QC Specialist

Job ID
REQ-10061287

9月 03, 2025

China

摘要

Specialist in the area of analytics, supporting the laboratory team with in-depth knowledge to ensure efficient performance of laboratory activities and related investigations in compliance with GxP and HSE guidelines. Performs review and approval of analytical data.

About the Role

Major accountabilities:

Operational

- 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
- Finish relate physical and chemical testing (pH, UPLC, TLC, dose calibration)
- 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)

HSE

- 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

Key Performance Indicators

- Analytical lead times
- Timely and GMP-compliant analysis and documentation of the results
- Error rate: Number of OOS (analysis errors) related to the number of analyzes
- No complaints about official inspections

Ideal Background

Relevant Experience

- 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.

Education & Qualification

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

Languages

Good (oral and written) in English; fluent in local language (oral and written)

Competencies

- 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

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部门
Operations

Business Unit
Innovative Medicines

地点
China

站点
Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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