QA Compliance Lead

Job ID
REQ-10060466

8月 25, 2025

China

摘要

Provide successful strategic and managerial leadership for the site / supplier in all quality related matters and ensure that key aspects of the operational business comply with cGxP. Provide guidance, support and leadership to teams within area of responsibility.

About the Role

Major accountabilities:

Operational

- Collaboration in GxP audits/inspections
- Oversight and implementation of Quality Management System
- Incident management

- GxP Audit and inspection management
- Site Regulatory oversight (incl. Reg-CMC facilitation)
- Exception management
- Supplier Quality management (local)
- Qualification and validation
- Quality Compliance
- Support the QA operation team and product release during project phase
- Responsible for deviation handling
- Responsible for Change Control management
- Responsible for system improving

Leadership & Culture

- Drives the talent agenda: Leads people processes through recruitment, training, coaching and performance to meet all operation requirements and supports a robust career path deployment and succession plan for area of responsibility
- Invest time in personally developing and coaching talents
- 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
- Support the T&L organization by identifying and reviewing the appropriate list of training for all in-scope associates
- Ensure that associates are qualified for a GMP task prior to independent performance
- Monitor overall training compliance for in-scope associates
- Identify and maintain a list of subject matter experts for in-scope areas of expertise
- Create a work environment that enables high employee engagement

- 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

HSE

- Promote and improve the Safety and Quality cultures, by implementing the necessary systems and actions in line with the evolution of the site
- Ensure overall inspection readiness for area of responsibility.
- Guarantee the effectiveness of the Business Continuity Plan within area of responsibility
- Responsible for participating in initial training and retraining
- HSE incidents reporting & action follow-up

Key Performance Indicators

- Successful oversight and implementation of Quality Management System
- Carry out improvements in GMP compliance
- Exception and Incident management

Relevant Experience

- Several years of experience (> 3 years) in the field of GMP production or QA or QC Professional experience from official and / or customer audits Expertise in GMP (sterile/non-sterile)
- Functional Breadth; People Leadership; Organization Scope; Scale and Complexity; Collaborating across boundaries; Project Management

Education & Qualification

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)

Languages

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

Competencies

- Collaboration; result-oriented; problem-solving-oriented
- Advanced communication skills; motivates colleagues and co-workers
- Maintains exchange of experience
- Leadership and change management, objective setting and performance management
- Budget management, Operational Excellence, Risk Management
- Project Excellence; Stakeholder Engagement; Organizational Savvy; Applied Business Insights
- Additional qualification in the GMP area
- Quality Assurance; Knowledge of GxP, Health Authorities, Supplier Relationship Management; Strategic thinking and planning; Quality decision making; Interdepartmental collaboration; Communication skills; Problem-solving-oriented; Goal-oriented
- MS Office applications and other standard IT applications supporting Quality activities

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部门
Operations

Business Unit
Innovative Medicines

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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