

QA Operations Team Leader

Job ID
REQ-10057660

10月 01, 2025

Austria

摘要

This critical role will be responsible for leading and managing a team of Qualified Persons (QPs) to ensure the compliant and efficient release of commercial and non-commercial pharmaceutical products in accordance with European Union (EU) Good Manufacturing Practice (GMP) regulations and marketing authorizations. The Team Leader will drive operational excellence within the QP team, foster a culture of quality and continuous improvement, and serve as a key point of contact for complex quality decisions and regulatory interactions.

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Lead, mentor, and develop a team of Qualified Persons (QPs), providing guidance, coaching, and performance management
- Manage team workload, resource allocation, and scheduling to ensure timely and efficient product release and QP activities
- Oversee and ensure the compliant and timely certification and release of medicinal products by the QP team in accordance with EU GMP, Marketing Authorizations (MAs), and relevant regulatory requirements
- Provide expert guidance and support to the QP team on complex batch release decisions, deviation management, change control, and quality investigations
- Responsibilities in the role of "Fachkundige Person" (GDP Responsible Person) for warehouses as stated in the Guidelines for GDP of medicinal products for human use (2013/C 343/01) & in the Guidelines for GDP of active substances for medicinal products for human use (2015/C 95/01)
- Ensure the QP team's activities are fully integrated into and compliant with the company's Quality Management System (QMS)
- Collaborate effectively with other departments including Production, Supply Chain, Regulatory Affairs, Quality Control, and Research & Development to resolve quality issues and facilitate smooth product flow
- Act as a point of escalation for critical quality issues and make informed decisions regarding product disposition in collaboration with relevant stakeholders

Essential Requirements:

- Pharmacist or other scientific discipline as per Article 48 of Directive 2001/83/EC (or national equivalent) allowing for QP qualification in an EU Member State.
- Must be a Qualified Person (QP) as per EU Directive 2001/83/EC, Article 48, and 2001/20/EC for IMPs (if applicable)
- Additional relevant certifications or postgraduate qualifications in Quality Management are a plus
- Minimum of 7 years of experience in Quality Assurance within the pharmaceutical industry, with a strong focus on GMP operations. (Suggest 7+ years)
- Minimum of 4 years of experience acting as a certified Qualified Person (QP) with a demonstrable track record of product release
- Proven experience in leading, managing, or supervising a team in a highly regulated environment and excellent analytical and problem-solving skills with a meticulous attention to detail
- Extensive knowledge of EU GMP regulations (EudraLex Volume 4), relevant national legislation (e.g., AMG, AMWHV in Germany), and other applicable international guidelines (e.g., ICH

· Fluent in English (written and spoken). Proficiency in German is highly desirable

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive:

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In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. 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 € 67.186 /year (on a full-time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

We are open for part-time and job-sharing models and support flexible and remote working where possible.

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive working environment and diverse teams, representative of the patients and communities we serve.

Adjustments for Applicants with Disabilities:

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.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

<https://talentnetwork.novartis.com/network>

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

部门

Operations

Business Unit

Innovative Medicines

地点

Austria

站点

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area
Quality

Job Type
Full time

Employment Type
Regul ä r

Shift Work
No

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