



HENDRY HERMANTO

QUALITY ASSURANCE & VALIDATION EXECUTIVE

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Languages: English (Full Professional)

PROFESSIONAL SUMMARY

Registered Pharmacist and Executive Quality Leader with over 15 years of robust experience steering quality management systems (QMS), validation lifecycles, and quality control frameworks within local and multinational pharmaceutical corporations across both sterile and non-sterile manufacturing facilities. Demonstrated expertise in building high-performing teams, instilling a cross-functional quality culture, managing complex budget optimization projects, and leading manufacturing facilities to flawless, zero-critical-finding BPOM GMP certifications. Proactive, fast, and accurate in executing key site milestones, regulatory dossier compliance, data integrity remediations, and lead-time reductions to drive supply chain supremacy.

CORE COMPETENCIES

- Quality Management Systems (QMS)
- Good Distribution Practice (GDP)
- Validation Master Plans (VMP)
- Laboratory Set-up & QC
- Qualification & Validation Frameworks
- Data Integrity Risk Mitigation
- Site Master Files (SMF)
- Budget & Cost Optimization
- Good Manufacturing Practice (GMP)
- Quality Risk Management (QRM)
- Continuous Improvement (Lean)
- Cross-functional Team Leadership

WORK HISTORY

Validation Manager

April 2026 – Present

PT Daewoong Pharmaceutical Indonesia

- Direct the validation department, strategically establishing and monitoring cross-functional calibration, qualification, and validation activities in absolute compliance with the newest GMP requirements, ISO standards, and health authority regulations.
- Formulate, execute, and dynamically maintain the site's Validation Master Plan (VMP) and associated lifecycle schedules to guarantee fully compliant and audit-ready site operations.
- Manage deep departmental involvement in the preparation for ISO Integrated Management System (IMS) certification, focusing on Quality Management (ISO 9001:2015), Environmental Management (ISO 14001:2015), and Occupational Health and Safety (ISO 45001:2018).
- Establish, review, and modernize core Standard Operating Procedures (SOPs) and Work Instructions within the department to systematically minimize data integrity risks and document lifecycle failures.
- Partner proactively with Production, QA, QC, and Engineering to deliver critical site milestones and introduce data-driven continuous improvement frameworks.

High-Impact Executive Achievement (Calibration Cost Optimization): Successfully identified and eliminated redundant external calibration parameters, substituting them with high-standard Internal Performance Qualifications to save an aggregate IDR 22,995,000 (approx. KRW 1,962,491).

Equipment / Parameter Scope	Before Improvement (2025)	After Improvement (2026) Action & Metric Impact	Direct Net Saving (IDR)
Laminar Air Flow (LAF) Clean Booth (1 unit)	External Calibration Expense	Substituted with High-Tier Internal Performance Qualification	7,500,000
Fume Hood ESCO (2 units)	External Calibration Expense	Substituted with High-Tier Internal Performance Qualification	15,000,000
Pycnometers (2 units)	External Calibration Expense	Completely Removed (Calibration of Grade A glassware is not mandatory)	495,000
Total Structural Budget Optimization Realized			IDR 22,995,000

High-Impact Executive Achievement (Environmental Sampling Efficiency): Decreased environmental monitoring sampling frequency by applying a new risk-based PQ HVAC sampling approach derived directly from BioPhorum guidelines, significantly shrinking operational overhead.

Operational Metric	Before (2025)	After (2026)	Net Reduction Performance
Sampling Points	320 petri	232 petri	88 petri (28% Drop)
Direct Budget Cost	IDR 34,155,000	IDR 20,031,000	IDR 14,124,000 Saved

Quality Assurance Manager

January 2022 – March 2026

PT Fahrenheit Synthron Pharma

- Directed and scaled the Quality Assurance Department (1 supervisor and 2 staff members) to orchestrate end-to-end quality assurance, quality management, and CQV for a high-complexity greenfield manufacturing expansion project.
- Built the entire QMS architecture and validation lifecycle workflows from scratch for a brand-new, state-of-the-art oncology manufacturing greenfield project, defining operational readiness.
- Authored the foundational corporate Quality Policy, Quality Manual, Site Master File (SMF), and Validation Master Plan (VMP) for the site.
- Formulated comprehensive QMS documentation control systems, covering Change Management, Deviations, and Training Management.
- Guided the executive board in successfully specifying and setting up the advanced Quality Control analytical laboratory.
- High-Impact Executive Achievement (Regulatory Approvals):** Successfully spearheaded the plant implementation and validation readiness team to secure the official BPOM GMP Certificate with zero critical findings under a single cycle of CAPA review.
- High-Impact Executive Achievement (Dossier Development):** Strategically collaborated with the product development groups to compile and clear critical technical dossiers, accelerating lines to final regulatory marketing authorization.

Quality Assurance Manager

April 2019 – December 2021

PT Takeda Indonesia

- Managed QA Operations and shop-floor oversight teams, leading 4 senior QA Specialists and 1 QA Administrator.
- Accountable for product batch reviews, raw material dispositions, and approving systemic investigations covering Deviations, OOS/OOT, and product complaints.
- Supervised Product Quality Reviews (PQR), performed systematic Quality Risk Management (QRM), and directed site mock recalls.

- Served as the primary site QA Subject Matter Expert (SME) for corporate validation frameworks and Data Integrity Remediation programs.
- **High-Impact Executive Achievement:** Restructured cross-functional releasing processes to systematically reduce batch release lead time from 3 days down to 1 day, significantly optimizing site supply chain supremacy.

Logistic Assistant Manager

August 2018 – March 2019

PT Mersifarma TM

- Commanded the full scale of Logistics operations (Warehouse & Dispensing), coordinating 2 supervisors, 4 coordinators, and a team of over 30 warehouse operators.
- Maintained rigorous warehouse control across raw materials, packaging components, finished goods, and required production supporting materials.

Validation Assistant Manager

August 2013 – June 2018

PT Mahakam Beta Farma

- Headed the plant-wide Validation Department composed of 2 supervisors, 3 senior staff, 5 inspectors, and 1 administrator.
- Oversaw all corporate calibration, equipment qualification, and manufacturing process/cleaning validations to meet strict GMP requirements.
- **High-Impact Executive Achievement:** Secured smooth, flawless GMP validation inspections for multiple site lines (solid dose, liquids, semisolids, cephalosporins, and sterile injectables), while achieving Grade A performance ratings for 4 consecutive years.

Quality Assurance Supervisor

November 2012 – July 2013

PT Menarini Indria Laboratories

- Handled day-to-day calibration, equipment qualification, and localized validation protocols at the factory floor to ensure regulatory alignment.

Quality Assurance Supervisor

January 2011 – November 2012

PT Kalbe Farma

- Managed process and cleaning validation activities, stability testing, Product Quality Review (PQR) reporting, and factory product complaint investigations.
- **High-Impact Executive Achievement:** Successfully optimized and updated the process validation standard, scaling its implementation across all group sister sites.

EDUCATION

Master of Management: Human Resources – Mercu Buana University, Jakarta	2018-08
Post-Graduate Certificate: Pharmacist – Surabaya University, Surabaya	2010-05
Bachelor of Pharmacy: Pharmacy – Surabaya University, Surabaya	2009-03