

apt. Arif R. Al Hakimi, S.Farm., M.A.B

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Registered Pharmacist and seasoned Quality Assurance Manager with nearly 10 years of robust experience in the pharmaceutical and highly regulated FMCG industries. Proven expertise in ensuring Good Manufacturing Practices (GMP/CPOB) compliance, managing Quality Management Systems (QMS), and leading end-to-end quality operations.

Adept at driving audit readiness (BPOM, WHO) with a track record of passing external regulatory audits with zero critical findings. Strong proficiency in overseeing Deviation management, CAPA, Change Control, Risk Management, and batch release protocols. Specialized in integrating QA with digital transformation, including Computerized System Validation (CSV), Data Integrity, eQMS, and IQ/OQ/PQ validation.

CORE COMPETENCIES

- **Quality & Compliance:** GMP/CPOB, QMS, WHO & BPOM Regulations, Batch Release, Internal/External Audits.
- **Validation & Controls:** IQ/OQ/PQ, Process/Cleaning Validation, CAPA, Deviation, Change Control, Risk Management.
- **Systems & Data Integrity:** GAMP5/CSV, eBR, LIMS, Document Control, Root Cause Analysis (5Why, FMEA).
- **Leadership & Optimization:** Cross-functional Leadership, Lean Six Sigma, Continuous Improvement, Team Development.

PROFESSIONAL EXPERIENCE

Indonesia Market Leader FMCG Company

Manager of Manufacturing System & Standardization - Manufacturing Excellence Mar 2026 - Present

- Spearhead factory operational standardization and strict quality execution discipline across 5 high-volume manufacturing plants to ensure production efficiency and safety compliance.
- Collaborate cross-functionally with Production, Engineering, QC, and R&D teams to bridge stringent pharmaceutical-grade quality rigor with fast-paced FMCG execution.
- Design and strictly enforce cross-contamination prevention protocols and material segregation, ensuring 100% adherence to regulatory and internal safety standards.
- Key Achievement: Fostered a proactive problem-solving culture by implementing Autonomous Maintenance (AM), reducing operational downtime, and restructuring manpower utilization to drive down labor costs.

PT Bio Farma (Persero)

Manager of Manufacturing Excellence - Integrated Supply Chain Division Sep 2023 - Mar 2026

- Directed group-level manufacturing operations and integrated supply chain strategies across a multi-site (10 manufacturing site) network producing highly regulated portfolios (vaccines, APIs, cosmetics, and herbal products).
- Managed capacity planning, facility monitoring (OEE, Utilization, OTD), and continuous improvement initiatives across diverse portfolios, including vaccines, APIs, cosmetics, and herbal products.
- Reconfigured processes and resources to optimize operational workflows, integrating data from IoT-based building and facility systems to ensure real-time machinery performance metrics.
- **Key Achievement:** Coordinated Lean Manufacturing synergies across the holding, successfully reducing overall operational downtime by up to 8%.
- **Key Achievement:** Successfully increased productivity in the vaccine packaging line by over 100%.

PT Bio Farma (Persero)

Manager of Solution Quality Assurance and Delivery - SBU Digital Health Care Mar 2023 - Sep 2023

- Developed and implemented comprehensive GAMP5-based Quality Assurance guidelines for corporate digital applications, ensuring robust Data Integrity across manufacturing operations.
- Led the rigorous validation (IQ/OQ/PQ) and release of GxP and non-GxP systems, ensuring all pharmaceutical quality standards and regulatory compliance were meticulously met.
- Managed the end-to-end software release lifecycle to safeguard regulatory compliance and data integrity across quality and production platforms.

PT Kimia Farma Tbk

Assistant Manager of Manufacturing System and Control - Plant Banjaran

Jun 2020 - Mar 2023

- Led the design, development, and validation of Manufacturing Systems & Controls, managing a cross-functional team of 20+ personnel across IT, Pharmaceutical, and Engineering departments.
- Directed the qualification and validation of GxP digital applications, overseeing QMS, eBR, and LIMS implementations.
- Acted as the primary Project Leader for regulatory compliance and audit readiness, including the planning and design of a new cosmetic facility (FS, Engineering Design, and URS released in less than 1 year).
- **Key Achievement:** Pioneered the first Data Integrity and CSV framework in Kimia Farma, which was successfully released and approved during WHO audits with zero critical findings.
- **Key Achievement:** Successfully released eBR (electronic Batch Record) and QMS systems, securing official approval from BPOM auditors.
- **Key Achievement:** Decreased planned downtime in the tablet production line by 40% utilizing Lean Six Sigma methodologies (BPOM approved).

PT Kimia Farma Tbk

Supervisor of Commissioning and Validation - Pembangunan Pabrik Baru

Nov 2017 - Jun 2020

- Led installation, commissioning, qualification, and validation (IQ/OQ/PQ) for civil works, machineries, and critical utilities for a greenfield pharmaceutical facility with a team of 15+ personnel.
- Managed the design, installation, and validation for SCADA-based critical utilities and production machineries, as well as LIMS-based laboratory equipment.
- **Key Achievement:** Acted as the Project Leader for BPOM Certification, successfully achieving operational BPOM GMP certification 3 months ahead of the target schedule.

PT Fonko International Pharmaceutical (Dexa Medica Group)

Quality Specialist

2017

- Executed meticulous qualification of aseptic sterile production equipment and critical laboratory instruments in strict accordance with GMP guidelines.
- Continuously monitored HVAC/EMS, water treatment systems, and stability/storage chambers to support pristine quality operations.

EDUCATION

- **Master of Business Administration** (Operational Management) | Tanri Abeng University | 2022–2024
- **Apothecary Profession** (Production & Quality Control) | Institut Teknologi Bandung | 2016–2017
- **Bachelor of Pharmacy** (S.Farm) | Universitas Jember | 2011–2015
 - 2nd Place, Most Outstanding Student – Faculty of Pharmacy
 - Student Executive Body President (BEM), 2014

ADDITIONAL INFORMATION

- Lean Six Sigma Practitioner
- Experienced in vaccine, API, pharma, cosmetic, and FMCG, highly regulated and high-volume manufacturing environments
- Strong exposure to BPOM, ISO, WHO, GMP, and other regulatory standards
- Manufacturing Systems: ERP (SAP), MES, eBR, SCADA Automation.
- Fluent professional English
- Willing to be placed in Sukabumi, West Java