QC Lead

Job ID
REQ-10041445

8月 05, 2025

Singapore

摘要

Responsible to ensure compliance to cGxP standards for products within area of responsibility (during development,
transfer and commercialization), including safety testing, monitoring and trending.
Provide guidance, support and leadership for implementation of test methods, specifications and analytical standards.

About the Role

Key Responsibilities:

- Ensure QC activities executed according to cGxP standards
- Collaboration in GxP audits/inspections. Ensure methods and procedures are up-to-date.
- Ensure compliance of products and packaging materials with specifications and with

corporate, health authority, and customer requirements.
- Management of documentation and methods according to cGxP (in A S & T for bulk, QC for packaging & smaller sites)
- Ensure qualification/calibration status of analytical equipment. Ensure on-time testing of samples. Ensure compliance of analytical laboratory operations and development according to applicable regulatory requirements and guidelines
- Exception management. Complaint investigation support. QC testing review and approval. Ensure training according to cGxP requirements. Stability protocol/report review and approval.
- Follow trends in the field of analytics, and take responsibility for consistent and efficient operation of the quality control function within the Group. Seek opportunities for productivity improvements, and coordinate their implementation. Ensure any additional local legal requirements are fulfilled. Equipment qualification review/release.
- 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
- 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

Essential Requirement:

- 5-10 years professional experience in the field of GMP production or QA or QC. Professional experience from official and / or customer audits
- Responsible to establish and maintain a QC unit in full cGMP-compliance. (Raw materials, IPC, Phys/Chem, Bioanalytical, Microbiological, Environmental Monitoring, Stability). Ensure quality systems for QC meet HA regulations and global guidelines.
- Establish and optimize work flows and methods/procedures for testing, results release and CoA generation pursue an ongoing quality assurance program
- Ensure and maintain qualified status of lab equipment and methods for intended use in QC laboratories
- Ensure adequate management of QC related validations, transfers, investigations related activities (deviations, OOS, OOE, OOT, CAPAs, trending), and Change Control systems.
- Procure site validation and qualification support, support site launches of manufacturing products
- Prepare and participate to health authorities inspections and internal audits in his area. Ensure that QC personnel is duly conducted and documented for all performed activities. Responsible for the site Quality Control Budget planning, execution and adherence. Establish Quality Control Strategic Plan to support Site Operations.

Desirable Requirement:

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy,

Biology, Biochemistry, or equivalent)

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部门
Operations

Business Unit
Innovative Medicines

地点
Singapore

站点
Tuas South Avenue

Company / Legal Entity
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd

Functional Area
Quality

Job Type

Full time

Employment Type
Regular

Shift Work
No

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