NOVARTIS

# Senior QA Operations Expert; Qualified Person (m/f/d)

Job ID
REQ-10074153
апр 22, 2026
Австрия

### Сводка

#LI-Hybrid

Location: Schaftenau, Austria

The Qualified Person (QP / Sachkundige Person) is responsible for the final certification and release of medicinal products in accordance with § 7 of the Arzneimittelbetriebsordnung (AMBO 2009).
Based in Austria, you will ensure that every batch is manufactured and tested in full compliance with the Austrian Medicines Act (AMG), the Marketing Authorization, and current GMP requirements. With clear legal accountability, you will verify product quality and documentation to ensure no batch is released—whether for the Austrian market or for export—without confirmed compliance.

### About the Role

**Key responsibilities:**

- Technical Release and Market Release (Certification) of secondary packed drug product batches (FDF batches) for commercial purposes.
- Tasks of a Qualified Person in accordance to the “Arzneimittelbetriebsordnung (AMBO) 2009” and Annex 16 to Volume 4 of the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use.
- Lead and oversee **critical negotiations** with internal and external stakeholders to secure compliant, timely outcomes.
- Provide **people leadership** (coaching, performance management, capability building) to drive a strong quality culture.
- Manage **technical operations execution**, ensuring effective day-to-day quality support and issue resolution.
- **Collaborate across functions and boundaries** to align on priorities, risks, and delivery commitments.
- Participation in escalations, recalls, critical complaint investigations, deviations, evaluation of process changes
- **Plan and deliver projects** to agreed quality, scope, and timelines; ensure readiness for key milestones.
- Ensure **inspection and audit readiness**; coordinate responses and drive timely, sustainable CAPAs. Support preparation of and participation in audits and inspections
- Maintain and improve **Quality Management System** processes to meet cGMP and GxP requirements.
- Oversee **release management** activities to ensure compliant disposition decisions and documentation quality.
- Report **technical complaints, adverse events, and special case scenarios** related to Novartis products within **24 hours** of receipt.
- Coordinate **distribution of marketing samples** (where applicable) in accordance with applicable procedures and compliance standards.

**Essential Requirements:**

- Proven experience in **Audit and Inspection Management**, including inspection readiness and follow-up actions.
- Strong working knowledge of **cGMP** and broader **GxP** requirements within a regulated environment resulting in strong decision making skills.
- Hands-on experience with **Release Management** and compliant batch disposition processes.
- Solid expertise in **Quality Management Systems (QMS)**, **Quality Assurance**, and **Quality Compliance**.
- Background in **Technical Operations** with strong **technological aptitude** and a focus on continuous improvement.
- Demonstrated **people leadership** capability with sound **decision-making (correctly interprets analyses and evaluations and correctly identifies which measures should be taken**) in a patient-focused environment.
- Strong **collaboration, communication, problem-solving**, and ability to **navigate ambiguity** effectively.
- High commitment to **data integrity** and **digital proficiency**; **fluent English** required.

Novartis Austria is one of the most modern and innovative manufacturing sites in the Novartis network. The sites in Tirol have approximately 3,500 employees and there are approximately 350 employees in the marketing & sales office in Vienna.
The site in Tirol is in the middle of the Austrian Alps with excellent infrastructure.

**Benefits & Rewards :**

In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 73.122,90/year (on a full-time basis).In most cases, the actual salary will be higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications, and individual competencies.

**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.

**Accessibility and Accommodation:**

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

**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
Австрия
Сайт
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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