Specialist Quality Operations

Job ID
REQ-10015908
Juli 18, 2024
Indien

Summary

-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

Major accountabilities:

Key performance indicators:

- 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, qualificationreports 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

Minimum Requirements:
Work Experience:

- Functional Breadth.
- QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &.
- Collaborating across boundaries.
- cleanliness zones.

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.

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

Division
Operations
Business Unit
Innovative Medicines
Standort
Indien
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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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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