



INTAN PERMATASARI

Quality Assurance professional with more than 4 years of experience in the biopharmaceutical industry, currently serving as a Drug Substance (DS) Process Operation Supervisor. Known for being proactive, detail-oriented, and dependable in a fast-paced environment. Eager to grow in a global quality or compliance role with strong systems and learning opportunities.

Training & Certifications

- On-going Process Verification - 2026
- Pharmacovigilance Auditor - 2025
- Leadership Foundation - 2025
- cGMP Training Marathon by WHO - 2024
- GMP Auditor Training - 2022
- Introductory Course for Standard Practice (GxP Course) by IVI - 2023
- Microsoft Excel for Dashboard Design - 2024
- Lean Six Sigma White Belt - 2023

Recognition & Achievements

- KGM's Employee of the month - July 2024
- Candidate for KGM's Employee of the Year - 2024
- Recognized for reliability, initiative in QA activities, and effective cross-departmental coordination to support quality and compliance goals.

CONTACT INFORMATION

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EDUCATION

Pharmacist Universitas Indonesia, Jakarta

2021 - 2022 | GPA 3,60

Bachelor of Pharmacy Universitas Ngudi Waluyo, Semarang

2018 - 2020 | GPA 3,79

Theresiana Pharmacy Academy, Semarang

2012 - 2015 | GPA 3,63

WORK EXPERIENCES

PT Kalbio Global Medika (A Kalbe Company) | 2022 - Now

Jan 2025 - now DS - Process Operation Supervisor

Jan 2022 - 2024 Quality Assurance Officer

primarily responsible for the drug substance (DS) line

- **Batch Review**
 - Supported the execution of manufacturing operations by ensuring alignment with validated procedures and GMP expectations. Involved in the review of the master batch record and the executed batch record.
- **Deviation Handling**
 - Lead the deviation investigation. Collaborate with the related department to find the root cause and define the CAPA to prevent recurrence.
- **Quality Oversight**
 - Routine line inspection to control the quality unit over all GMP processes, and enhancing the quality awareness in the manufacturing area
- **Product Quality Review (PQR)**
 - Collected and analyzed process data using Minitab to evaluate trends, assess process consistency and capability, and identify opportunities for process improvement.
- **Product Complaint**
 - Conducted complaint investigations related to product quality, including root cause analysis and CAPA determination. Provided feedback to complainants and coordinated with the Pharmacovigilance team for acknowledgement of serious adverse events (SAEs).
- **Recall Management**
 - Developed and implemented procedures for product recall and mock recall activities. Responsible for planning and executing mock recall scenarios to assess recall readiness and system robustness.
- **Audit**
 - Listed as part of the internal auditor. Contributed to internal GMP and pharmacovigilance audits. Attended auditor training sessions on GMP and Pharmacovigilance principles.
 - Actively supported regulatory audits, including those from BPOM (Indonesia), MFDS (Korea), and TMMDA (Turkey) by serving as a scribe to ensure smooth communication between auditors and auditees, facilitate document retrieval, and clarify findings. Also participated as a subject matter expert (SME) for QA-related areas.