Sr. QA Operation Specialist, RLT CN

Job ID
REQ-10066649

11月 12, 2025

China

摘要

Responsible to ensure compliance to cGxP standards for products within area of responsibility (during development, transfer and commercialization) and product release.
Provide guidance, support and leadership to teams within area of responsibility. Functionally report to QA Operations Lead

About the Role

Major accountabilities:

Operational

- Local SOP initiation
- Documentation Management and archiving
- Training management and compliance tracking

- Support validation activities
- CAPA management and follow up
- Support NDA dossier readiness
- Collaboration in GxP audits/inspections
- Oversight of Quality Operations
- Batch Record review
- QA Operational Excellence
- Complete other tasks be assigned by line manager
- Might run shifts to support product release according to business needs.

HSE

- Promote and improve the Safety and Quality cultures, by implementing the necessary systems and actions in line with the evolution of the project
- Ensure overall inspection readiness for area of responsibility.
- Guarantee the effectiveness of the Business Continuity Plan
- Being part of the project crisis management team and depending on skills, expertise and experience can be appointed to one of the NEM roles (Novartis Emergency Management). By delegation of the project Manager may be required to take decisions and take the necessary actions, in particular within the framework of the on-call management system.
- Responsible for participating in initial training and retraining
- HSE incidents reporting & action follow-up

Key Performance Indicators

- No project delay caused by the unit
- No critical observations during authority inspections
- No delay with new product introductions caused by the unit
- Timely closing of deviations/complaints
- Achieve project quality budget
- Timely closing of deviations/ complaints.

Ideal Background

Relevant Experience

- Minimum: 3-5 years ' experience in the field of Quality Assurance and
- Sterility Product Manufacturing in a pharmaceutical industry environment or equivalent
- Sufficient experience on audit and inspection preparation and management
- Deeply understanding on cGMP

Education & Qualification

- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent

Languages

Fluent (oral and written) in English; local language desired

Competencies

- Collaboration; result-oriented
- Advanced communication skills;
- Risk Management
- Audit Management; Health Authorities; Technical Launch and Transfer
- Knowledgeable on GMP Quality Assurance and Manufacturing Process/Product Expertise
- Expertise in GxP operations

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部门
Operations

Business Unit
Quality

地点
China

站点
Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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