

Manufacturing Systems Expert

Job ID
REQ-10014091
Jul 05, 2024
India

Summary

Expert for the implementation of cGMP requirements in the manufacturing units, expert for plant qualification

About the Role

Manufacturing Systems Expert

Location - Hyderabad

About the Role:

Expert for the implementation of cGMP requirements in the manufacturing units, expert for plant qualification

Key Responsibilities:

- Operative support in various quality and GMP compliance aspects
- Acting as a flexible interface between individual manufacturing units and other departments such as Quality Assurance, MS&T, Engineering, Facility Management, etc.
- ensure compliance with local and global operating procedures and Novartis Quality Modules (QMs) relevant to the local quality system
- operational support of individual units in dealing with compliance issues (e.g. conducting deviation investigations, definition and implementation of CAPAs) and as coordinator in qualification projects
- Creating, reviewing and approving GMP-relevant documents such as risk assessments (RAs) or (validation/qualification-related) protocols and reports
- Creation and maintenance of general SOPs for DSK taking into account existing SOPs, QMs and guidelines
- Support in relation to current GMP compliance issues
- Participation in health authority inspections, GCA audits and self-inspections

Essential Requirements:

- Minimum 3-5 years of experience in Manufacturing / MS&T operations
- Fix-its/Turnarounds, Project Management, Collaborating across boundaries.
- Operations Management and Execution.
- Meet established validation milestones according to approved validation plans.
- Audit and inspection outcomes as a measure of validation compliance with global regulatory expectations.
- Timing and quality of technical reports.
- Timely and successful implementation of transfer activities (e.g. lab-to-lab transfer in launches).

Desirable Requirements:

- Academic Degree (PhD, MSc)
- English: fluent in written and spoken language, German skills would be an advantage
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Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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