

# Senior QA Compliance Specialist

Job ID REQ-10053208

6月 11, 2025

Austria

#### 摘要

The Complaint Specialist is responsible for performing complaint investigations (initial assessments, escalations, investigations and approval) and it is responsible for identifying improvements of complaints across all products.

Additionally, there is the responsibility regarding the management of samples and all related activities.

All these tasks are to be performed while ensuring GxP compliance of all relevant quality systems, as well as keeping high health & safety standards.

About the Role

Major Accountabilities

Accountable for investigating technical and mixed product complaints.

Accountable for the quality of the investigations.

Responsible for coordinating the actions of different departments to complete the investigations.

Responsible for prioritizing the workload to meet deadlines.

Support for the approval and closure of complaints.

Accountable for the sample management process.

Responsible for identifying improvement opportunities and support implementation.

Support the standardization of the complaint processes and the implementation of the process for new products.

Support the complaint team in preparing for internal/external audits.

Responsible for keeping complaint procedures and work instructions up-to-date with current regulation and global procedures/quality manuals.

Support the communication between complaints and key stakeholders.

Support in training new employees of the complaints team.

Support other functions as required.

#### **Key Performance Indicators**

Maintaining the Key Quality Indicators associated with the Complaints Department (on-time completion, effective CAPAs, extension rate, etc)..

#### Education

Degree in the natural sciences (pharmacy, chemistry, medicine, biology, microbiology).

#### Experience

Experience in the field of manufacturing medicinal products for human use; work experience in the field of GMP production/Quality Assurance or Quality Control; good knowledge of MS office applications and other standard IT applications. Must be capable of setting priorities and working under pressure. Ability to work well with internal and external participants is essential.

#### Language

Fluent in English and German ideally.
Impact on the organization
Ensuring the GMP guidelines in the assigned area of responsibility.
Specific Professional Competencies
Ease of use with office software. Structured work ethic. Goal oriented and transparent. Team player. Excellent communication skills across all levels in the organization. Can motivate colleagues to work towards common goals. Oriented towards problem-solving & logical thinking. Demonstrates high level of accountability and ownership.
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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>
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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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### 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 <a href="mailto:disabilities.austria@novartis.com">disabilities.austria@novartis.com</a> 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.

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