QC Analyst III - Analytical

Job ID
REQ-10018195
Set 03, 2024
Singapore

Sommario

This role will be responsible to establish and ensure testing of drug substance release and stability testing including testing of intermediates in process control samples and lab operations are accordance with written testing SOP's and local/international regulations.

About the Role

Position Title: QC Analyst III (Analytical)

Location – Singapore

About the Role:

Execution of assigned tasks in the quality control laboratory in accordance with cGxP regulations. Performance of laboratory specific activities such as analyses, maintenance, calibration and qualification of analytical equipment.

Key Responsibilities:

- Sample storage and management
- Analytical testing and documentation of API / drug substance / drug product / finished product / Complaints / stability / packaging material samples
- Ensure all activities in compliance with cGxP, incl. data integrity
- Stability (when not centralized)

o Testing/Sample storage and management

o Analytical documentation of stability samples to cGxP standards

- Comply with all HSE guidelines
- Detect and report potential accident, risks and propose solutions
- Responsible for participating in initial training and retraining
- Able to support rotating shift hours (Day/night).

Role Requirements:

Essential Requirements:

- Preferred: Previous experience working in a laboratory environment in the pharmaceutical industry (quality assurance, production), aseptic technique.
- Administrative activities and GMP and HSE-compliant, efficient production and documentation of standardized tasks in the infrastructure
- Breakthrough Analysis; Being Resilient; Operational Excellence; Continuous Learning; Digital & Tech Savvy
- Laboratory equipment; Quality Control (QC) Testing; Quality Control Sampling; knowledge of TQM and related industry GxP standards and processes; Laboratory Excellence; Quality decision making
- Ensure proper maintenance of QC IPC/DS lab equipment and systems to ensure full cGMP-compliance as part of shift team.
- Perform product testing and analysis under cGMP to meet required timelines.
- Provide technical support to run and validate necessary test methods on lab equipment and in developing method transfer/validation protocols and reports.
- Perform routine testing for in process, release and stability test samples and validation samples.
- Support and validate necessary test methods on lab equipment under cGMP.
- Prioritizes workload to ensure documents are reviewed and testing is performed in a timely manner.
- Support and coordinate laboratory investigations and facilitates root cause finding.
- Prepare and check QC documents, including assays of least to average complexity, to ensure completeness, accuracy, consistency, and clarity and that materials or final products have been manufactured, tested, or inspected according to specification and cGMPs.
- Support the execution of improvements to optimize test procedures or efficiency whenever possible.
- Prepare and participate in health authorities inspections and internal audits in respective area.

Desirable Requirements:

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

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