

ARIANI PUSPA WIDIYANINGSIH

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Professional Pharmacist with 2 years of experience in pharmaceutical manufacturing, specializing in Computerized System Validation (CSV), Process Validation (PV), Equipment Qualification (IQ/OQ/PQ), Cleaning Validation, and Calibration. Experienced in GMP compliance, GDP, risk assessment, CAPA, Change Control, and cross-functional manufacturing operations, with a strong focus on quality, efficiency, and continuous improvement.

Work Experiences

PT Darya-Varia Laboratoria Tbk.

Aug 2024 – Now

Validation Pharmacist (Staff)

- Accelerated process validation timelines by 85% (from 12-16 weeks to 2 weeks) by optimizing project planning and cross-functional coordination, while maintaining full GMP compliance and successfully delivering 14 validation protocols, 33 batch executions across 13 products, and 21 validation reports.
- Led the end-to-end Computerized System Validation (CSV) lifecycle in accordance with GAMP principles, completing 3 validation protocols, 20 execution runs, and 13 validation reports. Streamlined documentation workflows, reducing the average protocol and report completion time from 3 months to less than 1 month while ensuring regulatory compliance, and ALCOA+ data integrity.
- Executed end-to-end equipment qualification (IQ/OQ/PQ), delivering 7 protocols, 13 execution runs, and 6 qualification reports to support manufacturing readiness and regulatory compliance.
- Studied and observed Cleaning Validation activities, including the application of Permitted Daily Exposure (PDE) principles, strengthening understanding of cleaning validation requirements in pharmaceutical manufacturing.
- Reviewed calibration procedures, acceptance criteria, and documentation for GMP-regulated equipment to ensure compliance with established standards.
- Successfully managed and closed 63 Quality Management System (QMS) processes (38 Change Controls and 25 CAPAs) through structured root cause analysis, and cross-functional collaboration, strengthening quality systems and operational reliability.
- Performed regulatory gap assessments and optimized 6 SOPs to improve compliance, process consistency, and operational efficiency.
- Developed the company's first CSV Matrix and facilitated GxP risk assessments, establishing a standardized validation framework that enhanced governance and audit readiness.
- Supported internal and external GMP audits (BPOM and LPH) by preparing validation evidence, resolving compliance gaps, and contributing to continuous improvement initiatives.
- Delivered the 2025 and 2026 Master List Equipment on schedule, enhancing qualification planning, calibration management, and asset traceability.
- Investigated and documented deviations identified during process validation, CSV, and qualification, performing root cause analysis and supporting Corrective Action and Preventive Action (CAPA).
- Coordinated cross-functional teams (Production, QA, QC, Engineering, and PPIC) to ensure timely execution of process validation, CSV, and qualification projects while fostering effective collaboration

Outlier

Jun 2024 – Dec 2024

AI Training for Indonesian Writers (Freelance Daily)

- Evaluated and refined AI-generated Indonesian content to enhance linguistic quality, factual accuracy, and contextual relevance.
- Assessed AI-generated responses against project guidelines, ensuring consistency, coherence, and adherence to quality standards.
- Provided structured feedback and data annotations that contributed to improving AI performance in Indonesian language understanding and content generation.
- Applied critical thinking and attention to detail to identify linguistic, logical, and contextual inaccuracies.
- Thrived in a fast-paced, remote environment by consistently meeting quality benchmarks and project deadlines while adapting to evolving guidelines.

PT Dankos Farma (a Kalbe Company)

Feb 2024 – Mar 2024

Production Qualification (Internship)

- Initiated and developed a digital reporting system that improved the efficiency and accuracy of qualification documentation, successfully validating its performance using Tunnel Machine Performance Qualification data.
- Assisted in the creation and execution of PQ protocols for Autoclave and Tunnel Machines, contributing to equipment validation and GMP-compliant manufacturing readiness.

- Prepared Performance Qualification (PQ) protocols for Washing Machines, Tablet Printing Machines, Mixing Tanks, and NBL Lockers to support equipment readiness and process reliability.
- Optimized environmental monitoring documentation by redesigning microbial monitoring layouts and revising sampling point plans for Class A, B, and C aseptic manufacturing areas.
- Completed comprehensive training in GMP (CPOB), Halal Assurance System, and production qualification processes while developing a strong understanding of USP, Farmakope Indonesia (FI), GLP, and GCP guidelines.
- Collaborated with cross-functional teams to support qualification activities and strengthen manufacturing quality and compliance.

Bioz Inc.

Jan 2024 – Feb 2024

AI Training Scientific Article Data Reviewer (Freelance Daily)

- Reviewed and evaluated scientific literature from multiple research databases to ensure data accuracy, relevance, and consistency for AI model training.
- Analyzed scientific content with strong attention to detail, identifying inaccuracies, inconsistencies, and opportunities for data quality improvement.
- Applied critical thinking to interpret complex scientific information and ensure adherence to project guidelines and quality standards.
- Communicated findings and collaborated with project stakeholders to resolve data quality issues and improve annotation consistency.
- Strengthened scientific literature analysis, research evaluation, and evidence-based decision-making skills through the review of diverse scientific publications.

Pharmacy Faculty of Universitas Gadjah Mada.

Feb 2021 – Feb 2023

Biochemistry Laboratory Assistant; Drug, Cosmetic, and Food Analysis Laboratory Assistant; Experimental Pharmacology and Toxicology Laboratory Assistant; and Physical Pharmacy Laboratory Assistant

- Facilitated undergraduate laboratory sessions across multiple pharmaceutical disciplines, ensuring compliance with laboratory procedures and safety standards.
- Guided students in experimental techniques, scientific data analysis, and interpretation of laboratory results.
- Evaluated laboratory reports and provided constructive feedback to strengthen scientific writing, analytical thinking, and data interpretation skills.
- Assisted in laboratory preparation, instrument readiness, reagent management, and practical session coordination to ensure smooth laboratory operations.
- Strengthened expertise in biochemistry, pharmaceutical analysis, physical pharmacy, pharmacology, toxicology, and cosmetic and food quality evaluation through hands-on laboratory experience.

Education Level

Apothecary, Universitas Gadjah Mada

Aug 2023 – Aug 2024

- GPA: 3.87

Bachelor’s Degree with Major in Pharmacy, Universitas Gadjah Mada

Aug 2019 – Aug 2023

- GPA: 3.68
- Thesis: The Development of Real-time Polymerase Chain Reaction Using Species-Specific Primer Targeting on Cytochrome-b for Identification of Canine Meat in Mackerel Meatballs for Halal Authentication.

Organizational Experience

Start Date	End Date	Organization Name	Position	Work Description
Jan 2023	Jan 2024	Program Kreativitas Mahasiswa (PKM) Center, UGM	Vice Chairman	• Contributed to UGM's outstanding achievement at the National Student Scientific Week (PIMNAS), where the university earned 11 Gold, 9 Silver, 9 Bronze medals, and 1 Honorable Mention through effective coordination and operational support. • Assisted the Chairman in leading and coordinating organizational activities involving 45+ committee members, ensuring effective collaboration and successful program execution. • Served as the primary liaison between students, faculty members, and the Directorate of Student Affairs, facilitating clear communication and stakeholder engagement. • Oversaw the Data & System Information and Facilitator divisions, coordinating technical operations, monitoring project progress, and supporting team performance.
Jan 2022	Jan 2023	Program Kreativitas Mahasiswa (PKM) Center, UGM	Data & System Information Staff	• Collaborated with a team of 5 members to collect, organize, and maintain data from PKM student teams and academic supervisors, ensuring data accuracy and accessibility. • Managed and prepared technical documents and administrative materials to support the efficient execution of PKM preparation and submission processes. • Coordinated information flows among stakeholders to facilitate timely

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				communication and smooth operational activities.
Jan 2021	Jan 2022	BEM KM Farmasi UGM	Head Secretary	- Led a team of 6 members in managing monthly secretariat operations, improving administrative efficiency and supporting cross-departmental activities. - Collaborated with multiple departments to coordinate documentation, administrative processes, and organizational programs, ensuring smooth execution of key initiatives. - Contributed to securing over IDR 200 million in approved proposal funding through effective proposal preparation, documentation management, and coordination with internal stakeholders. - Initiated and organized the organization's first online Secretarial Webinar, attracting 100+ participants and expanding access to administrative knowledge and best practices.
Oct 2021	Dec 2021	Herba Feast by HerbHero.id	Program Associate	- Planned and coordinated educational webinar programs, including topic development, preparation of Terms of Reference (TOR), event rundowns, and supporting documentation. - Successfully organized the "The Art of Herbs in Beauty Products" webinar, attracting 200+ participants by coordinating with subject matter experts and ensuring seamless event execution. - Collaborated with internal teams and external speakers to deliver engaging, high-quality educational programs while meeting project timelines and participant expectations.
Aug 2021	Dec 2021	PORSENIGAMA, Forum Komunikasi Unit Kegiatan Mahasiswa UGM	Secretary Head	- Led 1 Secretariat member while collaborating with the Chairman to oversee organizational administration, including the preparation and management of proposals, official documents, and correspondence to ensure efficient organizational operations. - Developed and standardized the organization's Standard Operating Procedures (SOPs) for administrative processes, improving governance, consistency, and operational efficiency. - Contributed to securing IDR 606.35 million in approved proposal funding through effective proposal management, documentation, and coordination with internal and external stakeholders.
Mar 2021	Dec 2021	Pharmacious, Fakultas Farmasi UGM	Event Division Staff	- Collaborated with 5 team members to organize national pharmaceutical competitions, webinars, and talk shows, including topic development, preparation of Terms of Reference (TOR), event rundowns, and operational documentation. - Coordinated event planning and execution, successfully attracting 300+ webinar participants, 300+ talk show participants, and 26 competition teams from universities across Indonesia. - Worked closely with internal committees, speakers, and participants to ensure the successful delivery of educational and professional development programs.
Mar 2021	Oct 2021	Pelatihan Pembelajar Sukses bagi Mahasiswa Baru (PPSMB), Fakultas Farmasi UGM	Event Division Staff	- Collaborated with 10 team members to plan and organize campus orientation and introduction programs for 240+ new students, including topic development, preparation of Terms of Reference (TOR), event rundowns, and operational documentation. - Served as a presenter during the orientation program, delivering key information and engaging participants to ensure an effective and interactive onboarding experience.
Jan 2020	Jan 2021	BEM KM Farmasi UGM	Secretary Staff	- Collaborated with 6 fellow Secretariat members to manage organizational administrative documentation, ensuring accurate record-keeping, efficient information management, and smooth organizational operations. - Developed and standardized the organization's Standard Operating Procedures (SOPs) for administrative processes, improving consistency, efficiency, and governance. - Supported cross-functional departments by maintaining organized documentation and ensuring timely access to administrative resources.
Nov 2020	Dec 2020	PIMNAS 33, Direktorat Jenderal Pembelajaran dan Kemahasiswaan KEMENRISTEK-DIKTI, Republik Indonesia	Ceremonial Event Division Staff	- Served as Person in Charge (PIC) for the Welcome Dinner, coordinating the reception for the National PIMNAS Jury at Rama Shinta Garden Resto, Prambanan, and ensuring seamless event execution. - Developed the creative concepts for the Opening and Closing Ceremonies of PIMNAS 33, contributing to an event that attracted 107,000+ viewers on Universitas Gadjah Mada's official YouTube channel. - Prepared comprehensive event rundowns and coordinated with internal committees, vendors, and guest stars—including Guyon Waton and Letto—to ensure the successful execution of large-scale ceremonial events.
Aug 2020	Dec 2020	PORSENIGAMA, Forum Komunikasi Unit Kegiatan Mahasiswa UGM	Event Division Staff	- Planned and executed the Opening and Closing Ceremonies of Porsenigama, contributing to successful event delivery and attracting 9,000+ viewers on the organization's official YouTube channel. - Conceptualized and produced the "Kilas Balik" (Event Highlights) video, which received 680+ views and enhanced audience engagement through creative storytelling. - Recognized as one of the Best Event Division Staff for outstanding performance, resulting in nomination and appointment to the Head of Secretariat position for the following organizational term.
Mar 2020	Dec 2020	Pharmacious, Fakultas Farmasi UGM	Event Division Staff	Collaborated with 7 team members to plan and organize national pharmaceutical competitions, webinars, and talk shows, including topic development, preparation of Terms of Reference (TOR), event rundowns, and operational documentation.

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				Contributed to the successful execution of the events, attracting 250+ participants from universities across Indonesia through effective coordination and event management.
Mar 2020	Oct 2020	PPSMB UGM	Co-Facilitator	- Collaborated with 300+ facilitators to deliver Universitas Gadjah Mada's orientation program, introducing new students to academic systems, campus life, and extracurricular opportunities. - Mentored and facilitated a group of 20 freshmen, leading discussions, coordinating class projects, and fostering an engaging and supportive learning environment.
Mar 2020	Oct 2020	Pharmadays, Fakultas Farmasi UGM	Event Division Staff	- Collaborated with 8 team members to organize national pharmaceutical competitions and webinars, including topic development, preparation of Terms of Reference (TOR), event rundowns, and operational documentation. - Contributed to the successful execution of the events, attracting 200+ participants from universities across Indonesia through effective event planning and coordination.

Skills, Projects, & Achievements

- **Training, Lessons, Courses (2026):** Minitab (2 hours) and Internal Audit (8 hours).
- **Training, Lessons, Courses (2025):** Computerized System Validation (2 hours), Cleaning Validation (2 hours), On-going Process Verification (4 hours).
- **Project (2021):** Utilization of Red Beet Tubers (*Beta vulgaris* L.) in Food Powder Preparations as Support for Breast Cancer Therapy through Apoptosis Induction.
- **Achievement (2021):** Silver medalist of Pekan Ilmiah Mahasiswa Nasional (PIMNAS) launched by the Kementerian Pendidikan dan Kebudayaan.

Other

- **Language:** Indonesian (Active), English (Active).
- **Hard Skills/Core Competencies:** Computerized System Validation (CSV), Process Validation, Equipment Qualification (IQ, OQ, PQ), Cleaning Validation, Calibration, Scientific Literature Review, Research Documentation, Research and Development, Formulation, Technical Report Writing, CC, CAPA, RCA, Risk Assessment, Good Manufacturing Practice (GMP), CPOB, Good Documentation Practice (GDP), Quality Assurance, Quality Management System, Pharmaceutical Manufacturing, Regulatory Compliance, Data Integrity (ALCOA+), Qualification Documentation, SOP Development, GMP Audit Support, and Environmental Monitoring Documentation.
- **Soft Skills:** leadership, team coordination, cross-functional collaboration, stakeholder management, relationship building, analytical thinking, critical thinking, scientific problem solving, decision making, continuous improvement, innovation mindset, scientific curiosity, learning agility, initiative, adaptability, attention to detail, time management, organization, accountability, resilience, communication, presentation skills, public speaking, and mentoring & facilitation.
- **Software Skills:** Microsoft Office (Word, Excel, PowerPoint), Minitab, Canva, CapCut