

## QA Specialist

Job ID  
REQ-10080394  
Июн. 07, 2026  
Индонезия

### Сводка

Act as Responsible Pharmacist with accountability for the oversight of all distribution activities, ensuring PT Novartis Indonesia is in full compliance with Good Distribution Practices (GDP/CDOB), applicable local Health Authority regulations, and Novartis Quality Standards requirements to maintain product quality, safety, and integrity throughout the distribution chain.

### 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.

#### Key performance indicators:

- Local GMP/GDP Quality System in place and continuously updated, as required.
- GMP/GDP risks proactively identified and effectively mitigated.
- The number and severity of GMP/GDP issues identified during internal and external audits.

#### Work Experience:

- Complaints Management
- Product Recall Management

- Quality Management Systems
- Change Control Management
- Deviation Management
- Audit & Inspection Management
- Batch Record Review
- Corrective and Preventive Action (CAPA) Knowledge
- Quality Assurance
- Quality Compliance
- Release Management
- GxP Experience
- SOP (Standard Operating Procedures) development

**Skills:**

- Analytical thinking
- Leadership
- Communication skills
- Data Saviness
- Digital saviness
- Change Management
- Dealing With Ambiguity
- Good Documentation Practice
- Collaboration
- Regulatory requirements knowledge
- Problem Solving Skills
- Data Integrity

**Languages:**

- English.

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Дивизион

Operations

Business Unit

Quality

Место

Индонезия

Сайт

Jakarta

Company / Legal Entity

ID03 (FCRS = ID003) PT Novartis Indonesia

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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