

QP Quality Lead Pilot Plant

Job ID

REQ-10082990

Jul 13, 2026

LOC_AT

About the Role

Major Accountabilities:

- Serve as Qualified Person (QP) for Pilot Plant operations
- To serve as a Qualified Person (QP) under Austrian law (AMBO 2009), all requirements listed in §7 of AMBO must be met
- Provide independent quality oversight for manufacturing, testing, warehousing, and release activities.
- Ensure compliance with Novartis Quality Standards and applicable global regulatory requirements.
- Act as a final quality decision maker for critical quality and compliance issues.
- Establish, maintain and continuously improve a robust Quality Management System aligned with GxP, FDA 21 CFR Part 4, FDA 21 CFR Part 820/QMSR, EU MDR 2017/745, ISO 13485, ISO 14971.
- Support health authority inspections notified body audits, self-inspections and customer audits.
- Provide QA oversight for manufacturing, testing, technical batch release, GMP laboratories, warehousing, qualification and validation activities.
- Ensure effective management of deviations, OOX/OOS events, complaints, CAPAs, change controls and risk assessments.
- Routine tasks focus on QA oversight of manufacturing, batch record review, failure investigations and deviation, change controls, and release activities. Ensure that compliance with cGMP/ GxP is maintained in TRD (Technical Research and Development).
- Partner with GDPD Pilot plant, Manufacturing, Technical Development, Regulatory Affairs, Device Development, Engineering and Supply Chain functions.
- Coach and mentor quality associates while fostering a culture of compliance and continuous improvement.

Minimum Requirements:

- Master's Degree in Pharmaceutical Sciences, Biotechnology, Engineering, Chemistry, Life Sciences or related discipline.
- Qualified Person certification according to Directive 2001/83/EC
- Minimum 8 years of experience in Quality Assurance, Manufacturing or Quality Compliance within the pharmaceutical, medical device or combination product industry.
- Demonstrated experience acting as a Quality Lead within GMP-regulated environments.
- Experience supporting or leading health authority inspections and audits.
- Experience with clinical supply manufacturing and release activities preferred.
- Experience with drug-device combination products strongly preferred.

Technical Expertise

- Qualified Person (QP)
- Validation and qualification principles
- Data Integrity

- Drug-Device Combination Products

Leadership Competencies

- Strategic leadership, Quality decision making, Stakeholder management, Communication Skills, Continuous Improvement mindset, Data integrity, Dealing with Ambiguity, Digital savviness, Problem Solving Skills, Regulatory Requirements knowledge, Collaboration

Language Skills

- Fluent English and German (written and spoken).

Benefits & Rewards

At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: €85,300 to €158,300

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

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 \(PDF 30 MB\)](#)

Primary location salary range

€85,300.00 - €158,300.00

Division

DIV_GD

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

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List of links present in page

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