

SUMMARY

Dita is a licensed pharmacist graduating from Universitas Indonesia (graduated as a cumlaude), with strong interest in pharmaceutical industry, mainly in quality assurance, regulatory affairs, product management, bussiness development, and medical. Experienced for almost 1 year in quality assurance departement as process validation supervisor, Dita is known as a contributive team member or team leader with excellent communication skill, likewise a fast learner and favorable at critical thinking as well as problem solving. She is known as someone who actively seeks new experiences and perspectives on all things. She is energetic, self-driven, and keen learner who has some experiences in managing a project, building a relationship, and learning something new quickly. It's proven by my records of participating in some extracurricular activities during my study, such as organizations, committees, and internships.

EDUCATION

University of Indonesia – Depok, Indonesia

2022 – 2023

Apothecary Professional Degree

- **GPA:** 3.84/4.00
- Obtained a perfect GPA (4.00) in 2nd Semester
- Joined as Pharmaceutical Laboratory Assistant
- Completed my 7 months internship program (Praktik Kerja Profesi Apoteker/PKPA) in 5 different places (Pharmaceutical Industry, Hospital, Drugstore, Pharmaceutical Wholesalers, and Public Health Center)

University of Indonesia – Depok, Indonesia

2018 – 2022

Bachelor of Pharmacy

- **GPA:** 3.52/4.00
- Conducted final thesis titled “Cost-Effectiveness Analysis of Ceftriaxone Injection Compared to Chloramphenicol Injection on Pediatric Typhoid Fever Inpatient at Ciawi Regional Public Hospital in 2019-2021”

WORK EXPERIENCE

PT. Harsen Laboratories – Jakarta, Indonesia

Validation Supervisor

November 2024 – now

- Establish standard operating procedures and work instructions for validation activity.
- Preparing Validation Master Plan, including the annual schedule for validation activity.
- Review validation documents, including process validation, cleaning validation, media fill validation, and transport verification.
- Supervise and validate testing parameter in accordance with international standars such as ISO and GMP.
- Coordinate with other departements to complete validation according to project timelines.
- Mitigate and apply remediation measures to existing pharmaceutical process deviations.
- Involved in continuous improvement project.

PT. Guardian Pharmatama – Bogor, Indonesia

Process Validation Supervisor

August 2023 – November 2024

- Lead process validation projects for multiple product lines to ensure compliance with regulations and industry standards.
- Process validation program development and implementation, including defining validation strategies, developing protocols, and conducting validation studies.
- Collaborate with cross-functional teams including R&D, manufacturing, quality and regulatory affairs to ensure alignment and achieve project goals.
- Monitor and analyze process performance data to identify trends and areas for improvement.
- Generate and present validation reports to senior management and regulators to demonstrate regulatory compliance and product quality.
- Recruit, qualify and train validation inspectors to ensure high levels of performance.
- Responsible as the person in charge of 6S working area.

PT.Novell Pharmaceutical Laboratories – Bogor, Indonesia

Dossier Export and International Registration

March 2023 – April 2023

- Review Compedial, CTD Guideline, Countries specific regulatory requirements and analyze the impact to the products to ensure the compliances with the requirements
- Review MBR, CoA
- Planning the timeline and strategies to develop the new dossier
- Review the raw documents both API and finished product to ensure the completeness and consistency according to the guidelines
- Supported international marketing to completed registration submission, renewal and variation projects to ASEAN and European countries
- Provided the additional documents data and answer all queries from Ministry of Health during registration renewal submission in tight deadline

PT. Kimia Farma Trading & Distribution – Bogor, Indonesia

Distribution Intern

December 2022-Januari 2023

- Conducted internal CAPA
- Conduct corrective action and preventive action based on BPOM inspection: analysis on ordering amount of narcotics and psychotropics at KFTD Bogor Branch
- Assisting consumption forecast and drugs procurement
- Developing validation master plan for chiller mapping and evaluate the function of temperature warning alarm of CCP chiller
- Assisting to make report to e-Report Kemenkes and e-Was BPOM
- Conduct a self-inspection of the Indonesian GDP Compliance - Recording of goods in and out on card stock
- Develop mapping and relocating storage area of drugs in accordance with GMP rules
- Ensure pharmaceutical products distribution in accordance with rules and regulations based on CDOB

ORGANIZATION EXPERIENCE

Student Representative Body of Faculty of Pharmacy Universitas Indonesia

Head of Human Resources

January 2019 – December 2020

- Success to run an activities “Team Building” which cannot be implemented in previous period
- Do research and evaluating work programs held by the organization
- Engage and contribute in all relevant internal activities
- Responsible for the recruitment, screening and interviewing candidates of the organization
- Work as a Controller on "PPAA FF UI 2020" known as annual event held by Faculty of Pharmacy to welcome freshman
- Responsible in creating a good and comfortable connection between members of the organization

PSAMabim FFUI (Student Orientation Program)

Deputy Head of Medical Division

April 2020 - February 2021

- Responsible to ensuring the health of new students and even's committee.
- Responsible for the availability of the remedies and first aid kits.
- Give first aid to new students or committee members who are sick.
- Responsible to provide information regarding first aid to division members
- Manage schedules and distribution of tasks for division members.

LICENSES & CERTIFICATION

- CPOB & CPOTB di Laboratorium dan Office, Nomor 197/QA-GMP/II/2024
- ISO 9001:2015, Nomor 1336/Q-GMP/XI/2023
- Cara Pembuatan Kosmetik yang Baik, Nomor 120/QA-GMP/II/2024
- Sistem Jaminan Halal, Nomor 094/QA-GMP/I/2024
- Farmakovigilans, Nomor 040/QA-GMP/I/2024

CAPABILITIES

Skills: Analytical Thinking, Pharmaceutical knowledge (concept/theory/practical of pharmaceutical subject), Communication, Microsoft Office, Leadership Team Building, Public Speaking

Languages: Native in Bahasa Indonesia and Fluent English Proficiency

