

QC Specialist II (m/f/d), Schaftenau, Tirol

Job ID REQ-10024381 Ott 03, 2024 Austria

Sommario

We are looking for a highly skilled and experienced laboratory professional who contributes to the Good Laboratory Practice by ensuring efficient and timely review of laboratory analyses, compliance to industrial standards, investigation of deviations and complaints, training of personnel and coordination of device maintenance.

About the Role

Major accountabilities:

- Preparation of protocols and associated reports (e.g device qualification)
- Training of laboratory personnel
- Participation of SOP authorship
- Support in preparation and implementation of regulatory inspections and audits
- OOx/Deviation handling and CAPA definition
- KPI trending
- Review and approval of analytical tests (analytical release). Ensure all activities in compliance with cGxP, incl. data integrity review and approval of analytical data / tests (analytical release) Stability -Stability testing (Projects) protocol preparation, evaluation, report preparation.
- Reporting (Stability plan preparation, trend analysis, evaluation)
- Performance of Stability studies, protocols and comparative reports for supplier qualification
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.
- The relevant KPIs that are defined in the Quality Control areas apply: e.g. analytical lead times: Timely and GMP-compliant analysis & documentation of the results.
- Error rate: Number of OOS (analysis errors) related to the number of analyses
- Individual performance is assessed using the PMP performance dialog together with the manager

Minimum Requirements:

- BSC or MSc in natural sciences with 4 years of relevant experience in Pharma/Manufacturing sector in analytical lab, or PhD with 2 years of experience.
- Continuous Learning, dealing With Ambiguity, decision Making Skills.
- Experience with Industry Standards and Quality Control (QC) Testing, laboratory Equipment, Quality Control Sampling, GMP.
- Fluent in both German and English, both written and spoken.

Benefits and rewards: Read our handbook to learn about all the ways we'll help you thrive personally and $\frac{1}{3}$

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 €58.199,96 /year (on a full-time basis). The actual salary may be higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

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.

Commitment to Diversity and Inclusion:

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

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

Divisione

Operations

Business Unit

Innovative Medicines

Posizione

Austria

Sito

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work
No
Apply to Job

Adjustments for Applicants with Disabilities

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- 6. mailto:disabilities.austria@novartis.com
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