

Shofiah Nur Rohmah

Bogor, Jawa Barat | +6281317024712 | shofia.nr@gmail.com | <https://www.linkedin.com/in/shofiah-nur/>

Licensed Pharmacist with experience in product development operations, regulatory documentation, and cross-functional coordination within FMCG and healthcare industries. Experienced in supporting end-to-end product development processes, regulatory compliance (BPOM, Halal), technical documentation, and post-market activities. Detail-oriented, proactive, and accustomed to working across R&D, QA, Regulatory, and Marketing teams.

EDUCATION

University of Indonesia

Apothecary, Pharmacist Profession

- GPA 3.85 / 4.00

Depok, Indonesia

August 2023 – August 2024

University of Indonesia

Bachelor's Degree Pharmacy

- GPA 3.76 / 4.00

Depok, Indonesia

August 2019 – August 2023

WORK EXPERIENCE

PT Kino Indonesia Tbk

Product Development Specialist

Tangerang, Indonesia

October 2024 – Present

- Led coordination of product development monitoring for 50+ SKUs across health and wellness categories, ensuring full compliance with BPOM regulations, GMP standards, and quality requirements from formulation through market launch.
- Coordinated with R&D, QA&QC, RA, Production, Project, PPIC, Procurement, and Marketing for cross-functional execution of formulation changes, packaging adjustments, and product improvement, ensure adherence to quality standards and regulatory timelines.
- Handled cross-border projects involving Kino as both exporter and importer, coordinating directly with external partners (OEM manufacturers and importers) to align on product documentation, regulatory, and quality requirements.
- Support regulatory documentation and product feasibility assessment for new and existing products (local & export) including product specifications, ingredient lists, design, labels, and claims in accordance with BPOM, Halal, and export standards.
- Supported international business operations through preparation of export documentation and coordination with regulatory teams for market-specific compliance requirements.
- Collaborated with QA & QC teams in investigating and resolving product quality issues, deviations, and customer complaints, implementing corrective and preventive actions (CAPA) in alignment with GMP requirements
- Contributed to product innovation pipeline through market analysis, competitor benchmarking, and product rejuvenation initiatives to support new product development and portfolio improvement.

PT Enseval Putera Megatrading Tbk

Quality Assurance Intern

Jakarta, Indonesia

April 2024 – April 2024

- Conducted operational qualification of cold chain product facilities, including protocol development, execution, data analysis, and report preparation.
- Performed thermometer calibration and issued calibration certificates following established documentation standards and quality procedures.
- Analyzed temperature trends from data logger outputs to identify critical control points and deviations.
- Supported regulatory audit preparations through documentation review, compliance gap analysis, and implementation of corrective action plans to ensure GMP compliance.

PT Forsta Kalmedic Global

Quality Assurance Intern

Jakarta, Indonesia

November 2023 - December 2023

- Developed Installation and Operational Qualification (IQ/OQ) documents for medical device projects, including equipment specifications, testing protocols, and acceptance criteria establishment.
- Assisted in audit CAPA implementation for audit findings and compliance tracking, ensuring continuous compliance with quality management systems.
- Coordinated calibration scheduling and reporting, maintaining compliance with quality management system.
- Created and updated SOPs for manufacturing processes, waste management, and equipment maintenance.

OTHERS INFORMATION

Skills: CPOB/GMP | Quality Management Systems | Regulatory Documentation | CAPA Implementation | Project Management | Cross-functional Collaboration | Ms Office | Google Workspace

Training & Certifications: [Foundations of GMP](#) by USP | [Regulatory Affairs](#) by JadiPraktisi | [Awareness ISO 13485:2016-CPAKB](#) | [ISO 22716:2007](#) by TemanGroup | [CPPKRTB](#) by TemanGroup | [Product Management](#) by MySkill