NOVARTIS

R&D Quality Manager

Job ID
REQ-10039553
Feb 06, 2025
India

Summary

The Quality Manager responsible for handling technical complaints is tasked with investigating and managing technical complaints raised by clinical investigator sites regarding Investigational Medicinal Products (IMPs) and Medical Devices.
Support data integrity incidents, manage escalations, and contribute to global DI (Data Integrity) networks and initiatives.

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 14 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.
- Experience in handling the Peptides.
- 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

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? https://www.novartis.com/about/strategy/people-and-culture

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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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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