

SINTIA INTAN AGSARI

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Quality Assurance professional with 4+ years across multinational FMCG (food & confectionery), pharmaceutical, and medical device industries. Driving continuous improvement through quality risk management (FMEA), process optimization, and cross-functional Quality Projects. Certified Yellow Belt Lean Six Sigma practitioner with a strong record of leading statistical analysis-based improvement initiatives, change management, deviation management, laboratory testing management, and regulatory compliance (ISO13485, ISO9001, FSSC 22000, PICs). Backed by a Bachelor's degree in Biochemistry from IPB University. Effective communicator and team leader known for curiosity and initiative in driving a culture of continuous improvement across departments

WORK EXPERIENCE

PT Menarini Asia Pacific (Multinational Pharmaceutical & Medical Device Company)

Senior Quality Excellence & Continuous Improvement (OPEX)

January 2026 – Present

- Evaluated quality metrics and led periodic discussions to drive performance improvements
- Led strategic Quality Projects, ensuring compliance with all quality goals (e.g. fulfillment of quality agreements for all suppliers, alternative supplier qualification, reduction of overdue CAPA, anticounterfeit project, etc)
- Handled and led Management Review as data preparer and presenter for GMP, ISO13485, and Halal Assurance System
- Handled and led the development of proactive risk assessment using FMEA principles & monitoring risk controls
- Partnered with the Operational Excellence (Opex) Team to identify and implement process optimization initiatives
- Acted as an internal auditor for GMP, ISO13485, and Halal Assurance System to ensure regulatory compliance and continuous quality improvement

Senior Quality Operational

May 2025 – December 2025

- Handling issue report and conduct investigation related to quality issue and define CAPA to prevent recurrence issue
- Responsible for create PQR (Product Quality Review), OPV (On Going Process Verification), review regulatory document, validation document, and analyzing statistical data to identify quality problem and driving continuous improvement
- Handled change control process for critical, major, and minor changes, including impact assessment, determination of required qualification/validation, and closure in compliance with GMP and QMS requirements
- Support agreement & toll manufacturing process for global 3rd party products (Sanofi & Roche Indonesia)

Supervisor Quality Compliance (Short Term Assignment, 2 Terms)

April 2023 - September 2023 | June - November 2025

- Managed customer complaint and deviation management processes, ensuring proper investigation, impact assessment, and monitored CAPA effectiveness
- Oversaw documentation control & batch record review to ensure compliance with GMP and internal quality standard
- Leading quality improvement and winner QCC program with project for improve quality behavior & knowledge for all department related
- Leading & Initiated regular meeting called "shopfloor daily meeting" held in the production area to discuss various matters related to operations, productivity, issue, quality, and efficiency
- Initiated and led quality digitalization, including digital training systems, issue reporting platforms, and statistical data processing improvement, and ensure with global procedures and Indonesian regulatory requirements

Quality Compliance Staff

April 2023 – April 2025

Project : Improvement data analysis (Minitab Software), Digitalization issue reporting, Digitalization training program (M-learning), Improve quality behavior & knowledge (QCC program), Improvement Logbook System

PT Perfetti Van Melle Indonesia (Multinational FMCG Company; Confectionery : Candy & Gum)

Nov 2021-April 2023

QC Laboratory Engineer

- Winner project idea phase-1 2022 at Perfetti Van Melle and leading project reduce QC release time
- Collect sample RM PM, and carries out analytical tests for raw material, in-process sample, and finished product. Also maintain SAP material master data
- Ensure quality analysis process are aligned with global guideline and perform troubleshooting HPLC (High Performance Liquid Chromatography) tools for analysis of vitamin C, capsaicin, sucrose glucose ratio, color contamination, acidity
- Conduct validation method analysis, stability test, and perform data related to titration, viscosity, gravimetric, and spectrophotometry
- Analyze and provide evaluation report of lab trial and pilot trial, also responsible for managing stock of raw material & finished good
- Updated standard method and supported audit of KAN accreditation for laboratory (ISO17025), Food Safety Management (FSSC 22000), HACCP, and Good Manufacturing Practices

Project : Create method Capsaicin analysis for Golia, create method color analysis for Big Babol, reduce QC release time

Eijkman Institute (Under the Auspices BRIN)

2021

Research Student (Internship)

- Led a microbiology research project investigating maggots in Indonesia with potential antibacterial activity against respiratory pathogenic bacteria
- Coordinated laboratory activities including isolation & characterization of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Staphylococcus aureus* as well as identification, serotyping, and antimicrobial susceptibility testing of maggot extracts as potential medical candidates
- Formulated research problem, designed scientific approaches, and guided the team in executing experiments and analyzing results using systematic scientific methods

Achievement : Gold Medal Winner ASEAN Innovation Science Competition

EDUCATION

Institut Pertanian Bogor (IPB University)

Aug 2017 – Oct 2021

Bachelor of Biochemistry, GPA : 3,09

Awardee Scholarship : Bidikmisi, Paragon Scholarship (Pondok Inspirasi Dormitory), Laznas Scholarship for Final Year Project

PROFESSIONAL CERTIFICATIONS

Statistical Process Control	 PT. Elpharma Multi Solution	2026
Learn about SPC principles, control chart interpretation, process capability analysis (Cp/Cpk), and data-driven decision making		
Yellow Belt Lean Six Sigma	 MF Operational Excellence	2026
Learn about DMAIC framework, waste elimination, process mapping, and root cause analysis tools		
Knowledge Management	 ISPE-ID	2025
Learn about knowledge capture and strategies, and building a sustainable knowledge-sharing culture within quality organizations		
Continued Process Verification	 PT. Elpharma Multi Solution	2024
Learn about CPV lifecycle approach, critical process parameter monitoring, and early detection of process variability		
Troubleshooting HPLC	 BRIN	2023
Learn about systematic troubleshooting of HPLC systems, chromatogram interpretation, and preventive maintenance practices		

PROJECTS

CAPA Backlog Recovery Project	2026
- Led structured CAPA recovery roadmap through risk-based mapping and prioritization of overdue CAPA, defining a committed closure timeline across sites - Kicked off site leadership CAPA monitoring on a weekly basis to drive systematic backlog closure and sustain long-term compliance	
Supplier Quality Agreement & Alternative Supplier Project	2026
- Conducted risk level analysis to prioritize suppliers by criticality, supporting fulfillment of quality agreements across all suppliers - Prioritized critical suppliers based on risk analysis to determine which required alternative supplier qualification first, mitigating supply continuity risk	
Global Anti-Counterfeit Implementation	2026
- Managed end-to-end change control for the global implementation of anti-counterfeit features across multiple countries, ensuring proper documentation, regulatory alignment, and cross-functional coordination (Regulatory, Supply Chain, Production, and Quality) - Conducted risk assessments to evaluate potential impacts on product quality, packaging processes, supply continuity, and compliance during implementation	
Quality Digitalization & Data Optimization Initiative	2025
- Initiated and led the digital transformation of quality systems from paper-based processes to structured digital platforms, including the development of issue reporting systems (by dashboard) and digital training management (M-learning) to improve traceability and compliance - Spearheaded the transition of statistical data processing from manual Excel-based analysis to Minitab-driven analysis, establishing alert mechanisms to detect data trends and potential violations proactively	

AWARDS & PUBLICATIONS

- ASEAN Innovation Science Competition (Gold Medal and Best Persentation)
- 1st Winner Of National Science Competition (1 out of 20 team)
- 1st Winner Student Scientific Competition (1 out 60 team)
- Finalist Of National Student Scientific Competition (PIMNAS 32) by Kemenristekdikti (1 out of 625 participants)
- Presenter in Japan Tech Planter Competition (1 out of 3 team from Indonesia)
- Best Persentation International Biomedicine Conference by Brawijaya University (1 out of 10 participants)
- Biosensor from Hemolytic Bacteria to Measure Blood Hemoglobin (<https://journal.ipb.ac.id/index.php/cbj>)
- Antibacterial Activity of Black Solder Fly Againts Pathogenic Bacteria (<https://ejournal.jares>)
- Innovation of Torbangun leaf extract-based instant noodle as a breast milk stimulant product (<https://patenttorbangun>)
- Arrowroot Tuber (Maranta arundinacea), Alternative Source of Inulin (www.warstek.com)

SKILLS SUMMARY

- Tools** : Minitab, SPSS, Trackwise, Excel, PowerPoint
- Technical Competencies** : Issue Investigation & Impact Assessment, Quality Risk Assessment, Product Complaint, Product Quality Review, Statistical Process Control, Documentation Control, Audit Management, Troubleshooting Instrument, Method Validation
- Soft Skills** : Training & Facilitations, Stakeholder Communications, Decision Making Under Risk, Leadership, Public Speaking, Leadership
- Languages** :
 - Indonesian – Native proficiency (oral and written)
 - English – Professional proficiency (oral and written)