QA Specialist QMS Support

Job ID
REQ-10045026

4月 23, 2025

India

摘要

Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems

About the Role

Location - Hyderabad #LI Hybrid

Key Responsibilities:

- Responsible for managing day to day process of Complaint management activities under complaint hub responsibility.
- Identification, reporting and escalation of critical complaint events followed by building the strong collaboration with NCQ sites to ensure customer service, compliance and efficiencies.
- Responsible for performing reconciliations with stakeholders, e.g. NPS and MedInfo and

responding client with the final outcome of complaints.

- Responsible for preparing Quality trends, evaluate and support team for driving Continuous improvement for processes and product quality performance.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all GxP related activities and that compliance with cGMP is maintained through training and internal audits.
- Ensures the timely collection, monitoring, and reporting of Quality Key Performance Indicators (KPIs) for management reporting Assists in Health Authority inspections and internal audits by supplying information and documentation in a timely manner -Support and track the implementation and maintenance of the local Quality system in in accordance with the Novartis Quality Manual -Manages processes and systems for all GxP Quality Assurance e.g. Change control, Training Management, Escalation Management, Risk Management.
- Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.
- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Ensures adequate tracking and on time completion of corrective and preventive actions (CAPA), inc escalation of issue related to the closure of CAPA, as appropriate.
- Proficiency in speaking and writing Japanese is a plus and will be considered an added advantage.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments -Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation -Supports Compliance review of projects and inspection readiness and management -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- Quality standards are understood, designed into work activity, and achieved.
- In accordance with departmental objectives such as support of projects with agreed quality and delivery date, passing of internal and external inspections

Desirable Requirements:
Work Experience:

- Functional Breadth.

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part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Head 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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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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