QC Specialist II (Microbiology)

Job ID
REQ-10059802

8月 18, 2025

Singapore

摘要

Establish and ensure testing of drug substance release and stability testing including all testing of intermediates in process. Control samples and lab operations are in accordance with written testing SOP ' s and local/international regulations.

About the Role

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) 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)

- Comply with all HSE guidelines
- Detect and report potential accident, risks and propose solutions
- Participate in HSE risk assessments
- Preparation and participation to internal HSE audits
- Responsible for participating in initial training and retraining

Essential Requirement:

- Professional experience (6+ 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 Requirement:

- Technical education & 3-5 years relevant experience or University degree in Microbiology, Biochemistry 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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