QA Operations Lead, RLT CN

Job ID
REQ-10030193
Nov 15, 2024
Cina

Sommario

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. Might provide on shift support per business needs.

About the Role

Key Responsibilities

- As per local regulatory requirement and global guidance/SOP to set up local documentation hierarchy, manage quality system. Oversight of Quality Operations. Set up training matrix and curriculums in 2025
- Validation Batch Record review; Validation protocols review; Deviation management; On site Quality monitoring. Support and oversight validation activities. Master Batch Record review and approval
- As site QP or delegation to release product, Initiate and maintain Site Master File
- Local supplier qualification and management
- Audit and Inspection preparation and readiness. Collaboration in GxP audits/inspections
- Function representative to be involved in global and/or local project if any.
- Actively support and promote talent exchange for the benefit of the individuals and organization. Ensure the consistency between career development processes and the business strategy. Ensure that associates are qualified for a GMP task prior to independent performance. Monitor overall training compliance for in-scope associates. Role model the culture aspiration of being Curious, Inspired and Un-bossed and ensure leaders and associates are aware and aligned on expectations and hold them accountable for success of culture journey
- Promote and improve the Safety and Quality cultures, by implementing the necessary systems and actions in line with the evolution of the project. 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:

- 8-10 years’ experience in the field of Quality Assurance and Sterility Product Manufacturing in a pharmaceutical industry environment or equivalent

- Project management, Operations Management and Execution, People Leadership, Collaborating across boundaries, Functional Breadth, Project Management, Financial Management, Industry/ Business Exposure
- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent
- Fluent (oral and written) in English; local language desired
- Collaboration; result-oriented
- Advanced communication skills; motivates colleagues and co-workers
- Leadership and change management, objective setting and performance management

Desirable Requirements:

- Knowledge of GMP Quality Assurance, Quality Control (QC) Testing and Manufacturing Process/Product Expertise
- Rich experience on audit and inspection preparation and management

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

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