

ZELENA ISABEL TANOWIDJAJA

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PROFESSIONAL SUMMARY

Biomedical Science graduate with 4 years of experience in the pharmaceutical industry, a compliance professional with hands-on experience in GMP-regulated pharmaceutical environments.

Skilled in CAPA and deviation management, OOS investigation, SOP enforcement, and audit preparation. Strong laboratory background in microbiology, bioprocessing, and analytical techniques.

Passionate about contributing to global pharmaceutical innovation, ensuring product safety, quality, and regulatory integrity.

PROFESSIONAL EXPERIENCE

Microbiology Scientist — Kalbio Global Medika, Indonesia (May 2025 – Present)

- Conduct bioburden, endotoxin, and sterility testing for pharmaceutical products.
- Perform and review environmental monitoring (EM) and microbial identification to maintain sterile manufacturing conditions.
- Carry out microbial identification using VITEK and API systems.
- Perform disinfectant efficacy testing and antimicrobial effectiveness testing.

Compliance & Data Integrity Officer — Kalbio Global Medika, Indonesia (Feb 2023 – Apr 2025)

- Managed OOS cases and CAPA implementation for QC department, ensuring timely closure and preventive measures.
- Collaborated with QA to investigate deviations and ensure GMP compliance.
- Monitored QC SOP adherence and scheduled IPC inspections.
- Assisted in internal and external audit preparation to ensure inspection readiness.

Intermediate & Finished Goods Scientist — Kalbio Global Medika, Indonesia (Jan 2023 – Feb 2023)

- Performed analytical tests including protein content, osmolality, CCIT and dose accuracy.
- Conducted molecular and protein analyses: Western blot, PCR, SDS-PAGE, ELISA.

BTP 3 Trainee — Kalbio Global Medika, Indonesia (Jul 2022 – Dec 2022)

- Trained in cell culture handling, clone development, protein purification, and bioprocess techniques.
- Gained practical experience in upstream/downstream processing, viral clearance, and sterility assurance.

EDUCATION

Bachelor of Biomedical Science — La Trobe University, Australia (2019 – 2021)