Senior QA Operations Specialist, RLT CN

Job ID
REQ-10030206
nov 17, 2024
Chine

Résumé

About the role:
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
Might run shifts to support product release according to business needs.

About the Role

Key Responsibilities

- Local SOP initiation. Documentation Management and archiving.
- Training management and compliance tracking
- Support validation activities. CAPA management and follow up. Batch Record review
- Collaboration in GxP audits/inspections. Oversight of Quality Operations
- QA Operational Excellence. Complete other tasks be assigned by line manager
- 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

Essential Requirements:

- Minimum: 5-8 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 .
- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent
- Fluent (oral and written) in English; local language desired
- Knowledgeable on GMP Quality Assurance and Manufacturing Process/Product Expertise. Expertise in GxP operations
- Audit Management; Health Authorities; Technical Launch and Transfer. Risk Management. Collaboration;

result-oriented. Advanced communication skills;

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Business Unit
Innovative Medicines
Emplacement
Chine
Site
Haiyan (Zhejiang Province)
Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.
Functional Area

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

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