NCQ QA Manager

Job ID
REQ-10026335
Oct 20, 2024
Taiwan

Resumen

-To lead the QA function thereby ensuring that all processes and procedures, tasks, responsibilities and projects are in compliance with all pharmaceutical laws, the Novartis Quality Manual and Policies as well as Industry Best Practices. This role comprises special GxP requirements and has to be executed in accordance with these. Ensure that all quality relevant processes are compliant and that non-compliance is appropriately addressed via corrective and preventive actions (CAPA) and/or escalation of issues

About the Role

Major accountabilities:

- Ensure implementation of applicable Quality Standards and governance processes through the implementation of the Novartis Quality Manual and Policies.
- Ensure that regulatory controls are in place in relevant process steps -Ensures adherence to GxP, any further legal and company internal regulations for manufacturing, control and distribution operations and to HSE guidelines and requirements -Ensure implementation of defined Key Quality Indicators in the area of responsibility to monitor on an on-going basis that relevant processes are in control and compliant.
- Ensure regularly review and assessment of KQIs at the Leadership Team level.
- Ensure adequate escalation of issues and support their timely resolution and provide quality oversight for deviations and ensure that adequate corrective and preventive actions (CAPA's) are implemented.
- Provide quality oversight for planned changes.
- Ensure adequate regulatory inspection preparation, management and follow-up in the area of responsibility.
- Ensure communication with local Health Authorities is adequately shared within the organization and commitments tracked and closed on time.
- Ensure implementation of adequate training within the area of responsibility for all GXP activities by defining, planning and supporting training activities.
- Ensure that processes are in place to communicate country specific requirements to the Region and headquarter organizations for all GXP areas and assess their implications for the compliance of existing processes and systems.
- Initiate remediation activities, as necessary, to ensure ongoing compliance.
- Ensures adequate processing of complaints.
- Establishes an efficient recall organization as well as ensure development of talent within the local Quality unit.
- Develop adequate succession candidates for the Quality organizations.
- 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:

- Implementation tracking of issued Quality Manual modules consistently in place -Performance against Key Quality Indicators Delivery of the Quality Plan and budget -The number and severity of GXP issues identified during internal and external audits.
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Minimum Requirements:
Work Experience:

- Industry/ Business Exposure.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.
- People Leadership.
- Project Management.

Skills:

- Agility.
- Audit Management.
- Business Acumen.
- Business Partnering.
- Collaboration.
- Communication Skills.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Goal Oriented.
- Guideline.
- Inspection Preparedness.
- Leadership.
- Logical Thinking.
- Problem Solving Skills.
- Qa (Quality Assurance).
- Quality Decision Making.
- Quality Management.
- Regulation.
- Self Awareness.
- Stakeholder Management .
- Teamwork.
- Technological Expertise.

Languages :

- English.

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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
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