



apt. RAHMAT KARIM., S.Farm

Quality Assurance Pharmacist & Q-EHS Manager

 rahmatkarim.rk@gmail.com |  linkedin.com/in/rahmat-karim-714448aa |  Parung, Bogor, West Java

PERSONAL INFORMATION

Date of Birth : 30 December 1992
Marital Status : Married
Address : Kierana Indah Residence 1, Blok B6, Baburahman, Desa Waru, Parung, Bogor
Height / Weight : 165 cm / 72 kg
Hobbies : Basketball, Badminton, Futsal
Instagram : @rahmat_karim01

EDUCATION

Professional Pharmacist (Profesi Apoteker)

Padjadjaran University | 2014 – 2015 | GPA: 3.72 / 4.0

Practical training activities:

- Clinical Pharmacy Practice at RSUD Kota Bandung (City General Hospital)
- Community Pharmacy Practice at Kimia Farma Pharmacy No. 240, Bandung
- Industrial Pharmacy Practice at Lembaga Farmasi Angkatan Udara (Air Force Pharmacy Institute)

Bachelor of Pharmacy (S.Farm)

Padjadjaran University | 2010 – 2014 | GPA: 3.18 / 4.0

Final Research Project:

"Variant Reactions of Sodium Hydroxide Concentrate towards Microcrystalline Cellulose Production Processing from Boehmeria nivea, L. GAUD. as a Pharmaceutical Excipient"

ORGANIZATIONAL EXPERIENCE

Indonesian Health Student Network (JMKI) – Priangan Region

 2010 – 2014

Role: Member of the Regional Supervisory Board

Served on the regional supervisory board overseeing health student activities and inter-university coordination across the Priangan region.

UNPAD Pharmacy Village Development Center

 2010 – 2014

Role: Public Relations

Managed external communications and community engagement for the Pharmacy Village Development Center at Padjadjaran University.

JMKI Pharmacy UNPAD Chapter

 2010 – 2014

Role: Commissioner

Acted as commissioner of the JMKI (Indonesian Health Student Network) chapter at UNPAD Pharmacy Faculty, overseeing organizational governance and student representation.

BEM KEmafar UNPAD (Pharmacy Student Executive Board)

 2010 – 2014

Role: Community Service Staff

Organized and executed community service programs on behalf of the Faculty of Pharmacy Student Executive Board, contributing to public health outreach and social responsibility initiatives.

PROFESSIONAL EXPERIENCE

PT. Biotis Pharmaceuticals Indonesia | Bogor, West Java | January 2022 – Present

A leading Indonesian biopharmaceutical & vaccine manufacturer. Progressive career across 4+ years with concurrent and promoted responsibilities reflecting broad cross-functional leadership.

Key Achievement

- Certification of the manufacturing facility** for Cell Preparation and Expansion, Virus Inoculation and Propagation, Virus Harvesting, Inactivation, Purification, Sterile Filtration, Bulk Antigen Filling, and Bulk Ready-to-Fill Formulation and Filling of the SARS-CoV-2 Vaccine (Type: Inactivated Virus Vaccine).
- Certification of the manufacturing facility** for Homogenization, Filling, and Secondary Packaging of Small Volume Injectable COVID-19 Vaccine in Vials (Type: Recombinant Protein Nucleocapsid Protein–Receptor Binding Domain (NCP-RBD) SARS-CoV-2 Vaccine).
- Certification of the manufacturing facility** for Homogenization, Filling, and Secondary Packaging of Small Volume Injectable COVID-19 Vaccine in Vials (Type: Inactivated Virus Vaccine).
- Certification of the manufacturing facility** for Filling and Secondary Packaging of Small Volume Injectable PCV-13 Vaccine.
- Halal certification** for **INAVAC** (Inactivated SARS-CoV-2 Virus Vaccine), **Pulmeera** (13-Valent Pneumococcal Polysaccharide Conjugate Vaccine), and **Pneubevax** (14-Valent Pneumococcal Polysaccharide Conjugate Vaccine).

Q-EHS Manager (Quality, Environment, Health & Safety)

 July 2026 – Present

- Orchestrated internal and external audit programs—including scheduling, audit plan development, and CAPA follow-up—ensuring zero major non-conformances.
- Ensured full regulatory compliance with applicable laws, government regulations, and national/international standards covering quality, K3, environment, biosafety, and biosecurity.
- Led workplace risk evaluation and hazard management company-wide, developing effective control measures to minimize accidents, occupational disease, and environmental impact.
- Managed hazardous and non-hazardous waste programs (B3/non-B3), pest control, Waste Water Treatment System (WWTP), and PPE facilities across all operational areas.
- Ensured training competency of all Q-EHS personnel through systematic training planning, execution, and evaluation covering quality management, K3, biorisk, biosafety, and biosecurity.

QA Manager (Quality Assurance Pharmacist)

 May 2025 – June 2026

- Ensured implementation and establishment of the pharmaceutical quality system in full compliance with CPOB (GMP Indonesia) and applicable BPOM regulations.
- Initiated and led development of the company Quality Manual and company-wide quality documentation framework.
- Spearheaded periodic internal audits, self-inspections, and external supplier audits; evaluated and followed up on CAPA for all audit findings.
- Spearheaded qualification, calibration, and validation programs (equipment, utilities, and processes) across manufacturing operations.
- Managed batch release decisions—approving or rejecting finished pharmaceutical products for commercial distribution, assessing all quality-related factors and Marketing Authorization requirements.

- Ensured all drug batches were manufactured and tested in accordance with applicable regulatory requirements and Marketing Authorization specifications.
- Ensured technical compliance and fulfillment of BPOM regulations relating to finished product quality, including product registration and post-market surveillance.

◆ **Acting Regulatory Affairs Manager (Plt. RA Manager)** • *Concurrent Role*

 June 2025 – June 2026

- Orchestrated product registration strategies for new products and marketing authorization renewals in alignment with BPOM e-Submission requirements.
- Reviewed and submitted comprehensive registration dossiers—covering CMC, preclinical, and clinical data packages—to BPOM; monitored evaluation status through to issuance of Marketing Authorization.
- Ensured labelling, package inserts, and promotional materials complied with current regulatory requirements.
- Supported vaccine distribution activities to ensure compliance with Good Distribution Practice (GDP/CDOB).
- Conducting external reporting to BPOM (use of raw materials, production of finished products), Ministry of Industry (LKPM, SiINAS), Ministry of Health (distribution reporting, use of raw materials, production capacity) and others.

◆ **Person-in-Charge – Pharmacovigilance** • *Concurrent Role*

 June 2025 – June 2026

- Established and led the company's pharmacovigilance system, ensuring timely reporting of AEFI (Adverse Events Following Immunization) and ADR (Adverse Drug Reaction) to BPOM.
- Conducted signal detection, risk analysis, and mitigation recommendations for post-market safety monitoring.
- Managed the preparation and timely submission of PSUR/PBRER and ICSRs in accordance with national and international pharmacovigilance deadlines.

Assistant Manager – Quality Assurance

 April 2023 – April 2025

- Ensured robust implementation and continuous improvement of the pharmaceutical quality system (Sistem Mutu) across the manufacturing site.
- Initiated and supervised periodic internal audits, self-inspections, and external supplier audits; reviewed CAPA submissions and tracked corrective action effectiveness.
- Managed batch disposition decisions—approving or rejecting finished products for sale—based on comprehensive quality risk assessment and regulatory requirements.
- Spearheaded qualification, calibration, and validation programs (equipment, utilities, and processes) across manufacturing operations.
- Ensured compliance with BPOM technical requirements and all applicable regulations pertaining to finished product quality.
- Maintained direct liaison with government authorities—Ministry of Health, Regional Health Offices, and BPOM—on product quality matters.
- Supervised and mentored QA Supervisors and QA Staff; held authority to halt production processes when required; provided management cover as authorized deputy.

Halal Supervisor • *Concurrent Role*

 June 2022 – June 2026

- Orchestrated and supervised full implementation of the Halal Product Assurance System (Sistem Jaminan Halal/SJH) across the entire product lifecycle.

- Managed halal material procurement—from new raw material selection and vendor qualification to verification of halal documentation and certificates.
- Oversaw the Halal Product Process (PPH) covering personnel practices, equipment use, cleaning methods, and cross-contamination prevention in compliance with SJH requirements.
- Conducted halal raw material certification processes and managed deviations related to halal compliance issues.
- Served as primary company representative accompanying Halal Inspection Body (LPH) auditors during halal certification inspections.
- Certified with competency in Halal Supervision based on the National Work Competency Standard (SKKNI).

GMP Compliance Supervisor

 January 2022 – March 2023

- Managed the qualification of internal auditors for both internal and external audit programs within the pharmaceutical facility.
- Led the execution of internal audits and external (supplier) audits, including scheduling, conducting, and reporting findings.
- Reviewed and verified CAPA prepared by Auditees, monitoring implementation timelines and effectiveness of corrective actions.
- Handled change control procedures to maintain the validated states of critical systems, equipment, and processes in compliance with CPOB requirements.

PREVIOUS EXPERIENCE

PT. Tempo Scan Pacific | Indonesia

Tempo Scan Pacific is an Indonesian pharmaceutical and consumer goods company engaged in the development, production, marketing, and distribution of various health products. Its business portfolio includes prescription drugs, over-the-counter (OTC) drugs, health supplements, vitamins, nutritional products, cosmetics, and personal care and beauty products.

Production Foreman – Granulation

 March 2016 – October 2021

- Collaborated with the Granulation Supervisor to execute scheduled work plans in compliance with applicable procedures and CPOB manufacturing standards.
- Supervised subordinates to ensure discipline in CPOB application and regulatory compliance, achieving zero rejected products in the granulation process.

Key Projects & Achievements:

- Conducted holding time determination for OTC drug products.
- Increased batch campaign from 9 lots to 12 lots per sanitation cycle, significantly improving production throughput.
- Executed Cleaning Validation and Process Validation projects to enhance production efficiency.
- Developed an Excel-based OEE data processing system for Diosna, FBD, and Tumbling granulator machines; facilitated operator training on OEE understanding and reporting.