

QA Operations Team Leader - Release Support (m/w/d), Kundl, Tirol

Job ID REQ-10045133 Mar 24, 2025 Austria

Summary

Are you interested in leading a dynamic Quality Assurance team in the pharmaceutical manufacturing realm and making a real-world impact? Novartis DS Kundl invites you to be our Manager of the Quality Operations Batch Release Support Team. In this role, your expertise will be crucial for ensuring compliance with cGMP, Quality Assurance Agreements, and various regulatory requirements. Not only will you be a key player in supplying essential medicines to patients, but you'll also be instrumental in meeting the objectives of our site and our external customers. Join us in our mission to improve lives, apply today!

About the Role

Major accountabilities:

Leadership of QA Operations Release Support Team according to cGxP standards in the area of responsibility. This includes:

- Oversight of GxP functions across site and ensure product quality
- Ensure regulatory compliance and implementation of corporate quality standards and regulations
- Ensure planning and tracking of batch record review and release related activities to maintain business continuity
- Ensure timely and thorough exception (deviation, OOX and complaint) handling including global quality escalation whenever needed
- Ensure DI, eCompliance and compliance with all cGxP and all regulatory requirements for manufacturing, control and distribution operations
- Collaboration in internal and external audits
- Ensure any collaborations with 3rd parties are performed with adequate Quality Assurance Agreements in place
- Participation in the compilation, revision and approval of validations, transfers, SOPs and other GxP related documents as applicable

Minimum Requirements:

- Educational Background: Minimum University Degree in Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent.
- Experience: Professional experience in Pharmaceutical industry, with direct experience with Pharmaceuticals, Biopharmaceutical or API products and at least 3 years within QA, min. 2 years of management and/or project management experience, thorough knowledge of cGMP requirements as well

as proven track record with FDA / EMA and other Health Authorities.

- **Skills:** Strong communication, analytical, and pragmatic problem-solving and resilience skills. Proven people leadership and stakeholder management experience.
- Languages: Fluent in English and German.

You'll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

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.

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.

Attachments

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

Kundl

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Regular Shift Work No Apply to Job

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 <u>disabilities.austria@novartis.com</u> 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.

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