NOVARTIS

QA Specialist

Job ID
REQ-10080394
Jun 08, 2026
LOC_ID

About the Role

Major Accountabilities:

- A. Quality Management System
  - Act as the primary accountable person for the implementation and maintenance of the GDP/CDOB Quality Management System.
  - Review, approve, and control GDP-related policies, SOPs, and controlled documents.
  - Ensure effective implementation of Corrective and Preventive Actions (CAPA) arising from deviations, self-inspections, internal audits, and BPOM inspections.
  - Conduct Quality oversight and ensure Quality Plan is implemented in (Indonesia) Country Organization (namely for commercial batch release in compliance with Marketing Authorization, effective change control management, effective complaint management, effective risk assessment.
  - Conduct regular review and assessment of KQIs of relevant stakeholders.
  - Implement applicable Quality Manual/ Standards and ensure compliance with escalation processes in (Indonesia) Country Organization.
  - Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.
  - Supporting QA Lead in day-to-day activities in maintaining Novartis Quality Management System.

- B. Distribution Operation Oversight
  - Oversee receipt, storage, picking, and distribution of medicinal products in compliance with GDP.
  - Ensure products are distributed only to authorized and licensed parties.
  - Ensure appropriate storage conditions, including cold chain and controlled medicines.

- C. Documentation and Traceability
  - Ensure all distribution activities are accurately documented and fully traceable.
  - Ensure documentation systems support effective and timely product recall.

- D. Complaints, Investigations, Recall
  - Manage and assess distribution-related quality complaints, including to conduct the investigation.
  - Act as PIC for returned products, suspected falsified medicines, and recall activities.
  - Serve as the primary contact with BPOM and Kementerian Kesehatan.

- E. Personnel, Training, and Compliance
  - Ensure personnel involved in distribution are adequately trained and qualified.
  - Support the development and execution of GDP training programs.
  - Promote a strong quality and compliance culture.

- F. Self-Inspection and Regulatory Interaction
  - Coordinate and follow up GDP self-inspections.
  - Deliver successful GDP Regulatory inspections and internal/ external audits of (Indonesia) Country Organization.
  - Ensure timely and effective closure of inspection findings.

Requirements:

- Minimum education background: A registered pharmacist with active license (STRA – Surat Tanda Registrasi

Apoteker, Sertifikat Kompetensi Apoteker).
- Fluency in English and local language (oral and written).
- More than 1 year experience in pharmaceutical product distribution/QA/PBF is a plus.
- Understanding basic CDOB regulation and basic Quality Management System (QMS).

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_TO
Business Unit
Quality
Location
LOC_ID
Site
Jakarta
Company / Legal Entity
ID03 (FCRS = ID003) PT Novartis Indonesia
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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QA Specialist

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