

Wahyu Dirgantarah

Bachelor Degree of Science, Pharmacist

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PERSONAL DETAILS

Birth Date : June, 1995
 Sex : Male
 Address : Kota Jakarta Pusat, 10570, Indonesia
 Nationality : Indonesia
 Languages : Bahasa Indonesia/English

TRAINING & CERTIFICATIONS

2025	Applied Good Clinical Practice (GCP) IASMED Indonesia
2023	Method 1 Six Sigma Yellow Belt Certified Pfizer Indonesia
	Process Robustness (Ppk) Workshop Pfizer Indonesia Speaker: Paul Twiss (Pfizer Deployment Leader - APAC)
2019	Solid Dosage Manufacturing & Troubleshooting Training PT Darya-Varia Laboratoria Tbk Citeureup Plant. Speaker: Fred Anthony Rowley (President of Solid Dosage Training, Inc.)

PRACTICAL SKILLS

Clinical appraisal & interpretation of clinical data
 KOL and Stakeholder Engagement
 Scientific communication (presentation, medical training, slide deck dev., etc.)
 Validation and qualification project management
 Process improvement project management
 Implementation of quality management system & GMP standard
 Statistical analysis using minitab
Operating certain instruments & equipments:
 - Airborne Particle Counter - Anemometer & Ballometer
 - Temperature & humidity data logger - Digital Tachometer
 - Smoke Tester/Generator - Dissolution Tester
 - Tablet Hardness Tester - Friability Tester
 - Moisture / LOD Meter - Leakage Tester
 - KAYE AVS Validator
Familiar with:
 - Microsoft Excel to process statistical data
 - Soft-Wall Isolator Biodecontamination
 - Autoclave Steam Sterilizer & Oven Depyrogenation
 - Container Closure Integrity Test (CCIT)
 - CorelDRAW and Adobe Photoshop

ORGANISATIONS EXPERIENCE

Supervisory Board/2016-2017

Supervisory board of the student official scientific research organization, Consociatio Auri Cogitantis (CRITIS), Faculty of Pharmacy, Hasanuddin University.

Volunteer/2016

Volunteer at Makassar International Writer Festival (MIWF) 2016

Chief of Organizing Committee/2016

Chief of Organizing Committee of National Pharmaceutical Science and Research Competition (PRESCRIPTION) 2016

Chairman/2014-2015

Chairman of the student official scientific research organization, Consociatio Auri Cogitantis (CRITIS), Faculty of Pharmacy, Hasanuddin University.

INTEREST



EDUCATION

2018-2019

Apothecary Degree Program (Pharmacist)
 Faculty of Pharmacy, Hasanuddin University.
 Makassar, Indonesia.
 Graduated with **GPA 3.83 (Maximum 4.0)**

2013-2017

Bachelor Degree of Pharmacy Program
 Faculty of Pharmacy, Hasanuddin University.
 Makassar, Indonesia.
 Graduated with **GPA 3.50 (Maximum 4.0)**

WORK & ACADEMIC EXPERIENCE

PT Mitsubishi Tanabe Pharma Indonesia | Medical Science Liaison

May 2025 - Now

Department: Medical Affair | Therapeutic Area: Central Nervous System (CNS)
 Jakarta Pusat, Indonesia

Roles:

- Establish and maintain relationship with key opinion leaders (KOLs) or key healthcare professionals (HCPs) to create better understanding toward company products.
- Provide clinical and scientific support for HCPs toward company products.
- Prepare and deliver presentation on company products and participate in panel discussion.
- Provide medical information to internal and external customers, including regulatory affairs.
- Attend national and regional medical meetings and symposia as representative of company.
- Provide input to management regarding alternative therapies, business development opportunities/risks, & client feedback.
- Provide training to field force and ensure medical related knowledge is adequate.
- Medical inquiry handling including provide medical & scientific information to HCPs.
- Handling communication with HCPs for new product before obtain the marketing authorization.
- In coordination with business development department on new product development project.
- In coordination with marketing department on brand plan development, trend analysis, and competitor analysis.
- Ensure all promotional material from marketing department align with medical & scientific standard and compliance aspect.
- Ensure compliance with all applicable laws & regulations, guidelines, codes of conduct, and company's policies.
- Annual budgeting for assigned therapeutic area (TA) in medical affair department.

Pfizer Indonesia | Technical Services Validation Supervisor

April 2024 - April 2025

Department: Quality Operations | Division: Technical Services
 Jakarta Timur, Indonesia

Roles:

Support GMP Audit and CAPA Completion

- Support regulatory audits through preparation, defense, & interaction with auditors in areas related manufacturing process, equipment, facilities, & utilities.

Validation of Process and Cleaning Validation for Liquid and Solid Non-sterile products

- Protocol creation, execution, and provide validation report
- Troubleshooting during the execution
- Support investigation toward deviation & discrepancy
- Support & provide data for coordination with global SME

Site Validation Master Plan

- Support maintain validation master plan through plan creation, scheduling, & execution

Validation Periodic Review

- Create validation periodic review occurrence in gQTS and provide periodic review raw data & report

Validation Remediation Activity

- Support maintain validation remediation plan through plan creation, scheduling, & execution

Qualification for Machine and Facility

- Protocol creation, execution, and provide qualification report (including annual requalification)

Provide High Level Data Analysis Support for Quality Investigations

Manage Routine Quality Systems

- Such as change control, documentation, and investigations

Support Improvement Project

- Initiation & completion of continuous improvement project
- Support completion of manufacturing process improvement
- Support completion of cost improvement project

Risk Assessment

- Provide change based risk assessment by assessing potential impact of changes to qualified system
- Identify potential impact of change for CPP (critical process parameter) & CQA (critical quality attribute) and provide validation risk assessment

Pfizer Indonesia | Technical Services Validation Specialist

June 2021 - April 2024

Department: Quality Operations | Division: Technical Services
 Jakarta Timur, Indonesia

Roles:

Validation of Process and Cleaning Validation for Liquid and Solid Non-sterile products

- Protocol creation, execution, and provide validation report
- Troubleshooting during the execution and support investigation toward deviation & discrepancy
- Support & provide data for coordination with global SME

Validation Periodic Review

- Create validation periodic review occurrence in gQTS and provide periodic review raw data & report

Validation Remediation Activity

- Support maintain validation remediation plan through plan creation, scheduling, & execution

Qualification for Machine and Facility

- Protocol creation, execution, and provide qualification report (including annual requalification)

Consumable Material Order for TS Division

- Support to ensure readiness consumable material in TS area including in coordination with supplier/vendor.

RESEARCH GRANTS & AWARDS

WORK & ACADEMIC EXPERIENCE (Cont.)

The 1st Winner of Prokita 2.0 Awards 2020 (Continuous Improvement Awards) by PT Darya-Varia Laboratoria Tbk.
Receiver of Research Grant (Development of Photogenic Bacteria: Current Approaches to Produce Bio-Diagnostic Candidate Material Zinc Sulfide Quantum Dots) by Ministry of Education, Indonesia (2017)
Receiver of Futura Kusuma Sejahtera (FKS) Group Research Grant (<i>"Nata De Ni-Mo"</i>: Combination of Nira Aren (<i>Arenga pinnata</i> Merr.) and Sugar Factory Waste (Molasses) as Carbon Source in the Production of Nata by <i>Acetobacter xylinum</i>) by Futura Kusuma Sejahtera Group, Indonesia (2016)
2nd Winner (Runner Up) of Scientific Writing Competition in PHARMANESIA 2014 (Formulation Antiaging Cream from <i>Nephelium Extract</i> with <i>Phytosomal Delivery System</i>) by Faculty of Pharmacy, University of Gadjah Mada, Yogyakarta, Indonesia (2014)

PT Darya-Varia Laboratoria Tbk QA-Validation Pharmacist February 2019-2021 Department: Quality Assurance Division: Validation Citeureup, Indonesia Roles: Validation of Process for Powder Sterile, Liquid Sterile and Solid Non-sterile products: - Protocol creation, execution, and provide validation report - Coordination with Production, PPIC, QC, & RnD Team for validation schedule - Investigation toward deviation and/or discrepancy during process validation. Qualification (IQ, OQ, & PQ for Equipments, HVAC & Building): - In coordination with production team and engineering team for URS development - Protocol creation, execution, and provide qualification report - Join & support the online FAT during pandemic. Aseptic Process Validation (Media Fill) - Explain the media fill scenario and aseptic behavior to the production operators, - Conduct and supervise media fill process, - Ensure the inspection activities are performed as per agreed timeline. Cleaning Validation (Matrix Case Study of Product Marker, Protocol, Report, etc.): - Provide matrix case study, protocol, sampling plan, execution and report of cleaning validation Provide SOP/WI (Working Instruction) for Internal Validation Team Validation Project Leader for New Sterile Production Facility: - Ensure all the documents and activities in timeline are fulfilled based on predetermined time, - Arrange qualification schedule in coordination with relevant departments, - Involved in SAT activities and investigate machine or equipment troubleshooting during qualification.
Apotek Plus Group Pharmacist Assistant 2018-2019 Makassar, Indonesia Roles: - Dispensing & Compounding both for prescription & non-prescription medicine - Ensure & verifying order entries & incoming new medicine, maintaining medicine inventory, & removing expired drugs - Pharmacy services, advising medicine's information including any potential adverse effect or drug interactions to patients - Stock Opname.
PT. Konimex Internship Student 2018 Department: Quality Assurance Division: GMP Sukoharjo, Indonesia Role: Provide annual Product Quality Review (PQR).
Faculty of Pharmacy, Hasanuddin University Lecturer Assistant 2014-2017 Makassar, Indonesia - Sterile Dosage Formulation Laboratory - Liquid & Semisolid Formulation Laboratory - Basic Pharmaceutical Laboratory - Pharmaceutical Microbiology Laboratory