NOVARTIS

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

Job ID
REQ-10074153
Apr 15, 2026
LOC_AT

## 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.

---

Major Accountabilities:

- Critical Negotiations, People Leadership, Operations Management and Execution, Collaborating across boundaries, Project Management
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Key performance indicators:

- Successful support of projects with agreed quality & delivery dates, passing of internal and external inspections.
- Meet quality & timelines for all projects.
- Act in accordance with GMP, ethical, health safety and environment (HSE), and information security (ISEC).
- The number and severity of cGMP issues identified during internal and external audits.
- Year-end figures within budget.

Minimum Requirements:
Work Experience:

- Audit & Inspection Management.
- Good Manufacturing Practices (cGMP).
- Release Management.
- Quality Management Systems.
- Technical Operations.
- GxP Experience.
- People Management.
- Quality Assurance.
- Quality Compliance.
- Technological Expertise.

- Patient Safety.

Skills:

- Collaboration.
- Regulatory requirements knowledge.
- Dealing with ambiguity.
- Problem Solving Skills.
- Communication skills.
- Data Integrity.
- Digital saviness.
- Leadership.
- Decision Making.

Languages :

- English.

## Role Requirements

**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)

Division
DIV_TO
Business Unit
Quality
Location
LOC_AT
Site
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10074153

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

Apply to Job

---

**List of links present in page**

1. https://prod1.jobapi.novartis.com.cn/req-10074153-senior-qa-operations-expert-qualified-person-mfd
2. mailto:disabilities.austria@novartis.com
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-_REQ-10074153-2
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-_REQ-10074153-2