Senior QA Operations Specialist

Job ID
REQ-10061737

9月 11, 2025

Austria

摘要

Verwaltet Qualitätsaspekte und Projekte im Verantwortungsbereich.
Gewährleistet und unterstützt die GxP-Konformität und die Einhaltung der Qualitätsmanagementsysteme von Novartis.

About the Role

Key Responsibilities:

- Implement, comply with, and govern practices prescribed in the Novartis Manufacturing Manual

- Oversight of GxP functions across site and ensure product quality and ensure regulatory compliance and implementation of corporate quality standards and regulations

- Ensure status of local HA registration and qualified state of facilities and utilities; support in the preparation of PQR / APQR

- Ensure exception (deviation and OOX) and complaint management and investigation as well as ensure proper definition and implementation of CAPAs, training execution across site and 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 and ensure any collaborations with 3rd parties are performed with adequate Quality Assurance Agreements in place

- Ensure any additional local legal requirements are fulfilled, MBR review; review of specifications, sampling instructions, test methods and other quality control procedures; ensure Business continuity management

- Participation in and evaluation of changes to process and specification and preparatory activities for product release; 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 finalized apprenticeship in an area of the Pharmaceutical industry (e.g. chemical laboratory worker, chemical worker or related fields / internal specific education (‘ Modulausbildung ’) or equivalent

- Professional experience in Pharmaceutical industry, with direct experience with Pharmaceuticals, Biopharmaceutical or API products and ideally at least 2 years within QA, thorough knowledge of cGMP requirements as well as proven track record with FDA / EMA and other Health Authorities

- Fluent German required and English at intermediate level

- Knowledge of GMP and Management of Quality Audits

- Manufacturing Process/Product Expertise and support the batch release preparation

- Experience in Quality Control (QC) Testing, Regulations & Guidelines and technical Launch and Transfer

- Stakeholder Management, Operational Excellence / NOSSC

- Being resilient and Team player

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

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 € 59.781,96 /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 and Inclusion / EEO paragraph:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Accessibility and Accommodation:

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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部门
Operations

Business Unit
Innovative Medicines

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
Regul ä r

Shift Work
No

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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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