

# QC Analyst/ Specialist

Job ID REQ-10022512 Sep 13, 2024 Singapore

#### **About the Role**

Position Title: QC Analyst / Specialist

Location - Singapore

## 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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# **Role Requirements**

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Division

Operations

Business Unit
Innovative Medicines

Location

Singapore

Site

Tuas South Avenue

Company / Legal Entity

SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd

**Functional Area** 

Quality

**Employment Type** 

Regular

Shift Work

No

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