

SITI NURFAUZIANA

Production Supervisor | Manufacturing Operations | Process Control | Deviation & CAPA

+6289646624267 | sitinurfauziana@gmail.com | <https://www.linkedin.com/in/sitinurfauziana/>

Jakarta, Indonesia

Biology graduate from Institut Teknologi Bandung with nearly 2 years of hands-on experience supporting regulated IVD manufacturing through R&D, Quality Control, process monitoring, validation, and laboratory-to-production transfer. Supported 5 product programs from development through manufacturing readiness and commercialization, including routine production/QC activities for approximately 2-4 batches per month. Experienced in material and equipment readiness, process-parameter monitoring, in-process and finished-product quality checks, batch documentation, deviation investigation, root-cause review, CAPA follow-up, and cross-functional coordination with Production, QC, Quality, RA, Purchasing, laboratories, and principals. Strong in Microsoft Excel, structured reporting, workflow coordination, analytical problem solving, and leadership developed by leading 12 teaching assistants across 14 laboratory sessions.

LinkedIn



WhatsApp



Work Experiences

PT Bestari Sukses Makmur — Jakarta, Indonesia

Oct 2024 - Present

Research and Development Specialist

- Support 5 IVD product programs through process development, validation, manufacturing readiness, and commercialization.
- Prepare materials, reagents, consumables, equipment, and controlled documentation for planned production activities.
- Coordinate material and equipment readiness with Production, QC, Quality, Purchasing, and Regulatory Affairs.
- Monitor process parameters and product results to identify deviations, bottlenecks, and corrective follow-up needs.
- Completed 4 iterative formulation/process trials for a DNA extraction kit before commercialization and manufacturing handover.
- Support Viral Transport Medium formulation refinement and recurring process-improvement activities.
- Translate development outputs into SOPs, batch records, BOMs, specifications, and production-support instructions.
- Investigate technical issues through repeat testing, comparative review, root-cause analysis, and parameter adjustment.
- Support validation, verification, and stability studies under predefined process, test, and storage conditions.
- Maintain traceable process, batch, experimental, validation, and technical records across concurrent workstreams.

PT Bestari Sukses Makmur — Jakarta, Indonesia

Oct 2024 - Present

Quality Control Staff (concurrent role)

- Perform incoming-material, in-process, finished-product, packaging, verification, and release-related quality checks.
- Support Best's Calcium Activator production/QC at approximately 2-4 batches per month.
- Maintain 40+ CoA/batch-QC records and review results against specifications with complete traceability.
- Inspect product identity, physical condition, packaging, labels, and documentation before release-related follow-up.
- Document non-conforming findings and support repeat testing, root-cause review, corrective actions, and CAPA follow-up.
- Coordinate quality findings and production follow-up with R&D, Production, Quality, and Regulatory Affairs.

PT ProSTEM — Jakarta, Indonesia

Jul 2024 - Sep 2024

Laboratory Intern - Molecular Biology

- Processed approximately 10-20 clinical samples per week using SOP-controlled laboratory workflows.
- Prepared samples, reagents, consumables, equipment, and work areas for routine molecular testing.
- Maintained sample identity, equipment readiness, testing records, result traceability, and documentation.

Institut Teknologi Bandung (ITB) — Bandung, Indonesia

Jul 2023 - Oct 2024

Research Assistant & Data Analyst

- Supported experimental research involving 160+ structured interviews and controlled data collection.
- Analyzed quantitative datasets using MATLAB, EEGLAB, RStudio, Python, and GraphPad Prism.
- Performed data-quality checks, interpretation, visualization, and structured technical reporting.

Bandung Fertility Center — Bandung, Indonesia

Jul 2023 - Aug 2023

Data Analyst & Laboratory Intern

- Performed biological sample preparation, centrifugation, microscopy, and CASA-based laboratory analysis.
- Analyzed reproductive-cell quality parameters for 35+ IVF patients and maintained accurate records.

Education Level

Institut Teknologi Bandung — Bandung, Indonesia

Sep 2020 - Jul 2024

Bachelor of Biology, GPA 3.36

- **Achievement:** TELADAN Scholarship & Leadership Program Awardee by Tanoto Foundation
- **Thesis:** analyzed cognitive-test and EEG data from 35 students using quantitative methods.
- **Head Laboratory Assistant:** led 12 TAs and coordinated 14 laboratory sessions for 70+ students.
- **Lab Assistant:** supported Basic Chemistry and Animal Anatomy & Physiology laboratory activities.
- **Relevant areas:** Biochemistry, Microbiology, Biotechnology, Laboratory Techniques, Statistics, Data Analysis

Organization

Tanoto Scholars Association (TSA ITB) — Bandung, Indonesia

Jan 2021 - Jan 2023

Internal Affairs & Community Engagement

- Led internal engagement initiatives strengthening coordination across a community of 100+ scholars.
- Coordinated the Study Buddy mentoring program supporting 30+ elementary-school students.

Biology Student Association (HIMABIO ITB) — Bandung, Indonesia

Aug 2021 - Aug 2022

Treasurer

- Managed approximately Rp25,000,000 in organizational funds and maintained accurate financial records.
- Improved cash reserves by approximately 20-25% through budget control and resource allocation.

Selected Production, Process Control & Leadership Experience

• **Best's Calcium Activator - Routine Production & In-Process Quality Control**

- Support approximately 2-4 batches per month from material readiness through in-process and final verification.
- Maintain batch/QC, CoA, inspection, and release-support records and escalate deviations for follow-up.

• **Best's Spin Column DNA Extraction Kit - Process Optimization & Manufacturing Handover**

- Completed 4 iterative formulation/process trials before commercialization and manufacturing transfer.
- Prepared process, BOM, batch, validation, stability, SOP, and manufacturing-support documentation.

• **Production Deviation, Root-Cause Analysis & CAPA Support**

- Investigate unexpected process or quality results through repeat testing, comparative review, and root-cause analysis.
- Support corrective actions, CAPA evidence, controlled-document updates, action tracking, and closure follow-up.

• **Process Monitoring & Continuous Improvement**

- Review process parameters, material variables, product results, and recurring issues to identify improvement needs.
- Coordinate technical follow-up with Production, QC, Quality, RA, Purchasing, laboratories, and principals.

• **Quality-System & Manufacturing Documentation**

- Maintain SOPs, batch records, BOMs, specifications, QC records, validation/stability evidence, and traceability.
- Contributed approximately 65% of R&D/QC/Production-related activities for the CPAKB audit program.

• **Team Coordination & Operational Leadership**

- Led 12 teaching assistants and coordinated 14 laboratory sessions for 70+ students.
- Managed task allocation, schedules, readiness, instructions, and issue follow-up across recurring activities.
- Apply structured prioritization, communication, and problem solving to maintain execution quality under deadlines.

Skills

- **Production Operations:** Material Readiness, Equipment Readiness, Workflow Execution, Manufacturing Support
- **Process Control:** Process Monitoring, In-Process Checks, Specification Review, Deviation Escalation
- **Quality Control:** Incoming QC, In-Process QC, Finished-Product QC, Packaging/Label Inspection, Release Support
- **Production Documentation:** Batch Records, CoA, QC Logs, SOP, BOM, Specifications, Data Traceability
- **Deviation & CAPA:** Root-Cause Review, Repeat Testing, Non-Conformity Handling, Corrective Actions, CAPA Support
- **Continuous Improvement:** Process Evaluation, Parameter Review, Workflow Improvement, Follow-Up Tracking
- **Leadership & Coordination:** Task Allocation, Scheduling, Facilitation, Communication, Prioritization, Accountability
- **Data & Reporting:** Microsoft Excel, Word, PowerPoint, GraphPad Prism, RStudio, Python, MATLAB
- **Quality Systems:** ISO 13485, CPAKB, CDAKB, SOP Compliance, Audit Support, Controlled Records
- **Professional Strengths:** Execution, Discipline, Analytical Thinking, Teamwork, Adaptability, Problem Solving