QC Specialist I - Raw Materials

Job ID
REQ-10022148

10月 03, 2024

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

QC Specialist I (Raw Materials)

Location - Singapore

About the Role:

To support all activities in QC Raw Materials laboratory in accordance with written testing SOP ' s and local/ international regulations which contributes by performing testing, maintenance, calibration and qualification of analytical equipment. To plan day to day laboratory operation and lead change initiatives and laboratory investigation.

Key Responsibilities:

- 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)
- Maintain and calibrate equipment incl. plan preparation
- Support in supplier qualification
- Trending and analysis of KPI/KQI
- Support sample planning and sampling execution
- Stability (when not centralized)
- 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)

Role Requirements:

Essential Requirements:

- Professional experience (3-5 years) in the pharmaceutical sector or in the manufacture of active substances in analytical laboratories in a GMP environment or equivalent; Collaborating across boundaries; Functional Breadth; efficient inter and intra-departmental communications.
- Collaboration; result-oriented
- Breakthrough Analysis; Being Resilient; Operational Excellence; Continuous Learning; Digital & Tech Savvy
- MS Office applications and other standard IT applications supporting Quality activities
- Laboratory equipment; Quality Control (QC) Testing; Quality Control Sampling; Knowledge of TQM and related industry GxP standards and processes; Laboratory Excellence; Quality decision making

Desirable Requirements:

- Technical education & 3-5 years relevant experience or
- University degree in Pharmacy or Chemistry or equivalent + 0-4 years working experience

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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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