Quality Compliance Coordinator

Job ID
REQ-10026208

10月 24, 2024

T ü rkiye

摘要

-Manage cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators)
-Performs preparation and management of external and corporate audits and Health Authority inspections.
-Preperation PQR reports
-Ensure Data Integrity Check of Computerized Systems
-Follow implementation of the global procedures

About the Role

Major accountabilities:

- To ensure that GMP requirements, Novartis policies and ISO 9001 "Quality Management System" requirements are fully implemented & followed throughout the site
- To create and maintain related SOPs up to date
- To manage the ESOPs and Condor system as site key user and coordinate all individuals.
- Follow up and report Quality KQIs
- Quality Assurance Approval Role for Deviation, CAPA , QE and OPVR
- APQR Sytem Owner and site spoc
- Preperation PQR reports (including Change Requests, Medical and Technical Complaint, Advers Events, Effectiveness of CAPAs, Product Performance, Deviations, OOS Results, Release and Stability Performance of Product, Validation Studies, Recall, Manufacturing Volume etc.)
- GMP Document Archive Responsible-IGM/GRRS Responsible
- To support Excel Validation Protocol and Report Approval and to support QA for Engineering
- To ensure Data Integrity Check of Computerized Systems
- To support team during preparation for the quality/GMP Inspections performed by 3rd parties, Health Authorities and Novartis Global Quality, prepare the CAPA plan after the audit/investigation report is sent and ensure all CAPAs are completed on time and effectively
- Prepare desktop audit reports
- Support Global Escalation Management in Site level
- Follow implementation of the Site Quality Plan

Minimum Requirements:

- University degree in Pharmaceuticals, Chemical Engineering or Chemistry
- Minimum 4 years of experience
- Excellent communication skills in English
- Good negotiation skills in English
- Team working and customer oriented mindset
- Good at conflict management
- Knowledge of quality management systems such as deviation, complaint handling, change management
- Knowledge of regulatory systems and CMC processes
- Good analytical thinking and problem solving skills

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部门
Operations

Business Unit
Innovative Medicines

地点
T ü rkiye

站点
İ stanbul Kurtk ö y

Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sa ğ l ı k, G ı da ve Tar ı m Ü r ü nleri San. Ve Tic. A. Ş .

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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