Senior Expert / GMP Officer (m/f/d)

Job ID
REQ-10058967

7月 29, 2025

Austria

摘要

About the role:
#LI-Hybrid

We are seeking a highly motivated and experienced GMP Officer to support compliance activities and quality assurance processes across the Analytical Operations team in Austria (AO AT). As the GMP Officer you are coordinating and preparing inspections, assuring GMP compliance of all activities in the department and providing expert guidance on GMP compliance aspects including state-of-the art analytical technology and Data & Digital solutions. In addition, you lead quality-related strategic initiatives in alignment with the global Analytical Operations team.

About the Role

Key responsibilities

- Act as first point of contact for all GMP/compliance related aspects for team members and stakeholders.
- Assure audit readiness of the department and facilitate audits and inspections, including self-inspections, global audits and Health Authority visits and manage Corrective & Preventive Actions (CAPAs) resulting from inspections.
- Lead local and global quality related strategic initiatives in alignment with the global Analytical Operations team.
- Provide GMP/compliance guidance on documentation, systems use, SOPs/WPs/Guidelines, including state-of-the art analytical technology (e.g. lab automation systems, mass spectrometry) and Data & Digital solutions (e.g. ELN).
- Track updates and manage the review/implementation of global and local SOPs in collaboration with Subject Matter Experts (SMEs).
- Train new team members on general GMP topics and Standard Operating Procedures (SOPs).
- Act as an investigator for quality related incidents and create trending reports for investigations, including OOX and deviations.
- Conduct regular spot-checks for lab systems, instrumentation, and processes. Author and review SOPs.

Essential Requirements:

- Master ' s degree in biotechnology, biochemical engineering, biology, chemistry, biochemistry or similar with at least 4 years relevant industry experience or PhD in relevant field or equivalent and 2+ years of work experience within the pharmaceutical industry in a GMP regulated environment.
- Thorough knowledge of GMP, compliance regulations and quality assurance principles.
- Experience participating in audits and inspections.
- Certifications and hands-on experience with deviations, Data Integrity (DI), and CAPA processes are an advantage.
- Strong matrix leadership skills.
- Strong organizational and exceptional communication skills.

Desirable requirements:

- Proficiency in laboratory systems and reporting (e.g., 1QEM system, trending reports).

- Knowledge in SAP and LIMS application.

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 a 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.

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
Universal Hierarchy Node

地点
Austria

站点
Schaftenau

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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