

apt. Regita Soraya Andina, S.Farm

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Profile Summary

Industrial Pharmacist with 5 years of experience in Pharmaceutical Industry, FMCG and contract manufacturing. Specializing in pharmaceutical, personal care, medical device and oral care production. Experienced in production operations, GMP compliance, quality systems, risk management, deviation investigation, CAPA, change control, validation, and continuous improvement initiatives. Demonstrates strong critical thinking, strategic problem solving, and risk based decision making while driving operational excellence and regulatory compliance. Proven ability to lead cross functional projects, optimize manufacturing processes, and deliver sustainable business improvements through digitalization and Lean methodologies.

Education

Universitas Pancasila	Jakarta, Indonesia
Apothecary Student	2020-2021
GPA : 3.93 out of 4.00 (Cumlaude)	
Bachelor’s Degree of Pharmacy	2016-2020
GPA : 3.44 out of 4.00	
Thesis : <i>Formulasi sediaan kapsul nanopartikel fucoxanthin dari rumput laut coklat sebagai antikolesterol yang di uji secara in vivo</i>	

Recent Professional Experiences

Meiyume Manufacturing Indonesia	Jakarta,Indonesia
Senior Supervisor Production	June 2025- now
• Lead end to end manufacturing operations for oral care products, ensuring achievement of Safety, Quality, Delivery, Cost, and People (SQDCP) targets while maintaining full compliance with GMP, GDP, and regulatory requirements. • Drive quality culture by ensuring production processes comply with quality management systems, customer requirements, data integrity principles, and Good Documentation Practices (GDP). • Lead investigations for deviations, non conformances, customer complaints, and operational issues using structured Root Cause Analysis (RCA), risk assessment, and CAPA methodologies to ensure effective and sustainable corrective actions. • Collaborate with Quality Assurance, Engineering, Supply Chain, Validation, and Regulatory teams to manage change controls, validation activities, process improvements, and new product implementation. • Conduct comprehensive risk assessments (FMEA, HACCP, and Quality Risk Management) to identify manufacturing risks and implement preventive controls that enhance product quality and process robustness. • Act as the production representative during customer audits, regulatory inspections, and internal audits by demonstrating compliance with GMP requirements and ensuring timely closure of audit observations. • Lead cross functional continuous improvement and Lean Manufacturing initiatives to improve productivity, reduce waste, strengthen compliance, and enhance manufacturing efficiency. • Manage production performance through KPI monitoring, trend analysis, and data driven decision making to support operational excellence and quality objectives. • Develop and coach production teams through competency development, performance management, GMP training, and quality awareness programs to foster a high-performing and compliance-focused organization. • Support technology transfer, process validation, qualification activities, and new product launches while ensuring manufacturing readiness and quality compliance. • Lead digitalization initiatives to improve production documentation, workflow efficiency, data visibility, and operational control through automation and digital solutions. • Ensure effective communication and collaboration with customers and internal stakeholders to maintain high service levels, regulatory compliance, and successful project execution.	

AstraZeneca Indonesia**Cikarang, Indonesia****Production Specialist**

Aug 2021- June 2025

- Leading the production end to end process with production staff or operators to ensure that they are completing tasks correctly, safely, and on schedule.
- Review daily batch commercial production record.
- Create Working Instruction, SOP, Batch Record, etc.
- Create CAPA during Deviation or Quality Event, Create and Manage Change Control, Risk Assessment.
- Perform Self Inspection and Audit.
- Execute Qualification New Equipment or entities.
- Coordinating with other department (i.e Engineering, Quality Logistic, Warehouse, etc).
- Maintaining inventory of parts and materials needed for production.
- Execute project related to production area (OEE Improvement, Digitalization, Simplification documentation).
- Execute material improvement for production process with Technical Services and Quality Dept
- Recording production data, such as machine settings and work hours, to track production costs and labor efficiency using SAP.
- Coordinate and participate in Kaizen cost improvement activities.
- Utilize Kaizen to promote any possible change points need to standardize work or job area.

Bimbel VFK**Jakarta, Indonesia****Tutoring Teacher**

Des 2021 – Dec 2023

- Guiding around 200 students every semester in preparation for the UKAI exam for apothecary profession

Achievements**Lean Award – HY2 2024 | AstraZeneca Indonesia**

- Recognized for leading a Lean improvement project to **reduce production setup and startup time**, resulting in improved equipment availability, enhanced Overall Equipment Effectiveness (OEE), and increased manufacturing efficiency.

Safety Award – Q1 2025 | AstraZeneca Indonesia

- Awarded **Best Hazard Identification Observation** for proactively identifying potential workplace hazards and implementing preventive actions that strengthened safety culture and supported a zero-incident working environment.

Digitalization Award – Q1 2025 | AstraZeneca Indonesia

- Recognized for driving digital transformation by implementing **Digital Logbooks**, digitizing operational forms using **Tulip**, and developing **Low-Code/No-Code applications** to improve documentation accuracy, workflow efficiency, data visibility, and operational compliance.

Skills

SAP, QAD, MiniTab, SPSS, Trackwise, VeevaVault Quality, Power Apps, Power Automate, Ms. Form, Power BI, Ms. Word, Ms. PowerPoint, Ms. Excel, Operations Manufacturing, Quality Management System, Validation and Qualification, Communication, Problem solving, Decision making, Analytical thinking, Teamwork, Leadership, Time Management.

Certified Internal Auditor; ISO 9001:2015 (Quality Management System); ISO 14001:2015 (Environmental Management System); ISO 45001:2018 (Occupational Health & Safety Management System); ISO 13485:2016 (Medical Devices Quality Management System); CPOB (Good Manufacturing Practices for Pharmaceuticals); CPAKB (Good Manufacturing Practices for Medical Devices); CPKB (Good Manufacturing Practices for Cosmetics); Good Documentation Practices (GDP); Root Cause Analysis (RCA) & Corrective and Preventive Action (CAPA).

Languages: Indonesian (Native or bilingual proficiency), English (Professional working proficiency).