

QA Operations Specialist

Job ID
REQ-10029818
Nov 29, 2024
China

Summary

About the role:

Performs QA oversight of production and testing activities (shop-floor presence), ensuring compliance with cGxP and ISO9001 standard. incl. DI and eCompliance, eg. as OQA SPOC. Acts as reviewer/approver of production and QC records and documents, incl. MBR. Provides specialist support in the evaluation and execution of the investigations and changes.

About the Role

Key Responsibilities

- 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, Review and approval of production and QC documents and records, MBR review
- Supports change control activities
- IPC oversight
- Support OpEx improvement projects
- Support internal and external audit or inspection activities
- 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 Requirements:

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)
- Qualified Person (depending on local requirements)
- Good (oral and written) in English; fluent in local language (oral and written)
- 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

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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

Regular
Shift Work
No
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