

RIZKY ANANDYA

QUALITY ASSURANCE MANAGER

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PROFESSIONAL SUMMARY

Pharmacist with 8+ years of progressive experience in the pharmaceutical industry, covering Quality Assurance, Quality Compliance, Regulatory Affairs, Stability, Quality Management Systems, and project management. Currently leading QA operations with a focus on GMP/CPOB compliance, quality system effectiveness, validation and qualification, product release, deviation and CAPA management, change control, risk management, and audit readiness. Proven track record of strengthening and simplifying quality systems, improving compliance, and driving sustainable process improvements. Experienced in both local and global environments, with strong capabilities in cross-functional leadership, stakeholder management, problem-solving, and quality governance.

KEY ACHIEVEMENTS

- Built and modernized core quality systems from the ground up — CAPA, Deviation, Change Control, Quality Risk Management, and calibration — across multiple manufacturing sites.
- Built a new TrackWise system for the Change Control module.
- Led sterile manufacturing compliance initiatives (CCS, Environmental Monitoring, QRM) aligned with PIC/S GMP Annex 1 and CPOB.
- Delivered ±80 product regulatory submissions in under a year, with 70% approved ahead of schedule.
- Managed SAP and QMS implementation projects with zero delays, earning recognition from global stakeholders.
- Contributed strategic input that helped resolve BPOM findings during CPOB recertification.

PROFESSIONAL EXPERIENCE

Quality Assurance Manager

Apr 2026 – Present

PT IPHA Laboratories | Indonesia

Own the effectiveness of the Quality Management System in compliance with current GMP/CPOB regulations, driving compliance, quality oversight, and continuous improvement across operations.

- Lead and oversee qualification, process validation, and cleaning validation activities.
- Review and approve quality documents, including procedures, specifications, APRs, and batch records.
- Accountable for final product release in compliance with quality and regulatory requirements.
- Lead change control and deviation investigations, ensuring effective CAPA implementation.
- Lead supplier audit activities to ensure vendor compliance with quality standards.
- Support external audits and regulatory inspections, including gap analysis and timely CAPA completion.
- Review and approve product artwork for regulatory and company compliance.
- Coordinate cross-functionally to ensure quality documentation and compliance.
- Develop team capabilities through coaching and quality-culture building.

Key Accomplishments:

- Strengthened the company's compliance system, specifically in deviation management and calibration implementation, to ensure alignment with timelines and regulatory requirements.
- Led the development and implementation of a comprehensive Contamination Control Strategy (CCS) for sterile manufacturing in alignment with PIC/S GMP Annex 1 and CPOB requirements.
- Established a risk-based Environmental Monitoring (EM) Program for sterile products.
- Designed a new Change Control System to strengthen quality oversight, risk assessment, and regulatory compliance across manufacturing processes.
- Enhanced the Quality Risk Management (QRM) system by streamlining the risk assessment process and implementing a more comprehensive evaluation framework to strengthen risk-based decision-making and quality oversight.

- Streamlined and strengthened the Deviation Management System by consolidating and enhancing the end-to-end process within a single comprehensive framework, improving consistency, investigation quality, and CAPA oversight.
- Contributed strategic input in addressing BPOM findings during the CPOB recertification process.

Quality Compliance – Stability Coordinator

Jan 2025 – Dec 2025

PT Organon Pharma Indonesia | *Indonesia*

- Ensured the stability study program met global, health authority, and regulatory requirements.
- Drove continuous improvement in the stability study program and quality compliance.
- Collaborated with overseas stability testing sites as part of the global stability program.
- Investigated stability issues and assessed impact on product quality.
- Engaged in new product transfer projects with global project and technical operations teams.
- Performed qualification of Climatic Chamber equipment and its computerized system.
- Prepared monthly stability KPI reports for site and global quality council.

Key Accomplishments:

- Completed all Stability Coordinator training in under a month and moved to independent work immediately.
- Successfully carried two concurrent roles (Stability Coordinator and Plant Regulatory) while meeting all timelines.
- Recognized for completing qualification documentation in record time.
- Simplified the stability workflow to improve collaboration across stability, planning, and production teams without disrupting production.

Quality Compliance – Plant Regulatory

Jan 2024 – Dec 2025

PT Organon Pharma Indonesia | *Indonesia*

- Ensured GMP activities met global, Health Authority, and regulatory requirements.
- Conducted self-inspections and supervised timely CAPA implementation.
- Acted as quality approver for change controls.
- Ensured registered documentation aligned with Health Authority and company requirements.
- Coordinated with CMC and global regulatory affairs on submission documentation.
- Managed submission preparation for new products and engaged in product transfer projects.
- Ensured artwork and SAP production data aligned with registered and business requirements.

Key Accomplishments:

- Reached full independence in the Plant Regulatory role within 2 months of joining.
- Established new standard work for collecting regulatory submission data, preventing submission delays.
- Recognized for completing regulatory submission data for a ±80-product transfer project in under a year — 70% approved by market Health Authorities by early 2025.

Project Management Officer – SAP

Jan 2023 – Dec 2023

PT Organon Pharma Indonesia | *Indonesia*

- Developed and reviewed project schedules, allocating resources effectively across activities.
- Monitored project progress and proposed adjustments to ensure success.
- Assessed change impact of new systems on impacted roles and mitigation plans.
- Investigated project issues to identify root causes and propose solutions.
- Coordinated with local and global teams to monitor progress and resolve issues.

Key Accomplishments:

- Took over the role from a departing employee after a 1-month handover and worked independently thereafter.
- Built trackers to monitor the project team, eliminating delays against timeline expectations.
- Supported the Project Go-Live and received appreciation from global and local stakeholders.

Project Management Officer – QMS

Aug 2022 – Dec 2023

PT Organon Pharma Indonesia | *Indonesia*

- Accountable for strategic planning of the new Quality Management System implementation on-site.
- Coordinated with Topic Leads to identify implementation gaps.

- Investigated project issues and proposed root-cause solutions.
- Coordinated with global and local Topic Leads to monitor progress.
- Supported translation of QMS documents as needed.

Key Accomplishments:

- Coordinated Topic Go-Live with zero delays.
- Completed document translations well ahead of deadline.

Senior Quality Assurance Specialist

Dec 2018 – Aug 2022

PT Meiji Indonesia | Indonesia

- Ensured GMP activities met global, health authority, and regulatory requirements.
- Supported external and site audits and inspections.
- Assessed impact and contributed to deviation investigations, including CAPA determination.
- Evaluated CAPA effectiveness and defined actions for repeat deviations.
- Assessed risk and required actions for change control implementation.
- Ensured CAPA and change control actions were completed on schedule.
- Coordinated with local and global teams on deviation and change control implementation.

Key Accomplishments:

- Built the CAPA deviation system at PT Meiji Indonesia within 6 months of joining.
- Built a new TrackWise system for the Change Control module.
- Increased change control implementation rate from 85% to above 90%.

Quality Assurance Supervisor

Dec 2017 – Dec 2018

PT PIM Pharmaceutical | Indonesia

- Ensured GMP activities met global, health authority, and regulatory requirements.
- Conducted self-inspections and supervised timely CAPA implementation.
- Supported external and site audits, identifying root causes and defining CAPA.
- Assessed impact and contributed to deviation investigations, including CAPA determination.
- Evaluated CAPA effectiveness and defined actions for repeat deviations.
- Managed calibration, qualification, and validation schedules and teams.
- Conducted qualification and validation activities, ensuring results met specifications.
- Reviewed batch records to confirm compliance with specifications prior to QA release.

Key Accomplishments:

- Improved the calibration system for full traceability, eliminating recurring ISO audit findings.

EDUCATION

Pharmacist Professional Program

2016 – 2017

Airlangga University, Surabaya, Indonesia — GPA 3.66/4.00

Bachelor of Pharmacy

2012 – 2016

Airlangga University, Surabaya, Indonesia — GPA 2.80/4.00

CORE COMPETENCIES

Technical: Microsoft Office (Excel, Word, PowerPoint), SAP, Laboratory Management System (ORGLIMS), Minitab Statistical Software

Leadership & Compliance: Leadership, auditing, problem analysis and solving, time management, critical thinking, quality assurance & compliance, quality management, data analysis, GMP implementation, regulatory affairs, contamination control, environmental monitoring, quality risk management, deviation & CAPA management, change control

Languages: Fluent in Indonesian and English