

apt. SYARIFAH FADHLIRA HADDELINE, S.Farm

Licensed Pharmacist | Quality Systems Supervisor | GMP Compliance & Quality Excellence

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PROFESSIONAL SUMMARY

Licensed Pharmacist and Quality Management System Supervisor with over 3 years of experience in pharmaceutical manufacturing and GMP-regulated environments. Proven experience in building Quality Management Systems for new manufacturing facilities, developing GMP procedures, leading investigations, managing CAPA programs, conducting supplier qualification, and supporting regulatory compliance activities. Recognized for strong analytical thinking, problem-solving capabilities, and the ability to drive sustainable quality improvements through a risk-based approach. Passionate about continuous learning and aspiring to advance as a Quality Assurance and Quality Systems leader within a global pharmaceutical organization.

KEY ACHIEVEMENTS

- Contributed to the establishment of the Quality Management System for a newly established pharmaceutical manufacturing facility.
- Developed and implemented 20+ GMP procedures and quality documents to support operational readiness and compliance.
- Managed supplier qualification activities for 15+ suppliers and supported regulatory inspection CAPA programs involving hundreds of supporting evidence records.
- Promoted from QMS Staff to QMS Supervisor within approximately 2 years based on performance and contribution to quality system development.

CORE COMPETENCIES

- GMP Compliance
- Quality Management System
- CAPA
- Risk Assessment
- Internal Audit
- Eksternal Audit
- Supplier Qualification
- Change Control
- Product Recall
- Investigation
- Root Cause Analysis

PROFESSIONAL EXPERIENCE

PT CAHAYA MANDIRI FARMA

QMS Supervisor | 2025 – Present

- Lead Product Quality Review (PQR), In-Process Control (IPC), Continuous Improvement, Waste Management, and Pest Control functions to ensure sustainable GMP compliance and quality system effectiveness.
- Provide oversight for investigations, risk assessments, CAPA implementation, and quality system performance monitoring.
- Drive continuous improvement initiatives and support strategic quality decision-making across multiple departments.
- Maintain audit readiness and support regulatory inspections through effective quality system governance.

QMS Staff | 2023 – 2025

- Played a key role in establishing and developing the Quality Management System for a newly established pharmaceutical manufacturing facility.
- Developed and implemented more than 20 GMP-related SOPs and quality procedures to support operational readiness and compliance.
- Managed approximately 20 deviations annually, including investigation, root cause analysis, risk assessment, and CAPA implementation.
- Coordinated CAPA activities arising from regulatory inspections and quality audits, managing hundreds of supporting evidence documents to ensure timely and effective closure.
- Performed supplier qualification and risk assessment activities for more than 15 suppliers, strengthening supplier quality oversight and compliance.
- Led 2 internal audits and participated as an internal auditor in multiple cross-functional audit programs.
- Managed Change Control processes to ensure controlled implementation of facility, process, equipment, and documentation changes.
- Handled product complaints and recall activities in accordance with GMP and company requirements.
- Served as PIC for Pest Control and Waste Management programs, ensuring compliance with quality and environmental standards.
- Conducted trend analysis of critical support systems and quality metrics to identify risks and drive continuous improvement initiatives.
- Coordinated Toll In Manufacturing, Toll Out Manufacturing, and Toll Non-Manufacturing activities while maintaining compliance with established quality requirements.

PT LESSENTIAL

QMS Staff | 2022 – 2023

- Supported batch record review and product release activities to ensure only compliant products were released to the market.
- Performed bulk and finished product release processes in accordance with approved quality standards and procedures.
- Generated Product Quality Review (PQR) reports and trend analyses to support data-driven quality monitoring and decision-making.
- Issued Certificates of Analysis (CoA) and maintained quality documentation to support product traceability and regulatory compliance.
- Coordinated waste management activities, including third-party waste disposal oversight, ensuring compliance with applicable regulations.
- Supported manufacturing operations through timely preparation and control of production documentation and batch records.

EDUCATION

- Professional Pharmacist Program (Apt.)
Universitas Andalas
2021
- Bachelor of Pharmacy (S.Farm.)
Universitas Andalas
2020

LICENSES

- Registered Pharmacist (Apoteker)
- Active STRA

LANGUAGES

- Indonesian – Native
- English – Intermediate