

QA Compliance Expert

Job ID
REQ-10053171

6月 13, 2025

Austria

摘要

QA Compliance Expert is responsible for managing cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators). Performs preparation and management of external and corporate audits and Health Authority inspections.

About the Role

Major accountabilities:

- Supplier, technical service provider and contractor management/qualification (quality agreements, oversight, audit, medical device) including planning and surveillance of audit plans

- Establishment, maintenance and oversight of Quality Assurance Agreements affecting Drug Product Schafftenau (medical device); Audit and inspection preparation and support
- Ensure supplier-, contractor- and internal/HA/customer management in 1QEM as audit coordinator, preparation and performance of self-inspections
- Implementation of Quality Systems (incl. documentation management)
- Preparation/support and coordination of CAPA/follow-up and alert-/gap-/risk assessments; KPI / KQI reporting and trending
- Change control review/approval; ensure local deviation management; ensure process quality assurance acc. to regulations and supports local project-/regulatory management and Site Master File preparation
- Planning and supporting PQR/APQR activities; ensure applications, certificate maintenance etc. to local HA
- Support communication with HA, GCA / One voice / consolidated approach / synergies for all sites within same HA jurisdiction / country

Minimum Requirements:

- University education in natural sciences, chemistry, biology or similar
- At least 3 years or more experience in QA Experience in operations management and execution
- Knowledge of GMP required
- 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 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
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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