# **U** NOVARTIS

## **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**

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

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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 Apply to Job

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