

NURMALASARI

+62 89696486207 | March, 16 1998 | nrmala1998@gmail.com | <https://www.linkedin.com/in/nurmala16>

PROFESSIONAL SUMMARY

Pharmacist with experience in Regulatory Affairs-Distribution and Product Executive, including product registration, licensing (SKI, NIE, BPOM/MOH Distribution Permit, and BPJPH Halal Certification), and compliance with BPOM/MOH regulations, Detail-oriented with strong documentation and data handling skills. Experienced in Good Distribution Practice (GDP/CDOB, CDAKB) – Good Manufacture Practice (GMP/CDOB) and interested in process improvement and digital tools such as Excel and Power BI.

WORK EXPERIENCES

Registration Section Head - PT Samco Farma, Tangerang

Aug 2025 – Present

- Ensure product registration processes comply with BPOM regulations and applicable requirements
- Managed and prepare regulatory documents including dossier and supporting technical data
- Monitor registration timelines and coordinate with internal teams
- Handle variation, renewal, and pre-registration processes through New AeRO and ASROT systems with Monitor regulatory updates and implement corrective actions
- Manage licensing processes including SKI e-BPOM, SJPH, SIREKA, and SIAPIK system, covering product registration and advertisement approval processes
- Develop and implement SOPs for registration processes
- Review product dossiers and promotional materials (drugs & supplements), and ensure full compliance with BPOM advertising regulations before submission

Regulatory & Distribution Staff – PT Biotis Pharmaceutical Indonesia, Bogor

Feb 2025 – Jul 2025

- Handled licensing including OSS system, SKI e-BPOM, and distribution permits (PBF) in compliance with GDP/CDOB
- Handled variation, renewal, and pre-registration processes through New AeRO
- Prepared and submitted regulatory reports through LKPM (OSS), SIINas, e-Was, and SMILE systems
- Coordinated product distribution to Regional Health Office (Dinas Kesehatan)
- Develop SOPs to support regulatory and distribution processes
- Prepared and submitted regulatory documents to BPOM and related authorities
- Processed trademark & regulatory consultations with DJKI (Directorate General of Intellectual Property)
- Coordinated vaccine distribution and licensing with Ministry of Health and internal stakeholders

Person In Charge of Cosmetics Technical Affairs – CV Reyasa Nandamar Indah, Bekasi

Sept 2024 – Sept 2025

- Ensured compliance of cosmetic products with BPOM regulations and GMP standards
- Liaised with regulatory authorities for product notification and compliance
- Developed, reviewed, and maintained Product Information File (PIF/DIP) for cosmetic products
- Prepared and submitted regulatory documentation for cosmetic registration
- Prepared and submitted reports through SIINas system
- Maintained product registration and post-market compliance activities
- Coordinated with management and external partners to support contract manufacturing agreements

Product Executive – PT Sel Regenerasi Biotek, Bogor

Aug 2024 – Feb 2025

- Delivered product presentations to clients and healthcare professionals
- Conducted product training and product knowledge sessions
- Performed medical device demonstrations and usage coordination
- Supported marketing strategies and sales activities
- Handle aesthetic medical device support and usage coordination
- Conducted market research and supported product development initiatives
- Prepared promotional materials and training content
- Processed trademark & regulatory consultations with DJKI (Directorate General of Intellectual Property)

Person In Charge of Medical Device Technical Affairs – PT Clean and Well Pack Indonesia, Bogor

Jan 2022 – Des 2023

- Managed medical devices registration through OSS and Ministry of Health (MOH) system (REGALKES)
- Handled licensing including OSS system and distribution permits (PBF) in CDAKB certification & compliance
- Ensured regulatory compliance for product documentation
- Prepared and submitted reports through e-Report and SIINas systems

Registration Officer – PT Top Point Medical, Bogor

Aug 2021 – Jan 2022

- Assisted in medical device registration and documentation processes including OSS and Ministry of Health (MOH) system (REGALKES)
- Supported regulatory submission and compliance checking
- Prepared reports through SIINas, e-Report, SISPROKAL, and e-SUKA systems
- Processed trademark registration & regulatory consultations with DJKI (Directorate General of Intellectual Property)

EDUCATIONS

- Apothecary – Pancasila University : 2023-2024
- Bachelor of Pharmacy – Pancasila University : 2016-2020
- Senior High School – SMAS Daar el Qolam 2 (Program Excellent Class) : 2013-2016

SKILLS

- Regulatory Affairs (OSS, REGALKES, LKPM, SKI e-BPOM, e-Report, e-Suka, SISPROKAL, e-WAS production & Distribution, , SIINas, SMILE, New AeRo, ASROT, Notifikos, SJPH, DJKI, SIAPIK, SIREKA)
- Good Distribution Practice (GDP/CDOB), (CDAKB)
- Good Manufacture Practice (GMP/CPOB), (CPAKB), (CPKB)
- Documentation & Compliance
- Process Coordination & Regulatory Submission

LANGUAGES

- English
- Arabic