

QA Compliance Expert

Job ID
REQ-10038809

2月 05, 2025

Austria

摘要

This is a part time job: 70% employment

Ensure compliance and further development, support, maintenance and continuous review of quality systems and support projects as well as reporting of the necessary key performance indicators (KPIs) & quality indicators (KQIs). Support in the implementation of effective and efficient processes that meet regulatory requirements and expectations in a sustainable manner for the global Novartis product portfolio.

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Coordination and preparation of Health authority inspections, internal inspections (global compliance and auditing) and self-inspections. Support inspection execution as Back Office Lead and inspection follow up. Maintain oversight on CAPAs from audit and inspections and support reporting thereon.
- Maintain audit readiness at all times for DS Schafftenau; responsible for requests from Country Organization within Novartis on classified documents and information.
- Preserve status with Notified Bodies and HA for GMP-License and Manufacturing License
- Responsible for Site Master File and oversee CAPA implementation and notification towards HA
- Active participation in local process of action/information/compliance alert process coming from Novartis; implementation of the Novartis Quality Module and global documents in the area of engineering and qualification
- Build up / keep network and align with colleagues in inspection management at other sites; participate in Self Inspections as required
- Support continuous improvement of QA projects, of quality plan activities and by analysis of trend data and reviews and report Key Quality Indicator and Key Performance Indicator monthly/quarterly/yearly
- Compile and Assess Deviation Trend Reports; create and support implementation of local Quality Plan; support the implementation of new, global documents in area of responsibility

Essential Requirements:

- Work experience in a GMP regulated environment in the pharmaceutical industry
- Accountability and good communication skills
- Continued learning (dynamic knowledge development)
- Takes over responsibility and delivers reliably
- Teamwork: Good Cooperation with different Departments and Functions
- Experienced problem solving
- English fluent, German basic

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 € 64.023,54/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>

部门
Operations

Business Unit
Innovative Medicines

地点
Austria

站点
Schaffenau

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

Functional Area
Quality

Job Type
Part 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 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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