Specialist Quality Operations

Job ID
REQ-10015901

9月 03, 2024

India

摘要

Provide quality support in compliance with cGMP requirements and Novartis Quality Management System. Manage Quality aspects & projects within area of responsibility.

About the Role

Major accountabilities:

Have expertise in Supplier Quality management and QMS activities. Drafting of QRA, QAA and AMR documents. Handling Supplier Qualifications and change notification.

Interpret and compile APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.

Create and review GxP documents including SOPs, working procedures, trend reports, qualification

reports and technical investigations, as and when needed.

· Provide active support during internal and external audits by collecting and presenting the requested process/ data and reports

· Adherence to the current GxP and compliance policies of Novartis Perform and deliver Quality

Operations services in support of product quality compliance and regulatory workflows

· Hold accounts in workflow applications (such as SAP, Dragon, SUBWAY, TEDI etc.) to ensure

appropriate execution of service deliverables

· Generate and analyze predefined and ad-hoc reports in various applications (such as AGILE PLM, AQWA etc.) and perform follow-up actions if required

· Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed

product quality standards and service level agreements

· Support implementing service quality and process improvement projects, CAPA management within

Quality Service Centers

· Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket

management tools and other internal systems and processes

Requirements for the role

- Minimum 6 years of experience in Quality assurance activities in pharmaceutical company.
- GxP knowledge, Basic IT knowledge
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- English.

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部门
Operations

Business Unit
Universal Hierarchy Node

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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