QA Operations Expert (d/m/f)

Job ID
REQ-10068587

12月 15, 2025

Austria

摘要

Join Novartis as QA Operations Expert–play a key role in upholding cGMP compliance and ensuring top-quality products meet global standards. Your expertise will help release safe, trusted medicines every day!

Location: Schaftenau, Austria
#LI-Hybrid
Relocation Support: This role is based in Schaftenau, Austria. Novartis is unable to offer relocation support: please only apply if accessible.

About the Role

Key Responsibilities:

- Oversight of GxP functions across site and ensure product quality. Implement, comply with,

and govern practices prescribed in the Novartis Manufacturing Manual
- Act as release responsible person; ensure regulatory compliance and implementation of corporate quality standards and regulations. Ensure status of local HA registration and qualified state of facilities and utilities
- Review and approval of PQR / APQR; ensure exception (deviation and OOX) and complaint management and investigation as well as proper definition and implementation of CAPAs
- Ensure DI, eCompliance and compliance with all cGxP and all regulatory requirements for manufacturing, control and distribution operations; ensure adherence to HSE guidelines and requirements
- Collaboration in internal and external audits; ensure any collaborations with 3rd parties are performed with adequate Quality Assurance Agreements in place
- MBR review and approval; approval of specifications, sampling instructions, test methods and other quality control procedures
- Participation in the compilation, revision and approval of validations, transfers, SOPs and other GxP related documents as applicable
- Support transfer projects & validation studies; Author of SOPs and other GxP documents as applicable

Essential Requirements:

- University Degree in Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent
- Professional experience in pharmaceutical industry, with direct experience with Pharmaceuticals, Biopharmaceutical or API products and at least 2 years within QA
- Thorough knowledge of cGMP requirements as well as proven track record with FDA / EMA and other Health Authorities
- Knowledge of GMP and Management of Quality Audits
- Flexibility to work in a fast paced, quickly changing work environment
- Knowledge of Manufacturing Process/ Product Expertise
- Fluent knowledge of English and German (written and spoken)

You ' ll receive:
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). In most cases, the actual salary will be 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. For this position we are not offering relocation package.

Commitment to Diversity & Inclusion: We are committed to building an outstanding, inclusive work 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.

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

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
Quality

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
Regular

Shift Work
No

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