Quality Assurance Specialist

Job ID
REQ-10059637

8月 27, 2025

Malaysia

摘要

-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

Major accountabilities:

- Ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, Follow up the corrective actions.
- Archive relative documentations.
- Coordinate implementation of quality system and procedures for the implementation of Novartis Quality Manual and quality agreements.

- Ensure that all aspects of the handling and distribution of pharmaceutical products in the country comply with the requirements of the Novartis Quality Manual and Policies and meet all relevant cGMP regulatory and legislative requirements.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all cGMP/GDP related activities and that compliance with cGMP/GDP regulations is maintained through training and internal audits.
- Maintain current knowledge of local and international regulatory and legislative requirements and trends to ensure that technical support on all quality related matters is provided to the country.
- Establish a good working relationship with the Supply Chain Management (SCM), DRA and Medical departments.
- Ensure that coordinated contact is maintained with the Regulatory Authorities, the local partners (suppliers, third parties, licensees, and distributors) and Global Quality Assurance.
- Ensure that all incoming drug products are inspected prior to release to the market in accordance with the current in place procedures, registered specifications and with local/international regulations.
- Ensure that an effective Change Control process is in place.
- Manage complaints, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures.
- Support / participate in NEM cases as required.
- 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 requiredGMP/GDP risks proactively identified and effectively mitigated -The number and severity of GMP/GDP issues identified during internaland external audits.

Minimum Requirements:
Work Experience:

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

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Good Documentation Practice.
- Guideline.
- Knowledge Of Capa.
- Qa (Quality Assurance).
- Quality Management.
- Regulation.
- Self Awareness.
- Technological Expertise.

Languages :

- English.

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部门
Operations

Business Unit
Innovative Medicines

地点
Malaysia

站点
Selangor

Company / Legal Entity
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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