

Qualified Person (QP/Sachkundige Person) (m/w/d)

Job ID
REQ-10079932
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Австрия
Available in: English

Сводка

#LI-Hybrid
Location: Schafftenau, 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.

About the Role

This role is based in Schafftenau, Austria. **Novartis can offer relocation support** for this role: we look forward your application!

Major Accountabilities:

- Certify and release secondary packed finished dosage form batches for commercial supply, ensuring compliant technical and market release decisions.
- Act as **Qualified Person** in accordance with **AMBO 2009** and **EU GMP Annex 16**, covering medicinal products for human and veterinary use where applicable.
- Review and approve key GMP documentation, including bills of materials, master batch records, stability protocols and reports, APQRs, CAPAs, quarantine shipment requests, and re-packaging requests.
- Review and approve quality control documentation, including specifications, sampling instructions, test methods, and other QC procedures.
- Assess and approve deviations, OOX investigations, and quality events, ensuring robust root-cause analysis, appropriate corrective actions, and timely closure.
- Contribute to validation, technology transfer, risk management, SOP development, process change evaluations, recalls, complaint investigations, and other quality-critical activities.
- Lead or actively participate in quality and product-related projects, trainings, audits, and inspections to strengthen compliance, inspection readiness, and quality culture.

Obligatory Requirements:

- Qualification as a **Qualified Person** in accordance with **AMBO 2009**.
- University degree in **Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology**, or an equivalent scientific discipline.
- **At least 2 years of experience** as **Qualified Person** in the pharmaceutical or biopharmaceutical industry in Quality Assurance and/or Quality Control department.
- Thorough knowledge of **cGMP requirements** and applicable quality standards.
- Demonstrates accountability, sound decision-making, teamwork, results orientation, customer focus, and **a strong commitment to quality**, continuous improvement.
- Fluent **German and English** language skills, both written and spoken.

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 € 78.383,90/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.

Rewards

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

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 a minimum of 14 weeks paid parental leave.

Expected Annual Base Salary Range for role: EUR 85,300 – 158,300

The 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. Further details will be provided during the application process.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

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 \(PDF 30 MB\)](#)

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Primary location salary range
€85,300.00 - €158,300.00
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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