

Hakim Utomo

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Education

RevoU GPA: 98.55/100 <i>Full Stack Data Analytics</i>	(Jan, 2023 – Apr, 2023)
Institut Teknologi Bandung GPA: 3.54/4.00 <i>Program Studi Profesi Apoteker</i>	(Jul, 2018 – Sep, 2019)
Institut Teknologi Bandung GPA: 2.92/4.00 <i>Sains dan Teknologi Farmasi</i>	(Jul, 2013 – Apr, 2018)

Working Experiences

QC Person In Charge, PT Nellco Indopharma	(Jan, 2026 – Present)
- Managed and supervised QC laboratory operations, including chemical, physical, and microbiological testing of raw materials, packaging materials, in-process samples, and finished products. - Ensured all testing activities complied with approved analytical methods, pharmacopeial standards, and GMP requirements. - Reviewed and approved analytical results, certificates of analysis, and QC documentation to ensure data integrity and regulatory compliance. - Oversaw calibration, qualification, and maintenance of laboratory instruments to maintain continuous laboratory operations and compliance. - Led investigations of OOS, OOT, deviations, and laboratory incidents, ensuring timely root cause analysis and effective CAPA implementation. - Provided technical oversight for analytical method development, verification, and validation for raw materials and finished products. - Coordinated with Warehouse, Production, and other cross-functional departments to support manufacturing activities and ensure product quality.	
QC Staff, PT Daewoong Biologics Indonesia	(Feb, 2025 – Jan, 2026)
- Perform release testing for Stem Cell and its derivatives. - Perform release testing for Cosmetics products. - Create related specifications and testing methods for Cosmetic products. - Support pre-audit preparation and post-audit mitigation from Regulatory Inspection.	
Procurement Staff, PT Pasifik Agro Sentosa	(Aug, 2024 – Dec, 2024)
- Perform end-to-end procurement process for General Affairs Work Requisition and EHS Purchase and Work Requisition - Perform end-to-end procurement process for Marketing and General Affairs Purchase Requisition	
QC Chemical Section Head, Takeda Indonesia	(May, 2023 – July 2024)
- Organise routine testing for raw material, packaging material, semi-finished, and stability study testing in QC Lab - Organise non-routine testing in QC lab such as analytical method validation / verification, process validation, etc. - Manage CAPA and Change Control related to chemical testing in QC department. - Lead Investigator, Risk Assessment Facilitator and Data Integrity Champion for the Quality Control Department.	
QC Analytical Method Development, Takeda Indonesia	(Sep, 2019 – Apr, 2023)
- Manage end-to-end analytical method development and validation / verification process for raw material and semi-finished testing method. - Responsible for keeping all specifications and testing methods up to date with current compendial. - Manage CAPA and Change Control related to specification and analytical methods. - Lead Investigator and Quality Risk Management coordinator for the Quality Control Department. - Site representative for Global Compendial Review.	

Organization Experiences

- Value Ambassador, Takeda Indonesia
- (Jul, 2022 – Mar, 2024)
- Support the delivery of Speak Up and Listen to learn Capability Building Program for the site and act as a trusted voice and counsel for employees.
 - Contribute to the delivery of conflict-of-Interest awareness training for the site and support and guide employees when potential conflict of interest situations arises.
 - Support in the delivery of instructor led training where required to ensure at least 95% of site employees have completed mandatory E&C training courses.

Additional Information

Skills: Analytical Method Development and Validation, Failure Mode and Effect Analysis (FMEA), Laboratory Investigation, Pharmaceutical Industry, Decision-making, Critical thinking, Data Analytics, SQL, Python

Certification:

1. Full Stack Data Analytics, RevoU

2. Apoteker, ITB

3. Sarjana Farmasi, ITB

(Apr-2023)

(Sep-2019)

(Apr-2018)