

Manufacturing Systems Expert

Job ID
REQ-10014091
Juli 05, 2024
Indien

Zusammenfassung

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)
- Englisch: fluent in written and spoken language, German skills would be an advantage
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Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

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Abteilung

Operations

Business Unit

Innovative Medicines

Ort

Indien

Website

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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