NOVARTIS

Senior Quality Assurance Operations Specialist

Job ID
REQ-10077270
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Австрия

Сводка

The Senior QA Operations Specialist is responsible for providing quality assurance support for drug substance manufacturing activities, with a strong focus on batch record review and GMP compliance. The role ensures timely and compliant batch release, supports investigations and audits, and contributes to maintaining the Novartis Quality Management System.

About the Role

This position is a temporary, activity-based role and is limited to a fixed term of two years.

Key Responsibilities

- Review and approval of batch manufacturing records as part of the batch release process
- Review and assessment of analytical results, certificates, and specifications
- Control and verification of batch documentation and quality records
- Support audits, inspections, and regulatory interactions, investigations related to deviations, OOS/OOE, and complaints
- Support CAPA management activities and changes to processes, documentation, and quality requirements
- Preparation and review of certificates, reports, and quality-related lists
- Communication and coordination with internal departments and external partners
- Execution of tasks in a timely, efficient, and GMP-compliant manner

Obligatory requirements:

- Education: Master's degree - Other (e.g., MSc) in Microbiology.
- Solid experience in a pharmaceutical or GMP-regulated environment.
- Experience in quality assurance or quality control is preferred.
- Strong knowledge of GMP requirements.
- Results-driven mindset with continuous improvement focus
- Strong customer focus and communication skills
- Fluent in German and English

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Дивизион
Operations
Business Unit
Quality
Место
Австрия
Сайт
Kundl
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No

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