

# R&D Quality Manager

Job ID  
REQ-10028790  
Nov 07, 2024  
India

## About the Role

### Key Responsibilities:

- Manages technical complaints investigations to determine root causes and implement corrective actions to prevent recurrence.
- Collaborate with cross-functional teams to gather data, lead, and perform Root Cause Analysis to identify the likely root cause of events.
- Review and approve complaints as the site Investigation approver.
- Manage multiple investigations concurrently.
- Periodically analyze trends in technical complaints.
- Participate in audits and inspections, including inspection readiness activities.
- Handle data integrity escalations.
- Implement and drive global Data Integrity (DI) network initiatives

### Essential Requirements:

- More than Over 10 years of practical experience in the chemical/pharmaceutical industry or over 5 years of experience in pharmaceutical operations. In-depth knowledge of pharmaceutical facilities, manufacturing, and laboratory systems and processes-
- Proficient in conducting Root Cause Investigations. Effectively collaborate with the Investigation team to ensure timely completion.
- Experienced in cGMP manufacturing, Quality, and Compliance.
- Action-oriented with strong skills in building relationships, problem-solving, planning and organizing, conflict management, coaching, and analytical thinking.
- Capable of completing routine tasks with minimal direction
- Fast learning abilities, able to manage investigations related to small molecule, biologic and CGT products as well as medical devices, packaging and distribution related topics
- Able to promptly communicate roadblocks and challenges, ensuring timely delivery of investigations.
- Excellent verbal and written communication skills.
- Project Management
- Sound knowledge of current international regulatory regulations, cGxP requirements and best practices, including EU-GMP guidelines

## Role Requirements

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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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