

QA Operations Expert

Job ID

REQ-10039533

Mar 06, 2025

Austria

Summary

QA Operations Expert is responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures.

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance
- On-time and GMP-compliant release of dosage forms
- Support exception investigations
- Review and approval of production, QC, and AS and T records and MBR review
- Support OpEx improvement projects Qualified Person
- Executes batch release in compliance with registration
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)
- Successfully Support continuous improvement Projects

Essential Requirements:

- University Degree in Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent
- KLL - Kontrollaborleiter(in) qualification required for the role
- Professional experience in Pharmaceutical industry, Biopharmaceutical or API products and at least 2 years within QA, thorough knowledge of cGMP requirements
- Accountability: takes responsibility for his/her tasks and is reliable
- Decision Making: correctly interprets analyses and evaluations and correctly identifies which measures should be taken
- Ability to work in a team: has the ability to contribute constructively and reliably in a group as well as results driven when motivating himself/herself and others to obtain good results and ensures observance of ethical and legal principles
- Customer focus: gives customer satisfaction highest priority and continuously striving for improvement and quality focus when providing the highest quality products and services, which meet the

needs and requirements of internal and external customers

- English and German language required

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:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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 € 64.023,54 /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>

Division

Operations

Business Unit

Innovative Medicines

Location

Austria

Site

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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