

# Manufacturing Systems Expert

Job ID  
REQ-10014091  
Juli 05, 2024  
Indien

## 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)
- Englisch: fluent in written and spoken language, German skills would be an advantage
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Division  
Operations  
Business Unit  
Innovative Medicines  
Standort  
Indien  
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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