

APT., DIO GIOVANNI ARIEL, S. FARM

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PROFILE SUMMARY

Licensed Pharmacist and Sterile Manufacturing Subject Matter Expert (SME) with 4+ years of cross-functional experience in aseptic fill-finish and biopharmaceutical production. Deep technical authority in Grade A/ISO 5 cleanroom operations, EU GMP Annex 1 (2022) compliance, and continuous high-throughput vial/bag lines. Proven track record of scaling plant capacity by 80%, successfully defending processes in global health authority audits (WHO, FDA, BPOM, TGA), and leveraging data-driven lean methodologies to optimize complex biomanufacturing operations.

CORE COMPETENCIES & TECHNICAL SKILLS

- **Aseptic Operations:** Grade A/ISO 5 Cleanrooms, Lyophilization, Form-Fill-Seal (FFS), Barrier Technologies (RABS), PUPSIT, Contamination Control Strategy (CCS).
- **Quality & Compliance:** EU GMP Annex 1, FDA 21 CFR Part 211, ICH Q9/Q10, Root Cause Analysis (5-Why, Fishbone), CAPA, FMEA, Audit Defense.
- **Process Engineering & Data:** Lean Six Sigma, Process Debottlenecking, Automation & Data Analytics (Python, Pandas, Advanced Spreadsheet Dashboards).

PROFESSIONAL EXPERIENCE

Selatox Biopharma

Cikarang, Indonesia

Production Specialist (Drug Product - Aseptic Fill-Finish)

Jan 2026 – Present

- Operate and troubleshoot a high-throughput vial line, overseeing continuous operations across the Vial Washing Machine, Depyrogenation Tunnel, Vial Filler, Lyophilizer and Rotary Capping machinery.
- Lead critical aseptic line configurations and complex machine setups across Grade A/ISO 5 environments, enforcing strict barrier integrity to eliminate setup-induced deviations.
- Defended critical Computer System Validation (CSV) protocols during regulatory inspections as the primary operational SME, validating machine HMIs, audit trails, and automated fill-finish parameters to guarantee strict FDA 21 CFR Part 11 compliance.
- Authored comprehensive deviation reports and led cross-functional root cause investigations utilizing 5-Why and Fishbone methodologies, driving robust CAPA execution to resolve complex operational and cleanroom failures.
- Served as the primary operational lead for the Performance Qualification (PQ) of high-speed aseptic Filling Machines and Depyrogenation Tunnels, validating equipment readiness for commercial manufacturing.
- Executed the Performance Qualification (PQ) for Filter Integrity Testing (FIT) systems, validating rigorous PUPSIT (Pre-Use, Post-Sterilization Integrity Testing) protocols to guarantee strict compliance with EU GMP Annex 1 sterile filtration mandates.

Fapon Biotech

Cikarang, Indonesia

Production Engineering (Supply Department)

Apr 2025 – Dec 2025

- Managed the complex manufacturing of CLIA platform magnetic beads, AE working solutions, and POCT products within strict GMP-regulated cleanroom facilities. Oversaw rigorous environmental monitoring (EM) data, cleaning validations, and parameter controls (standard curves/concentrations).

- Spearheaded lean manufacturing and process debottlenecking initiatives, successfully driving an 80% increase in daily production output, scaling capacity from 2,500 to 4,500 units per day.
- Acted as the primary Subject Matter Expert (SME) for Risk Assessment. Utilized ICH Q9 principles (including FMEA tools) to identify process risks, executing mitigation plans, and investigating deviations.
- Served as the designated Production SME for ISO 13485 and CPAKB audits. Engineered a robust compliance system, developing comprehensive master checklists and master document files to ensure continuous audit readiness across the production floor.

Sanbe Pharma (Sanbe Sterile Plant)

Bandung, Indonesia

Production Supervisor (U3 Sterile Production)

Jan 2022 – Mar 2025

- Directed a massive cross-functional team of 300 personnel within the U3 Sterile Production Department, driving uncompromising adherence to cGMP, HSE, and Quality Management Systems (QMS) while consistently executing high-volume production quotas.
- Served as the core Subject Matter Expert (SME) directing the Site Acceptance Testing (SAT) and qualification of 6 advanced Bag Filling lines and 2 Form-Fill-Seal (FFS) machines. Successfully spearheaded the design, setup, and operationalization of a novel double-chamber soft bag production line.
- Engineered new operational standards and a robust reject rate analysis methodology, directly resulting in a 40% increase in filling machine output (scaling from 10,000 to 14,000 units/machine/shift) while significantly reducing equipment maintenance downtime.
- Acted as the primary SME, speaker, and field officer for the sterile filling process during critical pre-certification and certification audits conducted by the WHO, Indonesian BPOM, TGA, EU GMP and international health authorities (Kenya and Ghana FDAs).
- Led immediate floor-level troubleshooting and root-cause investigations (Fishbone diagrams) for deviations. Deployed comprehensive CAPA and Change Management protocols strictly aligned with ICH Q10 frameworks to maintain absolute sterility assurance.

EARLY CAREER & ACADEMIC RESEARCH

- **Research Assistant, Malaria Research Group, Brawijaya Univ. (Mar 2016 – Jan 2022):** Executed GLP-compliant biomolecular feasibility studies on *Streptomyces hygroscopicus*.
- **Pharmaceutical Intern, Daewoong Infion (Sep 2020 – Dec 2020):** Trained in cGMP compliance, QbD principles, and cross-functional operations (QA/QC/R&D).

EDUCATION

Professional Degrees of Apothecary, Brawijaya University

Jan 2020 – Feb 2021

Bachelor of Pharmacy, Brawijaya University

Aug 2015 – Dec 2019

ADDITIONAL SKILLS & CERTIFICATIONS

- **Technical & Operational Expertise:** Terminal and Aseptic Sterilization Processes, Sterile Fill-Finish Operations, Quality Risk Management (QRM), Root Cause Analysis & CAPA Execution, Production Planning, and Advanced Data Analytics (Process trending via Excel Dashboards, Pivot Tables, etc.).
- **Regulatory & Quality Frameworks:** Deep working knowledge of global cGMP regulations, EU GMP Annex 1 (2022), PIC/S PE 009, US FDA 21 CFR Part 211.113, and Korean MFDS standards. Strong proficiency in ICH Q9 (Quality Risk Management / FMEA) and ICH Q10 (Pharmaceutical Quality System).
- **Cleanroom & Contamination Control:** Expert in ISO 14644-1 classifications, execution of Contamination Control Strategy (CCS), and PUPSIT (Pre-use Post-sterilization Integrity Testing) methodologies.

- **Certifications & Specialized Training:** Advanced cGMP Compliance, QA/QC Technical Methodologies, GLP, and Pharmaceutical R&D Lifecycle Processes.
- **Languages:** Fluent in English (Professional Proficiency) and Indonesian (Native).