

Joandrival Agista, S.T.

082386052818 | joandrival24@gmail.com | Bekasi, Indonesia

<https://www.linkedin.com/in/joandrival-agista-106644151>



Results-oriented **Calibration and Qualification Specialist** with a strong background in **Chemical Engineering**, specializing in the analysis of instruments, equipment, machinery, and supporting utilities. Possesses approximately 8 years of experience in the pharmaceutical industry as a permanent employee. Demonstrates strong expertise in performing calibration and qualification activities, covering the entire process from protocol development, execution, to data processing and final reporting. In addition, has proven experience in validation and product return processes, and is highly proficient in digital data processing and analysis, including spreadsheets, pivot tables, dashboards, and Minitab (certified).

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)