

Alya Malidha Cesya

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Carrer Summary

Professional Pharmacist with > 5 years of experience in Quality Assurance and Quality System area within the pharmaceutical industry with extensive experience across multiple critical functions, including management batch record, Lead of Quality Event (deviation, complaint, lab investigation, supplier investigation), Lead of Packaging Development, perform Quality on The Shopfloor, Lead of Return and Recall-Mock Recall Management, CAPA Management, Validation, Qualification, Calibration and Self-Inspections, Internal-External Audit. Managing contract manufacturer (end-to-end) from Quality Aspects. Proven ability to perform gap assessments and implement effective solutions to ensure compliance and enhance operational efficiency.

Expertise in quality event investigation (Qualified as Lead Investigator), leading product quality review projects, Qualified Auditor, also as Certified as Halal Supervisor in Halal Management System. Seeking to leverage a comprehensive background in pharmaceutical quality, halal management and project management to drive continuous improvement and support the success of a forward-thinking organization. Committed to excellence in pharmaceutical and FMCG quality and eager to leverage expertise in a meaningful role.

Education

1. Apothecary Student
Gadjah Mada University | 2020
GPA 3.83 / 4.00
2. Bachelor of Pharmacy
Gadjah Mada University | 2014

Skills & Characters

- Responsible
- Analytical Thinking & Innovation
- Active Learning & Learning Strategies
- Complex Problem Solving
- Critical Thinking & Analysis
- Creativity, Originality, & Initiative
- Keeness to learn
- Microsoft Office
- SPSS 20
- TrackWise System
- Veeva System
- Focus System
- SAP Logon

Awards & Activities

- Certified Halal Supervisor in Halal Management in PT. Takeda Indonesia | 2024 – 2028
 - Recognition in Quality Team - FY2022 | FY2022
Successfully Performing Quality Must Win – Investigation Right First Time
 - Recognition in Global Artwork Community of Practice | FY2022
Teamwork - Acknowledgment of your contribution within the Global Artwork community of practice. You bring ideas and flag issues that the global team appreciates
 - IQS (Investigation Quality Standard) Assessor Bekasi Site | 2022 - Present
 - Qualified Lead Investigator Bekasi Site | 2021 - Present
 - Qualified Auditor in PT. Takeda Indonesia | 2020 - Present
 - PIC Artwork Center (Global Artwork Team Management) - Indonesia Site | 2020 - Present
 - Asia Pacific Pharmaceutical Symposium | 2016
Official Delegates of Pharmacy UGM in IPSF 15th Asia Pacific Pharmaceutical Symposium in Korea.
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Workshop & Training

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| • Halal Supervisor Training based on SKKNI & SJPH Implementation | September 2024 |
| • Competent in area of Halal Product Assurance with Qualification as Halal Supervisor | September 2024 |
| • APAC – Yellow Belt Training | November 2023 |
| • Global Investigator Training Program & Certification Team | May 2021 |
| • Auditor Qualification & Basic Auditor Training | May 2021 |
| • Quality Risk Assessment with FMEA Method Training | September 2020 |
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Working Experiences**PT. Procter and Gamble Home Product Indonesia****| 2025 – Present**

- **External Supply Solution – QA Lead**
 - Leading Contract Manufacturer Oversight (QA SPOC for all Indonesia Personal Health Care contract manufacturer sites – dosage form: solid, semi-solid, liquid, inhaler, and injection)
 - Deliver External Supply Solution QA capability and eliminate high risk by leading quality activity of contract manufacturer sites and other quality-related external business partner, eg. Quality Event Investigation (lab investigation, manufacturing investigation, complaint, supplier investigation), CAPA management, internal-external audit, validation, qualification, calibration, batch record review, change control management, QC Area (micro and chemical), data integrity, AMT-AMV, PQR, Recall - Mock Recall Management, etc.
 - Monitoring and preparing for corporate audit in contract manufacturer sites.
 - Develop contract manufacturer quality capability to meet local regulatory, export country, global and P&G standards and audit readiness through health check/ pre-assessment with MFT (Multi-Functional Team) collaboration.
 - Provide option analysis, quality risk assessment, and quality strategy on project/issue to local and regional leadership team for collective decision.
 - Manage day-to-day quality activity to support supply through strong collaboration with both internal and external MFT counterparts and ensure all products meet required standards.

PT. Takeda Indonesia - QA Specialist**| 2024 – 2025**

- Competent in area of Halal Product Assurance with Qualification as Halal Supervisor coordinate and execute implementation of Halal Product Assurance System
- Deviation & Supplier Investigation Handling
As Deviation Coordinator, to perform reviews and investigations (collaborate with other department). Attention to the root cause analysis, classification of root cause, analysis of evaluating recurring events (deviation, complaint, adverse event, etc.), technical completion and scope while ensuring accuracy of documentation contents, determining the right CAPA to cover the root cause and prevent similar issues from happen in the future.
- Reject & Return Product Management
 - Develop and maintain Standard Operating Procedures (SOPs) for handling product returns, including inspection, documentation, and disposition processes.
 - Coordinate with internal teams to ensure timely and accurate processing of product returns.
 - Conduct inspections of returned products to assess their condition, integrity, and compliance with quality standards.
 - Generate comprehensive reports and documentation of return product to be dispositioned by QA Manager.
- Mock Recall – Recall Product Handling
 - Establish and maintain recall Standard Operating Procedures (SOPs) and protocols in compliance with regulatory requirements.
 - Serve as the primary point of contact for initiating and executing product recalls, coordinating activities across departments and with regulatory authorities.
 - Conduct periodic mock-recall exercises to test the effectiveness of recall procedures and ensure readiness for potential recall events.
 - Manage communication and coordination internal team to ensure timely and accurate processing of recall activities.

- **Batch Record Review**

Perform review of processing and packaging batch record, QC testing results and ensure that all relevant document related to a batch such as deviation report, lab investigation report, change control approval or closure, etc., must be closed before giving disposition for the batch also Conduct review and approve master processing and packaging batch record

- **Quality on the shopfloor**

- Leading and executing end-to-end Quality on the Shopfloor program.
- Developing a comprehensive project charter that outlines the identified problem statement, specific targets, key success criteria, and milestones.
- Conduct a thorough risk assessment to evaluate potential risks and establish appropriate actions to address these risks effectively.
- Observe and monitor manufacturing processes to ensure compliance with quality specifications and standard operating procedures (SOPs) and ensure that all documentation complies with Good Manufacturing Practices (GMP) and regulatory requirements.
- Conduct in-process checks and inspections to identify and address any deviations or issues immediately. Document and report any deviations or non-conformances observed during production process. Collaborate with production and quality teams to investigate root causes and implement corrective and preventive actions (CAPAs).
- Suggest improvements based on observations and feedback from quality monitoring activities.

- **Product Quality Review**
 - Lead and coordinate Product Quality Review (PQR) projects, ensuring timely and effective completion.
 - Develop and manage project plans, including timelines, resource allocation, and deliverables.
 - Oversee the execution of the PQR process, including the collection and analysis of product quality data from various sources such as production, stability studies, and quality data.
 - Prepare Product Quality Review (PQR) by collating and analyzing data related to product quality, complaints, and deviations.
 - Review manufacturing and quality control records to assess product quality trends, identify areas for improvement, and evaluate the overall performance of products.
 - Circulate the review and approval of the PQR to Management. Managing and tracking of the progress, completion and effectiveness of any CAPA undertaken as a result of the PQR.

PT. Takeda Indonesia – QA Specialist

| 2020 – 2023

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- **Packaging Development | as Global Artwork Team Bekasi Site**
 - Perform development of packaging materials if there are proposed changes originating from the internal Bekasi Site, Health Authority regulations, improvement designs etc.
 - Create revisions/changes to the design of packaging material (artwork) based on proposed changes and collaborate with relevant departments (QA, QC, Supply Chain, Packaging, Regulatory Affairs, Marketing Team) also vendor in the review and approval process of artwork and color range packaging materials.
 - Ensuring the supplier of packaging material is qualified. Suppliers should be audited and assessed on a regular basis to ensure standard and relevant procedures are followed.
 - Ensuring change control related to requests for new designs/revisions related to packaging material design has been initiated and every change process is in accordance with Change Control Management.
 - Ensuring the proposed mock-up and/or approved artwork is complete, accurate, and in accordance with regulations or in accordance with requirements.
 - as GS1 Coordinator inform to related department regarding list of data needed and collecting the data needed for product barcode registration and perform submission process for product barcode registration PT. Takeda Indonesia in GS1 system.
 - maintain good communication with vendors regarding the development of packaging materials and ensure the development align according to the timeline and target date and there are no development delays based on targets.

PT. Sanofi Aventis Pharma – Internship Program**| Apr – May 2019**

- **CAPA (Corrective and Preventive Action) Handling**
Ensures CAPA Plan is commensurate with risk and impact of the Event. Ensures CAPA alignment with the triggering event or reason for CAPA, Reviews CAPAs, CAPA/Action Plan and implementation timelines. Monitors the effectiveness check of CAPA
- **Self-Inspection Handling**
Create an annual self-inspection plan based on the trend of the previous year's events and based on high-risk areas. ensure that the self-inspection schedule is carried out according to the schedule approved by the Quality department
- **Complaint Product Handling**
Collaborate with relevant departments in conducting investigations regarding product complaints. Review the history of previous complaint products also perform reporting of complaint investigation report