

QC Senior Specialist I

Job ID
REQ-10051197

5月 07, 2025

Singapore

摘要

-Highly skilled and experienced laboratory professional who contributes by performing analytical release testing, investigational support, research support, and stability testing

About the Role

Major accountabilities:

- OOX/Deviation handling .
- CAPA definition -KPI trending -Ensure all activities in compliance with cGxP, incl. data integrity review and approval of analytical data / tests (analytical release) Stability -Stability testing (Projects) - protocol preparation, evaluation, report preparation .
- Reporting (Stability plan preparation, trend analysis, evaluation) -Performance of Stability studies, protocols and comparative reports for supplier qualification -Review and approval of analytical tests (analytical release) -Microbiological QC -Perform Microbiological testing of

materials and utilities, environmental and personnel monitoring -Provide expert Support for site qualification and validation activities -Maintain and calibrate equipment incl. plan preparation -Support in supplier qualification -Trending and analysis of KPI/KQI -Support sample planning and sampling execution -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- The relevant KPIs that are defined in the Quality Control areas apply: e.g. analytical lead times -Timely and GMP-compliant analysis & documentation of the results.
- Error rate: Number of OOS (analysis errors) related to the number of analyzes -No complaints about official inspections.
- Individual performance is assessed using the PMP performance dialog together with the manager

Minimum Requirements:

Work Experience:

- Functional Breadth.
- 3-5years experience in Pharma/Manufacturing sector in analytical lab in.
- Collaborating across boundaries.
- a GMP environment/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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