Role

**Major Accountabilities:**

- Responsible for the release of the radiopharmaceutical products manufactured on site. Partner with Supply Chain to ensure timely release in support of a reliable supply chain.
- Release of batch analysis in accordance with the relevant requirements and the European Union pharmaceutical regulation Directive 2001/83/EC for medicinal products for human use and the National law.
- Ensure that deviations, CAPAs, Change Controls and Product Quality Complaints are timely and properly investigated by providing quality, compliance and technical expertise such that the internal and external customer expectations are met.
- Ensure that deviations and complaints with potential impact on patient safety and/or product supply are properly handled and escalated.
- Responsible for the quality oversight for the operational activities on site. Support the quality oversight process of the operational activities by ensuring QA review (for example maintaining the validation/qualification status of the production site, equipment, training of personnel, and management of quality management system). Additionally, write, review and approve GMP documentation such as procedures, work instructions, protocols and reports.
- Serve as Subject Matter Expert for assigned Quality Processes. Be the SME during Health Authority inspections and other internal- or external audits.
- Maintenance of the Quality Manual including internal audits.
- Establish and maintain strong working relationships with Business and Quality partners to ensure alignment of objectives and results.
- Strengthen the quality culture in the supporting departments by providing coaching and/or training on cGMP requirements.
- Work in shifts or provide on-call support with the team to supervise the quality assurance and quality control activities. Replace the Quality Operations Manager in case of absence.

**Essential requirements:**

- Master Degree in scientific disciplines.
- +3 years of experience in a similar role or in Quality Assurance roles within the pharmaceutical/biotech industry.
- Hands-on, proactive approach.
- Fluent in English.
- Demonstrate an agile mindset by setting clear priorities, collaborating openly, and using feedback to make step-by-step improvements – reflecting the core elements of Agile culture within the Dutch organization.

**Commitment to Diversity & Inclusion:**

*We are 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
Нидерланды
Сайт
Baarle Nassau
Company / Legal Entity
NL42 (FCRS = NL042) IDB Holland BV
Functional Area
Quality
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work

No

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