

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

Why Novartis: Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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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

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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