R&D Senior Quality Manager

Job ID
REQ-10058774

8月 04, 2025

Austria

摘要

Location: Schaftenau, Austria
Role Type: Hybrid, #LI-Hybrid

The Research & Development (R&D) Senior Quality Assurance (QA) Manager will Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.
They will also manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with Good Practice (GxP) regulations.

About the Role

Major accountabilities:

- Support maintenance of the regulatory-required files for health authority inspections and assist with health authority inspection management
- Support generation of Quality Plans (and review other plans for quality/safety aspects) for clinical programs
- Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems
- Support initiatives focused on quality, process and compliance improvement, including identification of opportunities and develop strategies aimed at improving quality while ensuring compliance with regulatory requirements
- Ensure information gained during quality and compliance initiatives, as well as audit and assessment results, are evaluated to identify any regulatory, compliance and QA training needs
- Aid in the identification of quality issues and assist with root cause investigations and Support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.
- Provide assistance in the remediation of deviations, Ensure follow up and monitoring of associated corrective and preventive actions.
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc.
- Review and approve quality deliverables to ensure compliance (including procedures, records, third party work, contractors, clinical trial material, components, gap assessments)
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt

Key performance indicators:

- Clusters Quality System in place and continuously updated, as required risks proactively identified and effectively mitigated
- Demonstrated/recognized leader of specific GxP; early external/industry engagement
- Financial knowledge (e.g., cost management, budget forecast, etc.)
- Being a role model of Novartis culture, values and behaviours

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Critical Negotiations.
- Project Management.
- Collaborating across boundaries.

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 € 55.700/year (on a full-time basis).

We also offer a potential market oriented excess payment in line with your experience and qualifications.

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.

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
Development

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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