

# MAHARANI AYU VIDYANNISA

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Bekasi, West Java, 17422

## Executive Summary

Pharmacist with over two years of experience in GMP and GxP regulated pharmaceutical industry, supporting quality compliance, operational excellence, and continuous improvement. Hands-on experience in qualification and validation, GMP document lifecycle management, product quality complaint investigations, risk-based decision-making, and change control governance. Skilled in cross-functional collaboration, data-driven approaches, and digital lean projects. Demonstrated agility in fast-paced, highly regulated environments, consistently simplifying complex quality processes to improve efficiency and compliance. Maintained a strong GMP compliance record with zero major deviations and no critical audit findings.

**Technical Tools:** electronic QMS (Veeva Vault) | Power BI-SPC Charts | Manufacturing Operations Platform (Tulip) | Microsoft Office (Advanced) | ERP System (SAP & Oracle)

## Work Experiences

### AstraZeneca Indonesia – Cikarang Site

Quality Assurance Specialist

Dec 2025 – Present

- Led the migration of electronic batch records and logbooks, serving as Change Control Owner and driving cross-functional alignment, managing risk, and developing new ways of working.
- Managed IQ/OQ qualification activities for new manufacturing lines, from protocol development and test execution to final reporting.
- Support the creation of protocol and design of experiments (DoE) trial-packing validation.
- Managed GMP document lifecycle, including revision as per gap assessment, periodic review, and archiving, to maintain data integrity within ALCOA++ principles.
- Facilitate investigation of Product Quality Complaints (PQC), ensuring timely investigation, root cause analysis, and CAPA to maintain patient safety and compliance.
- Managed GMP regulatory submissions and notifications to BPOM through the e-Atensi system.
- Analyzed quality performance trends and prepared quarterly reports to support Site Management Review.

Production Specialist (Packing Blister Line)

Apr 2025 – Oct 2025

- Qualified to perform line clearance, batch start up and closure, in process control, challenge test, and visual inspection activities.
- Review daily batch records and OEE to drive continuous improvement and operational excellence. Succeed to maintain OEE up to 80% while maintained zero major non-conformances in production area.
- Led team of 14 operators, maintaining training-certification, and managed schedule.
- Managed the timely closure of deviations, CAPAs, and effectiveness checks.
- Performed routine check of housekeeping, cleanliness, and safety in production area.

### PT. Ferron Par Pharmaceuticals

Purchasing Executive

Apr 2024 – Oct 2024

- Oversaw end-to-end purchasing of 300+ packaging materials, managing PR-to-PO cycles, monitoring outstanding orders.
- Drove estimated IDR 250M cost savings by leveraging supplier negotiation and demand forecasting analysis.
- Work closely with Packdev to handle development and change control of commercial artwork.
- Collaborate with cross-functional teams (PPIC, QA, and vendors) to resolve material defects, implement external CAPA, maintain quality and supply continuity.
- Managed vendor risk assessment, conducted monthly supplier performance evaluations, and served as co-auditor in vendor audit within QA team.

## Education Background

### Universitas Gadjah Mada

Apothecary Program (Apt.) – GPA: 3.88/4.00 (Graduated with honors)

Aug 2022 – Sep 2023

Bachelor of Pharmacy (S.Farm) – GPA: 3.52/4.00 (Graduated with honors)

Aug 2018 – Aug 2022

## Leadership, Research & Community Experiences

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### **Organizing Committee 22<sup>nd</sup> Asia Pacific Pharmaceutical Symposium of International Pharmaceutical Student Federation (IPSF), Yogyakarta 2023**

Coordinated Media & Publishing for a week-long international pharmaceutical symposium, ensuring broad international visibility and engagement.

### **Laboratory Assistant, Faculty of Pharmacy, Universitas Gadjah Mada (2020-2022)**

Supported teaching and assessment technical lab activities in Food, Drug, and Cosmetic Analysis; Liquid and Semi-Solid Formulation Technology; Chromatography; Immunology; and Molecular Biology.

### **Research Enumerator, SETARA Institute, on May-Jun 2022**

Conducted field interviews and survey-based data collection for a national research project, ensuring data quality and timely completion.

### **KKN-PPM Universitas Gadjah Mada, Tanjung Jaya, Banten, 2021**

- As coordinator of Sponsorship, led team of four to secured project funding through proposal development, stakeholder engagement, and sponsor negotiations, achieving budget targets.
- As medical team, delivered community health education on sanitation and COVID-19 prevention.

### **Researcher at Ministry of Research and Development BEM KM UGM (2019-2020)**

Conducted quantitative and qualitative research and published 50+ research-based insights to support student-focused policy recommendations.

## Honors and Awards

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- **Top 5 Finalist Asia-Pacific Region – IPSF APRO Focus Project: Change4SDGs (Aug 2020)**

*Developed artwork packaging for the visually impaired, combining functional design and sustainability.*

- **2<sup>nd</sup> Runner Up, Compounding Event – Pharmacy Olympic IPSF Asia-Pacific Region (Dec 2020)**

*Designed an oral liquid dosage form, including dose calculation and formulation design.*

- **2<sup>nd</sup> Winner Business Competition – Hari Ilmiah Farmasi, Faculty of Pharmacy UGM (Sep 2019)**

*Developed a comprehensive business proposal covering product design, manufacturing process, creation of the prototype, and feasibility of business analysis.*