QA Operations Expert

Job ID
REQ-10052087

May 15, 2025

Austria

Summary

Verantwortlich f ü r das Management von Qualit ä tsaspekten innerhalb des Verantwortungsbereichs und um sicherzustellen, dass das operative Gesch ä ft in Ü bereinstimmung mit cGMP (Current Good Manufacturing Practices), der Qualit ä tssicherungsvereinbarung, den regulatorischen Anforderungen und dem Novartis Qualit ä tshandbuch erfolgt und nach den entsprechenden Standardarbeitsanweisungen durchgef ü hrt wird

About the Role

Part time job: 50% employment

Key Responsibilities:

Your responsibilities include, but are not limited to:

- 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)

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 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

部門
Operations

部門
Innovative Medicines

国
Austria

勤務地
Schaftenau

Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area
Quality

職種
Part time

雇用形態
Regul ä r

Shift Work
No

Apply to Job.

Unterst ü tzungen f ü r BewerberInnen mit Behinderungen

Wenn Sie aufgrund einer Erkrankung, einer k ö rperlichen Behinderung oder eines neurodiversen Zustandes eine Unterst ü tzung bei terschiedlichen Teilen des Rekrutierungsprozesses ben ö tigen, wenden Sie sich bitte an disabilities.austria@novartis.com und teile n Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterst ü tzung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das ö sterreichische Gesetz sieht die M ö glichkeit vor, die ö rtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies w ü nschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.

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