

MULYANI DWI YANTI

R&D Department Head |
Pharmaceutical Product Development
& CMC Lead

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LANGUAGES & SKILLS

English

Speaking
Reading
Writing



Microsoft Office

Word
Excel
Power Point



TEACHING & SPEAKING

- **Guest Lecturer — Indonesia International Institute for Life Sciences (i3L), Faculty of Pharmacy**
Topic: **Analytical Method Validation** — principles, case studies, and pitfalls from industry practice (Year: 2023).
- **Guest Lecturer — Atma Jaya University, Faculty of Pharmacy**
Topic: **Current Trends in the Pharmaceutical Industry** — generic competitiveness, CMC expectations, and digital (Year: 2024).

PROFESSIONAL SUMMARY

A professional Research and Development Department Head with end-to-end ownership of portfolio delivery across ethical drugs, nutraceuticals, herbal, and personal care.

Experienced in CMC strategy, QbD, tech transfer, analytical method validation, and regulatory dossier readiness (BPOM/CPOTB). Track record of launching competitive products in Indonesia and leading cross-functional teams to scale from lab to commercial. Legal Responsible Pharmacist for Traditional Medicine. MBA (SBM-ITB) with a focus on operational excellence, Agile ways of working.

EXPERIENCES

PT. Imedco Djaja – Research and Development Dept Head February 2019 – Present

- New product development from concept to final commercial product: ethical drugs, supplements, herbal, and cosmetics
- Drive CMC strategy for smooth scaling up and product launch, oversee analytical method development & validation; lead technology & method transfer to QC/Manufacturing, approval of raw and packaging material
- Responsible for regulatory dossier completion and compliance
- Manage budget, resources and timelines of the R&D Department
- Collaborate with manufacturing team on application, technical aspect, improvement and trouble shooting of new and existing products to raise R&D throughput

PT. Imedco Djaja – Legal Responsible Pharmacist for Traditional Medicine February 2019 – Present

Co-led traditional medicine market release with QA; ensured adherence to standards and documentation integrity.

PT. Imedco Djaja Pharmaceutical – Research and Development Senior Scientist (2018 – 2019)

PT. Imedco Djaja Pharmaceutical – Quality Control Specialist (2016 – 2017)

EDUCATION

MBA, Business Leadership (BLEMBA), School of Business & Management, Institut Teknologi Bandung (SBM-ITB) — 2025

Focus: Operational excellence in pharmaceutical R&D, Agile & Scrum in regulated environments - Honors: *Cum Laude*

Apothecary/Pharmacy Professional Degree, School of Pharmacy, Institut Teknologi Bandung — 2016

Pharmaceutical Science and Technology, School of Pharmacy, Institut Teknologi Bandung — 2014

Focus: Transdermal formulation and evaluation, analytical method development - Honors: *Cum Laude*

ACHIEVEMENTS

- Achieved in vitro and in vivo biosimilarity with patent drug by formulation approach
- Launched taste-masked chewable that met sensory targets and secured competitive sales performance.
- Implemented the transfer technology projects of antiviral drug from toll manufacturer
- Involved actively in Traditional Medicine Certification, strengthened R&D document governance and improved CAPA closure effectiveness.

CORE COMPETENCES

- **R&D & CMC:** Product/formulation development, pre-formulation, scale-up, PPQ, control strategy, cleaning validation
- **Analytical Sciences:** Method development & validation (HPLC/UV/GC), dissolution, stability (IVB), technology & method transfer
- **Regulatory & Quality:** Dossier preparation, BPOM guidance & CPOTB 2021, ICH Q8–Q10, risk management (FMEA), CAPA
- **Execution & Leadership:** Portfolio management, cost & timeline control, vendor/CMO management, cross-functional collaboration
- **Communication:** Stakeholder alignment, teaching/guest lecturing, scientific writing & presentation