

Analyst Quality Operations

Job ID
REQ-10023160

Sep 20, 2024

India

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

Common Accountabilities: (Applicable to all services in QOP)

- Comply with internal functional requirements such as KPI reporting, ticket management tools and any other internal procedures and processes
- Assist the department on any other ad hoc activities/ requests to meet the business requirements
- Regularly communicate with partners and obtain feedback on services delivered
- Focus on timely completion of all relevant and assigned trainings
- Learn & develop understanding to generate insights through data and digital

- Ensure responsibility and ownership of the assigned tasks
- Comply with accuracy and timeliness of deliverables
- Comply to the applicable Novartis operating procedures as per legal/ IT/ P&O requirements
- 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
- Escalate service related GxP and non-GxP issues and ensure timely investigation and compliance with local and global operating procedures
- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements
- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket management tools and other internal systems and processes
- Assist the department on any other ad hoc administrative activities as per business requirements
- Regularly communicate with customers and partners to collect feedbacks on support services, report deliverable

Change Control Management:

- Manage different types of change control like product stewardship/Administration Stewardship/Asset Stewardship in electronic systems like Agile from Change Initiation to closure as needed
- Generate and analyze predefined and ad-hoc reports in various applications and perform follow-up actions as required.
- Perform Regulatory assessment on Change Controls as needed.
- Perform deviation investigations and CAPAs as part of change management.

Ideal Background / Requirements for the role:

- M. Pharm/ MBA / Engineering/equivalent from a reputed institute.
- Min 6 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/Medical device.
- GMP -knowledge, Broad IT-knowledge
- Fluent in English (written and spoken)
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

Languages :

- English

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Division
Operations

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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