

apt. Dela Amalia Putri, M.Farm.

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CURRICULUM VITAE

PROFESSIONAL PROFILE

Experienced Technical, Validation, and Product Development professional with over 15 years of expertise in pharmaceutical and consumer healthcare manufacturing. Demonstrated success in leading product development, technology transfer, validation programs, process optimization, and quality improvement initiatives across global and regional organizations. Recognized for delivering innovative solutions, driving operational excellence, managing cross-functional projects, and ensuring compliance with cGMP and regulatory requirements. A collaborative leader with strong project management, risk management, and stakeholder engagement capabilities, committed to advancing product quality, business performance, and continuous improvement.

CORE SKILL

cGMP, CPOB, ISO 9001, ISO 14001, OHSAS 18001, HACCP, Halal Assurance System 230000, Total Productive Maintenance, 5R, Lean Manufacturing, Quality Risk Management, Continual improvement

CAREER SUMMARY

Jan 19 - PRESENT

Technical and Validation Specialist (Technical Operation) &
VSR Administrator ASPAC (Global Kenvue)
PT. Integrated Healthcare Indonesia

Technical and Validation Specialist with extensive experience in pharmaceutical and cosmetic manufacturing environments. Expertise in technology transfer, process validation, cleaning validation, packaging validation, quality risk management, and continuous process verification. Proven track record in supporting product commercialization, driving process improvements, ensuring regulatory compliance, and managing validation programs across the Asia Pacific region. Strong knowledge of cGMP, CPOB, ISO standards, Lean Manufacturing, and continuous improvement methodologies.

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Key Responsibilities

- Lead product and technology transfer projects from R&D and other manufacturing sites to internal production facilities.
- Drive process improvement initiatives for existing pharmaceutical and cosmetic products to enhance quality, efficiency, and compliance.
- Plan, execute, and document process, packaging, and cleaning validation activities for new and existing products.
- Manage the Continued Process Verification (CPV) program to ensure ongoing process performance and product quality.
- Administer the Validation State Review (VSR) program across the Asia Pacific region under Global Kenvue requirements.
- Conduct quality risk assessments and develop risk mitigation plans for products, processes, and change controls.
- Support implementation of global and site compliance requirements related to validation and technical operations.
- Collaborate with cross-functional teams including Quality, Manufacturing, R&D, Regulatory Affairs, and Supply Chain to ensure successful project execution and regulatory compliance.

April 17 – Jan 19

Product Development (R&D) Manager

PT. Pharos Indonesia

As Product Development (R&D) Manager at PT Pharos Indonesia, I led product development activities across three internal manufacturing sites and external manufacturing partners. I was responsible for new product development and lifecycle management of pharmaceutical products in solid, semi-solid, liquid, injection, and infusion dosage forms. Additionally, I served as Project Manager for Oncology projects and led the site's Halal Assurance System certification program, ensuring compliance with regulatory, quality, and business requirements.

Key Responsibilities

- Led product development activities across all manufacturing sites, including three internal manufacturing facilities and external manufacturing partners.

- Managed the development of new products and lifecycle maintenance of existing products across various dosage forms, including solid, semi-solid, liquid, injectable, and infusion solutions.
- Directed cross-functional product development projects from concept through commercialization, ensuring compliance with quality and regulatory requirements.
- Served as Project Manager for Oncology product development initiatives, coordinating multidisciplinary teams to meet project timelines and business objectives.
- Served as Project Manager for Halal Assurance System certification, leading certification activities and ensuring compliance with halal regulatory requirements.

Collaborated with Manufacturing, Quality Assurance, Regulatory Affairs, Supply Chain, and Marketing teams to support successful product launches and continuous improvement initiatives.

Identified and implemented process improvements to enhance product quality, operational efficiency, and cost effectiveness.

Nov 09 – Apr 17

R&D Senior Supervisor
PT. Kalbe Farma

As an R&D Senior Supervisor at PT Kalbe Farma, I was responsible for the development and optimization of sterile pharmaceutical products, including infusion solutions, injection products, and hemodialysis solutions. My role encompassed formulation development, process improvement, packaging development, stability management, regulatory support, and sterilization validation, contributing to successful product launches, compliance, and cost optimization initiatives.

Key responsibility

- Developed and optimized sterile pharmaceutical formulations, including infusion solutions, injectable products, and hemodialysis solutions.
- Successfully reduced manufacturing costs by implementing process improvements and formulation optimization initiatives.
- Led packaging development projects covering primary, secondary, and tertiary packaging systems.
- Managed product stability programs and generated data to support product registration and lifecycle management.
- Executed autoclave sterilization validation studies, including bioburden and overkill approaches, ensuring regulatory compliance and product sterility assurance.
- Supported regulatory submissions through the preparation of comprehensive technical documentation and registration dossiers.

Education & Qualification

- Master of Pharmacy, Pancasila University (2018 – 2021); Graduated with a GPA of 3.86/4.00.
- Professional Pharmacy Program (Pharmacist/Apoteker), Pancasila University (2008 – 2009); Graduated with a GPA of 3.82/4.00.
- Bachelor of Pharmacy, Pancasila University (2004 – 2008); Graduated with a GPA of 3.67/4.00.

Key Achievements

- Led multiple process optimization and cost-saving initiatives, receiving awards for Filling Process Improvement, CIP Process Improvement, and Cost Reduction Projects (2025).
- Successfully managed strategic projects recognized through the Zyrtec Project Award (2025), Micro Reduce Testing Project Award (2023), and Bactidol Project Award (2023).
- Served as Project Manager for the successful implementation of Halal Certification across internal and external manufacturing sites (2017).
- Awarded Best A3 Report Improvement Project (2015) and Best Achievement A3 Report for four consecutive years (2012-2015), demonstrating excellence in continuous improvement and problem-solving.
- Honored with the Kalbe Award (2009) in recognition of outstanding academic achievement and exceptional performance upon graduation from university.