

## QA Operations Team Leader

Job ID  
REQ-10027440

12月 10, 2024

Austria

### 摘要

QA Operations Team Leader ensures that QA Operation activities in the area of responsibility are executed according to cGxP standards.

### About the Role

#### Key Responsibilities:

- Oversight of all production & testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance; Review and approval of protocols, reports, specifications, methods and procedures related to product manufacturing and testing
- Ensure compliance of products with specifications and with corporate, health authority, and customer requirements; Oversee the technical transfer of processes and method; Apply the site change control system and document management system
- Ensure exceptions are managed and escalated appropriately, including Reporting of technical

complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt

- Ensure timely and thorough investigation of Deviations, Out of Specification, Out of Expectation, Out of Trend results and technical compliant investigation
- Identification, submission and support of issues requiring global quality management escalation; Ensure timely and compliant release of products, including: QC test record review and approval; Stability protocol/report review and approval
- Foster continued improvements considering regulatory expectations and industry trends: follow trends in the field of product release; Drive consistent and efficient operation of the quality operations function in the area of responsibility and seek opportunities for productivity improvements, and coordinate their implementation; Contribute to the issuance and maintenance of SOPs in the area of responsibility
- Foster a culture of curious, unbossed, inspired and integral exchange: Support building up and leading the QA Operation Team for RPP1-CC in team culture in line with Novartis values and behaviors; Resource planning and control; Define and maintain the team 's structure and organizational principles; Develop team members individually and act as a "qualified person" or "responsible person" according to Austrian law.
- Make release decisions for API, bulk and intermediate products; Oversee all records related to product manufacturing and testing including all non-conformity issues (OOS, OOE, OOT, deviations, complaints) related to products released; Oversee the annual product quality review of products released; Qualified Person acc. AMBO

#### Essential Requirements:

- Minimum master degree or equivalent in life sciences or equivalent discipline (bioengineering, pharmacy, medical, biology, chemistry, etc.)
- Fulfilling the requirements to act as qualified person according to AMG §2 Abs 13b would be desired
- Knowledge of GMP and GDP standards and processes
- Proven people leadership experience; Collaborating across boundaries
- Critical Negotiations; Operations Management and Execution
- Project management; effective communication and managing resources
- Objective Setting and Performance Management; Risk Management and Quality Decision Making
- Fluent in German and English

#### 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 € 85.600/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](mailto: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

Kundl

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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