

## Global Health Quality Lead

Job ID  
REQ-10024327

Oct 07, 2024

Kenya

### Summary

-Assurance that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements. Ensure that relevant documentation is up-to-date and archived correctly. Ensure “state of the art” GxP know-how and future trends in the field of GxP

### About the Role

Major accountabilities:

- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
- Prepare, review and check the batch documentation for correctness, completeness and safety

archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.

- Monitor actions and corrections accordingly.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, follow up the corrective actions.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.
- Ensure investigations are correctly executed.
- Ensure all required actions are taken appropriately and in a timely fashion.
- Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required.
- Decide escalation to Senior Management Level and lead Global Quality Assessments and manage filing accordingly as well as ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Pharmaceutical authorities in respect to up-dated GxP provide latest know how in the field of GxP and other quality related fields.
- Identify repetitive activities and regulatory areas for which SOPs are required.
- Initiate the introduction of SOPs
- Plan, initiate and monitor basic GxP-training for all employees in regular intervals.
- Be responsible for annually training program and implementation.
- Establish and maintain cross-functional contacts with peer organization and authorities and, follow-up quality related developments in the field of Pharmaceutical products -Support launches of product in close collaboration with BD and L partner and/ or development organization.
- Ensure that all drug products are released to the market in accordance with the registered specifications and with local/international regulations.
- Ensure that coordinated contact is maintained with all parties (the Regulatory Authorities, the local partners and stakeholders and Global QA.
- ) -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:

- Local GMP/GDP Quality System in place and continuously updated, as required -GMP/GDP risks proactively identified and effectively mitigated.
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Minimum Requirements:

Work Experience:

- Participating in volunteer / community projects.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Change Control.
- Continuous Learning.
- Dealing With Ambiguity.
- Guideline.
- Product Release.
- Qa (Quality Assurance).
- Quality Management.
- Regulation.
- Risk Management.
- Self Awareness.
- Technological Expertise.

Languages :

- English.

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Division  
Operations

Business Unit  
Innovative Medicines

Location  
Kenya

Site  
Kenya

Company / Legal Entity  
KE03 (FCRS = KE003) NVS Kenya Limited

Functional Area  
Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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