Compliance & Quality System Manager

Job ID
REQ-10022678
Sep 23, 2024
Italy

Summary

-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) -Lead the preparation and management of external and corporate audits and Health Authority inspections.

About the Role

Major accountabilities:

- Oversight and implementation of Quality Management System -Incident management.
- GxP Audit and inspection management -Site Regulatory oversight (incl. Reg-CMC facilitation) -Exception management -Supplier Quality management (local) -Qualification and validation -Quality Compliance -Data Integrity and eCompliance -Site KPI / KQI maintenance / reporting -Initiate and drive local hiring process -Line responsibility and daily walkthrough -Lead OpEx Projects -Investigation of Deviation, OOx, Complaints -Define and implement CAPAs -Support transfer projects and validation studies -Track team metrics and ensure KQI/KPI meet requirements -Review and approve text and design -HSE incidents reporting and action follow-up -New equipment commissioning support (OQ, PQ) -Define improvement areas in process and products -Resource and capacity (people and equipment) planning and workload management -Performance and leadership support to specialist team -Ensure availability of equipment, chemicals and consumables, as appropriate -SOP review and revision -Perform local training and monitor training status -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Successful support of projects with agreed quality and delivery dates, passing of internal and external inspections.
- Meet quality and timelines for all projects.
- Act in accordance with Novartis standards.
- The number and severity of cGMP issues identified during internal and external audits -Year-end figures within budget.
- Successful coordination of departmental operational activities

Minimum Requirements:
Work Experience:

- Functional Breadth.
- People Leadership.
- Project Management.
- Collaborating across boundaries.
- Critical Negotiations.
- Operations Management and Execution.

Skills:

- Agility.
- Auditing.
- Business Acumen.
- Business Partnering.
- Collaboration / Teamwork.
- Communication Skills.
- Compliance Audits.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Employee Performance Evaluations.
- Finance Acumen.
- Gmp Procedures.
- Goal Oriented.
- Health Authorities.
- Leadership.
- Logical Thinking.
- Major Incident Management.
- People Management.
- Problem Solving Skill.
- Problem Solving Skills.
- Qa (Quality Assurance).
- Self Awareness.
- Smart Risk Taking.
- Stakeholder Management.
- Technological Expertise.
- Audit Management.
- Inspection Readiness.
- Product release.
- Organizational skills.

Languages :

- English.

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Division
Operations
Business Unit
Innovative Medicines
Location
Italy
Site
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) AAA Italy Srl.
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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