

YENNY SOESANTO



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QA COMPLIANCE | DEVIATION & CAPA SPECIALIST | PHARMACIST

Licensed Pharmacist and Quality Assurance Professional with more than 10 years of experience in pharmaceutical manufacturing environments, specializing in GMP/CPOB compliance, deviation management, complaint investigation, CAPA management, quality risk management, data integrity, audit readiness, and continuous improvement.

Proven experience in leading cross-functional investigations, performing root cause analysis, implementing CAPA effectiveness programs, managing quality documentation systems, and supporting regulatory inspections. Strong expertise in GMP, GDP, ALCOA principles, quality trend analysis, risk assessment, and compliance monitoring within multinational pharmaceutical organizations.

Recognized for driving sustainable quality improvements, strengthening compliance culture, and collaborating effectively with Manufacturing, Quality, Engineering, Supply Chain, and Regulatory stakeholders.

EXECUTIVE HIGHLIGHTS

- More than 10 years of pharmaceutical quality and compliance experience.
- Led Data Integrity program across 6 departments involving 215 employees.
- Successfully closed 25 audit observations through structured remediation programs.
- Successfully coordinate mock recall on site including remediation to prevent product recall.
- Achieved zero critical Data Integrity findings during audits and inspections.
- Supported successful CPOB certification for manufacturing operations.
- Contributed to successful TGA certification supporting exports to Australia and New Zealand.
- Reduced operational deviations and incidents by 30%.
- Certified ISO 9001 Lead Auditor and Six Sigma Green Belt.

CORE COMPETENCIES

- GMP and GDP Compliance
- Quality Management Systems (QMS)
- Regulatory Audits
- Product Complaint Investigation
- Product Recall Management
- Data Integrity Governance
- CAPA Management
- Technical Writing
- AI-Assisted Data Analysis
- Cross Functional Collaboration
- Root Cause Analysis (RCA)
- Risk Assessment
- Quality Risk Management (QRM)
- Deviation Management

QUALITY RISK MANAGEMENT EXPERTISE

- Risk Assessment using Quality Risk Management principles.
- Root Cause Analysis using Fishbone Diagram and 5 Why methodologies.
- CAPA Development and Effectiveness Verification.
- Trend Monitoring and Preventive Action Planning.
- Data Integrity and ALCOA Compliance.
- Investigation Report Writing and Technical Documentation.

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PROFESSIONAL EXPERIENCES

PT ORGANON PHARMA INDONESIA

PRODUCTION COMPLAINT INVESTIGATION SPECIALIST

APRIL 2020 – AUGUST 2026

Key Achievements:

- Improved deviation closure compliance from 75% to 98% by introducing investigation tracking, cross-functional review meetings, and CAPA monitoring systems.
- Reduced repeat deviations by 50% through enhanced root cause investigations using Fishbone, 5 Why, and risk assessment methodologies.
- Successfully led remediation activities and closed 25 audit observations through effective investigation, CAPA implementation, and compliance monitoring.
- Improved complaint investigation turnaround time from 30 days to 15 days while maintaining investigation quality and regulatory compliance.
- Reduced recurring product complaints by 40% through trend analysis, root cause investigation, and preventive improvement initiatives.
- Collaborate with Production and Engineering related to implementation of improvements and corrective actions to reduce recurring product complaints.
- Achieved 100% traceability during mock recall exercises within the required timeframe and improved site recall readiness.
- Developed deviation trending dashboards to identify recurring issues, enabling proactive corrective and preventive actions.
- Improved CAPA effectiveness rate from 80% to 95% through structured effectiveness verification and risk-based monitoring.
- Supported successful GMP inspections with zero critical observations related to deviations, complaints, and CAPA management.

PT MERCK SHARP DOHME PHARMA

OPERATION SUPERVISOR

2012–2020

Key Achievements:

- Reduced manufacturing deviations by 30% through implementation of structured root cause analysis, CAPA effectiveness reviews, and operator retraining programs.
- Improved OEE from 72% to 83% while maintaining GMP compliance.
- Supported successful CPOB and TGA certification programs through effective quality oversight and compliance management.
- Collaborated with QA teams on deviation investigations, CAPA implementation, and audit readiness programs.

EDUCATION & CERTIFICATIONS:

- Bachelor of Pharmacy – University of Surabaya
- Professional Pharmacist Program – University of Surabaya

Certifications:

- ISO 9001:2015 Lead/Internal Auditor (2026)
 - Six Sigma Green Belt
 - ISO 14001:2015 & ISO 45001:2018 Internal Auditor
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