

## QA Operations Expert

Job ID  
REQ-10050961

5月 13, 2025

Austria

### 摘要

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

### About the Role

Major accountabilities:

- Participation in the preparation and approval of validations, transfers protocols/reports and SOPs; approval of specifications, instructions for sampling, testing methods, Production Master Batch Records and other procedures in the area of responsibility
- Support, elaboration and approval of investigations on deviations, OOS / OOE and Complaints; evaluation and approval of CAPA measures and risk assessments
- Execution of batch release in compliance with cGxP and registration (in accordance with approval responsibility)

- Participation in and evaluation of changes in the process and specifications
- Collaboration in or management of project teams; participation in the preparation of Quality Assurance Agreements in line with Novartis Quality Manual & Policies
- Preparation and participation in audits and inspections; participation in and approval of APQR / APR; participation in and implementation of training Responsibility for release; support OpEx improvement projects
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt

#### Minimum Requirements:

- University degree in Engineering, Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent
- At least 3 years or more experience in QA
- Experience in operations management and execution
- Preferably experience in negotiations and global collaboration
- Fluent knowledge of English and German language (written and spoken)
- Flexibility to work in a fast paced, quickly changing work environment
- Ability to operate in a global matrix environment

#### 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 € 65.605,54/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](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>

## 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
- Quality Oversight for Technology Transfer
- On-time and GMP-compliant release of drug substance batches
- Support exception investigations
- Review and approval of production, QC, and AS and T records and MBR review
- Support OpEx improvement projects
- Inform Customer about relevant change requests and exceptions
- Collaborate with external partners according to QAA
- Successfully Support continuous improvement Projects

## Essential Requirements:

- University Degree in Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent
- Professional experience in Pharmaceutical industry, Biopharmaceutical or API products
- 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: 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  
Universal Hierarchy Node

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  
Regul ä r

Shift Work  
No

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## Unterstützungen für BewerberInnen mit Behinderungen

Wenn Sie aufgrund einer Erkrankung, einer körperlichen Behinderung oder eines neurodiversen Zustandes eine Unterstützung bei verschiedenen Teilen des Rekrutierungsprozesses benötigen, wenden Sie sich bitte an [disabilities.austria@novartis.com](mailto:disabilities.austria@novartis.com) und teilen Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterstützung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das österreichische Gesetz sieht die Möglichkeit vor, die örtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies wünschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.



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