

NADIRA AGNIA EDNA

Pharmacist

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Tangerang, Indonesia



SUMMARY

Detail-focused on dossier, well-versed in government regulatory affairs, respectfully communicates problems and recommends solutions. Expert on dossier bringing 2 years of expertise in pharmaceutical industry, effectively manages assignments and team members. Dedicated to self-development to provide expectation.

EDUCATION

Ahmad Dahlan University

Bachelor of Pharmacy
Pharmaceutical Science and Technology
2014 -2019
GPA 3.37

Ahmad Dahlan University

Apothecary Program
2020 - 2021
GPA 3.55

SKILLS

- Strong organizational and time-management skills
- Ability to work independently and as part of a team
- Detail-oriented and able to handle multiple tasks
- Analytical problem-solving
- Regulatory Compliance
- Documentation
- Quality review processes

LANGUAGES

- Bahasa Indonesia (Proficient)
- English (Intermediate)

PROFESSIONAL EXPERIENCE

Registration Officer

PT. LAPI Laboratories | 01/2022 - Present

- Implemented new regulation to keep ongoing compliance, communicating new processes and regulations across relevant departments.
- Kept up-to-date knowledge and understanding of all company products to inform compliance decisions.
- Review, asses and prepare the documents needed for regulatory submissions for new, variation and renewal of local drugs, traditional medicine, health supplement and import product
- Coordinate, organize and prepare for the administrative registration document
- Ensure the registration process is done in timely manner

Documentation and Registration Project Pharmacist

PT. Phapros Tbk. | 07/2020 - 12/2021

- Compile and review document for new product registration
- Coordinated with other departments to prepare Application Letter documents
- Involved in development and improvement electronic manufacturing batch record
- Monitoring implementation of simulation electronic manufacturing batch record until application go lived
- Support validation team for computerized system validation electronic manufacturing batch record
- Trained and coached employees to use application (electronic manufacturing batch record)