Specialist - Quality Operations

Job ID
REQ-10020519
Sep 03, 2024
India

Summary

- Responsible for handling of compliance activities as per QMS.
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

Specialist – Quality Operations

Location – Hyderabad

About the Role:

Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners.

Key Responsibilities:

- 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, etc.) to ensure appropriate execution of service deliverables
- Generate and analyse predefined and ad-hoc reports in various applications (like 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.
- 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 the accuracy and timeliness of deliverables

Essential Requirements:

- Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute

- Min 7-9 years of experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/ medical devices.

- Perform APQR Master plan coordinator role & support for creation of draft annual plan and sharing it for approval & KQI reporting activities.
- Acting as site owner for maintenance of SharePoint as requested by Business Partner
- Responsible to update the information on SharePoint/ trackers, review the applicable documents for correctness and archival of necessary documents on SharePoint.
- Provide Administrative support in preparation of Quality Management Review meeting slide deck & metrics reporting.
- Maintenance of distribution lists and Active Directory Group Management.
- Preparation, approval, and management of QAA & QAA tracker for clinical development (ESP QA).
- Self-Inspection (SI) Planner role in AQWA-A. Creation of the child record for required target site based on the final SI approved plan for NCQ.
- Author and approver role for metric reporting of QAA and QRA (ESO suppliers) in QADM tool.
- Develop and maintain process SOPs, working procedures and process maps.
- Act as QC admin support to perform “incident /access review”.
- Provide support for GMP External Audits and inspection management activities (HA and Self Inspection Audits)
- Maintain Approved supplier list for GxP vendors.
- Ensure the completeness of KQI metrics as per requirement of compliance team.
- Perform QARP role in AQWA-A for audit CAPA activities for audits of external suppliers/CMOs,
- Preparation of UQAP (Unified Quality Audit Program), Audit preparation support and QARP (Quality assurance responsible Person) Role for audit CAPA Management.
- Co-ordinating in process of assessment and implementation of Global Novartis Standards and procedural documents with wide applicability at Novartis Gene Therapies (GTx) and other applicable sites.
- Manage creation of New Supplier Records, Maintenance/Update of Current Active Supplier and Monitoring Suppliers in ESPIR

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Job Type
Full time
Employment Type
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Shift Work
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