R&D Quality Manager

Job ID
REQ-10028790

12月 09, 2024

India

摘要

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 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

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
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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