NOVARTIS

Qualified Person (QP)

Job ID
REQ-10072955
Июн. 12, 2026
Нидерланды

Сводка

The Qualified Person is responsible for batch release, ensuring product quality and compliance with applicable regulatory requirements, including cGMP, Dutch legislation, and relevant European pharmaceutical regulations.

This role provides quality oversight of operational activities and ensures the effective implementation, monitoring, and maintenance of a GMP-compliant quality system. The Qualified Person is also responsible for supporting a reliable supply chain through the timely release of radiopharmaceutical products.

Key responsibilities include the review and release of batch analysis in accordance with applicable requirements, the relevant Marketing Authorisation, and European Union pharmaceutical legislation, including Directive 2001/83/EC for medicinal products for human use.

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’s degree in a scientific discipline. Pharmacy is preferred.
- **3+ years of experience** in a similar role or in a **Quality Assurance** position within the pharmaceutical or biotechnology industry.
- Strong knowledge of **GMP requirements** and applicable pharmaceutical regulations.
- **Hands-on** and **proactive** working style, with the ability to take ownership and drive tasks forward.
- Demonstrates an **agile mindset** by setting clear priorities, collaborating openly, and using feedback to drive continuous, step-by-step improvements, reflecting the core elements of Agile culture within the Dutch organization.
- Fluent in **English**, both written and spoken.

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.

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
Regular
Shift Work
No

Job ID
REQ-10072955

Qualified Person (QP)

Apply to Job

Job ID
REQ-10072955

Qualified Person (QP)

Apply to Job

Source URL: *https://www.novartis.ru/careers/career-search/job/details/req-10072955-qualified-person-qp*

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/Qualified-Person_REQ-10072955
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Baarle-Nassau/Qualified-Person_REQ-10072955