

ANNISA SILMI HANIFAH

Bachelor of Pharmacy | Pharmaceutical Manufacturing & Quality Control

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PROFESSIONAL SUMMARY

Pharmacy graduate with 8+ years of experience in pharmaceutical manufacturing, quality control, and aseptic operations in GMP-regulated environments. Specialized in environmental monitoring within sterile and cleanroom facilities, including microbial sampling, aseptic process compliance, and regulatory documentation. Proven track record in supporting GMP audits, maintaining product quality, and ensuring regulatory readiness at leading Indonesian pharmaceutical companies.

WORK EXPERIENCE

PT. Bio Farma (Persero)

April 2021 – Present

Operator Production & Quality Control | Bandung, Indonesia

Aseptic Operations

- Qualified as an Aseptic Operator through participation in media fill processes, demonstrating compliance with sterile manufacturing standards.

Quality Control – Environmental Monitoring

- Conducted environmental monitoring (EM) sampling in classified cleanrooms, ensuring full compliance with GMP and aseptic processing standards.
- Executed sampling procedures for environmental monitoring in strict accordance with approved SOPs and regulatory guidelines.
- Maintained accurate EM documentation and reports to support GMP audits and regulatory inspections.
- Monitored sterile manufacturing environments consistently to uphold product safety and contamination control within vaccine production areas.
- Supported implementation of environmental monitoring programs to ensure ongoing compliance and product integrity.

PT. Kimia Farma (Persero)

September 2018 – September 2020

Staff – Quality Assurance & Packaging Administration | Bandung, Indonesia

Quality Assurance

- Managed quality assurance activities including product complaint handling in accordance with GMP and national regulatory requirements.
- Handled drug product registration and marketing authorization renewal processes in compliance with BPOM regulatory standards.

Packaging Administration

- Coordinated administrative functions for secondary packaging operations within a pharmaceutical manufacturing environment.
- Ensured availability of primary and secondary packaging materials and leaflets to support uninterrupted packaging operations.
- Oversaw secondary packaging processes to ensure products were properly packed and prepared for distribution.
- Managed workforce scheduling and payroll administration for temporary packaging staff to maintain operational efficiency.

EDUCATION

Bachelor of Pharmacy (B. Pharm)

October 2021 – October 2025

University of Al Ghifari — Bandung, Indonesia

Part-time / evening program while working full-time at PT. Bio Farma

Vocational High School – Pharmacy Major

2017

SMKN 7 Bandung — Bandung, Indonesia

Foundation in pharmaceutical production processes and hospital pharmacy services.

PUBLICATION

Research Journal – October 2025

"Antibacterial Activity of Extract and Fractions of Yellow Shrimp Plant Leaves (Pachystachys lutea L.) Against Staphylococcus aureus and Escherichia coli."

CORE COMPETENCIES

Aseptic Operations | Environmental Monitoring (EM) | Good Manufacturing Practices (GMP) | Sterile Manufacturing Operations | Aseptic Processing Compliance | Quality Control Sampling & Documentation | Cleanroom Monitoring | Pharmaceutical Packaging Operations | Quality Assurance Support | Regulatory Compliance (BPOM)

TECHNICAL SKILLS

Microsoft Word | Microsoft Excel | SAP (System Analysis Product) | LIMS (Laboratory Information Management System)