

Joandrival Agista, S.T.

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Bekasi, West Java

A highly accomplished Quality Assurance professional with over 8 years of progressive experience in pharmaceutical manufacturing. Proven expertise in ensuring product quality compliance, process optimization, and regulatory standards implementation to support consistent and reliable production outcomes. Currently serving as a Senior Quality Assurance Staff, with strong analytical capabilities across both instrument and non-instrument systems, enabling effective monitoring, validation, and continuous improvement of production processes. Recognized as a collaborative and results-oriented professional with the ability to perform effectively in independent, team-based, and leadership roles. Demonstrates strong accountability in achieving targets, coupled with a proactive mindset and high productivity in both core responsibilities and cross-functional initiatives.

Education Level

Universitas Muhammadiyah Jakarta

Feb-2026

Bachelor of Engineering (Chemical Engineering) (GPA 3.56 /4.00)

Working Experiences

PT Bintang Toedjoe

Apr 2017 – Present

QA Kalibrasi, Kualifikasi & Environmental Hygiene Monitoring (EHM)

- Capable of performing calibration of both instrument and non-instrument equipment, including report preparation and proper document control and archiving.
- Experienced in conducting equipment and machine qualification activities, covering Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) through to final report completion.
- Proficient in performing qualification of supporting systems, including Water Systems, Air Handling Units (AHU), and controlled rooms.
- Demonstrates a strong understanding of end-to-end processes related to calibration, qualification, and supporting utility systems.
- Able to manage schedules and projects effectively while ensuring timely completion in accordance with assigned targets and Key Performance Indicators (KPIs).
- Demonstrates a strong understanding and implementation of Data Integrity principles, including ALCOA+ and Quality System Management (QSM).
- Competent in calibration activities, supported by certifications in weighing scale calibration, measuring instrument calibration, and pressure instrument calibration.
- Experienced and recognized for achievements in Continuous Improvement (CONIM) initiatives, including idea contribution programs and Quality Control Circles (QCC).
- Knowledgeable in and actively implements QHSE 5R programs.

Validation & Quality Assurance

- Able to develop and manage validation schedules for process validation, cleaning validation, and general validation activities.
- Capable of preparing validation protocols, reports, and maintaining proper validation documentation and archiving systems.
- Experienced in analyzing and executing process validation, cleaning validation, and general validation activities.

- Strong scheduling and planning skills, with the ability to adjust validation timelines according to production conditions.

Product Return & Compliance Management

- Experienced in handling product return activities from branches.
- Capable of managing returned products in compliance with CPOB (Good Manufacturing Practice) standards.
- Proficient in processing and submitting reports through the Oracle system.

Product Return & Compliance Management

- Proficient in Oracle and Minitab.
- Skilled in basic computer applications, including Microsoft Word, Excel, and PowerPoint.

Organizational Experiences

Himpunan Mahasiswa Jurusan Teknik Industri FTUMJ

Jan 2020–Jan 2022

Member of Education Division

- Responsible for sharing a knowledge especially industrial engineering to member of HMTI and achieve 100% target program

Kualima PT Bintang Toedjoe

Oct 2024– Feb 2025

Chairperson

- Led a 25-member team to deliver company-wide KUALIMA (Man, Machine, Method, Material, Environment) quality improvement training.
- Achieved 100% participation rate and successfully organized the program's graduation ceremony within budget and timeline.

Certification

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| • Trained Panelist Sensory Team | January 2022 |
| • Training for How To Achieve Weighing and Calibration (USP Chapter 41) | Mar 2023 |
| • Trained Panelist Sensory Team | January 2022 |
| • Trained Panelist Sensory Team | January 2023 |
| • Mettler- Bring Your Pipetting Result to Boost Your Performance | August 2025 |
| • Mettler- Cara Mengoptimalkan Akurasi Pengukuran pH dan Perawatan Sensor yang Efektif | August 2025 |
| • Sertifikasi Getting Started With MINITAB | November 2025 |

Skills and Language

- **Soft Skills:** Leadership, Relationship Building, Project Management, Analytical Thinking, Team Work, Problem Solving.
- **Language:** English (Intermediate), Bahasa Indonesia (Native)