

Senior QA Operations Specialist

Job ID
REQ-10043408
Mar 13, 2025
China

Summary

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~ GxP

About the Role

Major Accountabilities

Operational

- Provide shop-floor QA support and oversight of production and testing activities, ensures compliance with cGxP, ISO9001, incl. data integrity and eCompliance
- Batch document review, support product release
- Support deviation and compliant investigations within MU, QC, Engineering and warehouse and other relevant areas.
- Performs routine documentation activities
- Supports change control activities
- Review and approval of production and QC documents and records
- MBR review
- IPC oversight
- Support OpEx improvement projects
- Support internal and external audit or inspection activities

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

- Executes product-related activities in timely manner according to cGxP and in compliance with registration
- Demonstrated positive trends in key quality management process measures. Successfully support continuous improvement projects

Experience:

- More than 3 years of experience in pharmaceutical quality control, quality assurance or production
- Operations Management and Execution; Functional Breadth; Collaborating across boundaries; Applied Practice

Education & Qualification:

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)
- Qualified Person (depending on local requirements)

Languages:

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

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Division

Operations

Business Unit

Innovative Medicines

Location

China

Site

Changping County (Beijing)

Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area

Quality

Job Type

Full time

Employment Type

Shift Work

No

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