

Curriculum Vitae

Personal Details

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Height, Weight : 168 cm, 85 Kg
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PROFESSIONAL SUMMARY

Licensed Pharmacist with over 15 years of experience in pharmaceutical manufacturing, including Production Management, Quality Assurance, Validation, and GMP Compliance. Proven track record of leading pharmaceutical manufacturing operations, implementing Lean Manufacturing initiatives, and driving Operational Excellence through continuous improvement and team development.

Experienced in CPOB/GMP compliance, production planning, validation, quality systems, continuous improvement, CAPA, deviation management, risk management, and regulatory inspection readiness. Strong cross-functional leadership with extensive exposure to pharmaceutical manufacturing environments.

CORE COMPETENCIES

Pharmaceutical Production Management

- ✧ GMP / CPOB Compliance
- ✧ Production Planning & Scheduling
- ✧ Lean Manufacturing
- ✧ Kaizen & Continuous Improvement
- ✧ Operational Excellence
- ✧ Quality Assurance
- ✧ Quality Risk Management
- ✧ Validation & Qualification
- ✧ CAPA & Deviation Investigation
- ✧ Root Cause Analysis
- ✧ Change Control
- ✧ OEE Improvement
- ✧ Productivity Improvement
- ✧ Team Leadership & Coaching
- ✧ Audit & Inspection Readiness
- ✧ Cross-Functional Collaboration

MANUFACTURING EXPERIENCE

Extensive experience in pharmaceutical manufacturing operations, technology transfer, process validation, production management, and GMP compliance across multiple dosage forms, including:

- ✧ Solid Oral Dosage (Tablet & Film-Coated Tablet)
- ✧ Hard Gelatin Capsule Manufacturing
- ✧ Capsule Filling & Encapsulation
- ✧ Powder Manufacturing
- ✧ Dry Syrup Manufacturing
- ✧ Oral Liquid / Syrup Manufacturing
- ✧ Cream Manufacturing
- ✧ Ointment Manufacturing
- ✧ Effervescent Tablet Manufacturing
- ✧ Granulation (Wet & Dry)
- ✧ Blending & Mixing Process
- ✧ Compression Process
- ✧ Coating Process
- ✧ Bottle Packaging & Blister Packaging
- ✧ Process Validation & Equipment Qualification
- ✧ Production Scale-Up & Technology Transfer
- ✧ GMP / CPOB Compliance
- ✧ Lean Manufacturing & Continuous Improvement

Education Background

Period			School / Institution / University	Dept	Score
1992	-	1998	Soka 3 Elementary School, Bandung	-	
1998	-	2001	Junior High School 27, Bandung		
2001	-	2004	Senior High School 10, Bandung		
2004	-	2009	Bandung College of Pharmacy	Pharmacy	3.16 / 4.0
2009	-	2010	University of Padjadjaran (UNPAD)	Professional Pharmacist Program	3.06 / 4.0

Training & Certifications

- ✧ Training Leadership - Parlindungan, 2011
- ✧ Training ISO 9001:1998 : Quality System, 2011
- ✧ Almega Sejahtera, Good Weighing Practice, 2012
- ✧ QA & QC Manager, Workshop “ Computerized System Validation and Equipment Qualification”, 2013
- ✧ ISPE, Pengolahan data Validasi Proses & PQR, 2016
- ✧ ISPE, Filter Validation Sterile Manufacturer, 2017
- ✧ Increase your Productivity with Our System - Larascipta, Bandung, 2017
- ✧ BPOM, Workshop penyusunan CAPA, 2017
- ✧ Training ISO 9001:2015 Quality Management System, 2019
- ✧ Training ISO 14001:2015 Environment Management System, 2019
- ✧ Lean Manufacturing, Kaizen Indonesia, 2021
- ✧ Training 5R, Kaizen Indonesia, 2022

Computer Literate

- ✧ Microsoft Office.
- ✧ Microsoft Project

Organization Experience

- ✧ Project Leader - Construction of Effervescent Tablet Manufacturing Facility PT Marin Liza Farmasi 2019
- ✧ Production Lean Manufacturing Lead PT Lucas Djaja 2020-2021
- ✧ Steering Committee Member - Lean Enterprise Lucas Group 2021 - Present

Summary of Working Experience

1. Quality Assurance Manager Lucas Group

(PT. LUCAS DJAJA – 2021 – 2023 & PT. Marin Liza – 2023 – Present)

Responsibilities

GMP Compliance & Regulatory Assurance

- ✧ Ensure the implementation and maintenance of quality systems in compliance with GMP requirements.
- ✧ Oversee readiness for internal and external audits (BPOM, clients, certification bodies).
- ✧ Ensure that all production, testing, storage, and distribution processes comply with quality standards.
- ✧ Manage deviation systems, CAPA, change control, and risk management processes.

Quality Management System (QMS)

- ✧ Develop, implement, and continuously improve the overall Quality Management System (QMS).
- ✧ Ensure qualification, validation, and calibration programs are executed according to plan.

Customer Focus

- ✧ Handle customer complaints systematically through scientific investigations.
- ✧ Ensure timely and effective complaint resolution.
- ✧ Identify complaint trends and propose systemic improvements.

Continuous Improvement

- ✧ Initiate and drive Continuous Improvement (CI) programs.
- ✧ Analyze quality data (PQR/APR, deviation trends, OOS, complaints) to enhance processes.
- ✧ Implement tools such as Lean, Six Sigma, and risk-based approaches.
- ✧ Promote and strengthen a culture of quality throughout the organization. across the organization.

Quality Risk Management

- ✧ Implement risk-based approaches in accordance with ICH Q9 guidelines.
- ✧ Ensure all quality-related decisions consider both patient safety and business impact.
- ✧ Oversee risk assessment processes for changes, deviations, and investigations.

2. Production Manager Lucas Group

(PT. Marin Liza – 2017 – 2020 & PT. LUCAS DJAJA – 2020 – 2021)

Responsibilities

- ✧ GMP Compliance: Ensure all manufacturing processes comply with CPOB/PIC/S/WHO GMP requirements and maintain audit readiness.
- ✧ Operational Excellence: Manage production planning and execution to achieve output targets, operational efficiency, and optimal utilization.
- ✧ Productivity & Efficiency: Optimize the utilization of resources (manpower, machines, and materials) while minimizing waste and downtime.
- ✧ Customer Satisfaction: Ensure on-time product delivery while meeting all quality standards and product specifications.
- ✧ Continuous Improvement: Drive data-based continuous improvement programs focusing on yield, OEE, and deviation performance.
- ✧ People Management: Lead and develop production teams, enhance employee competencies, and foster a culture of discipline and quality.

3. QA Validation PT. Otto Pharmaceutical Industries – 2013 – 2017

Responsibilities

- ✧ Prepare qualification and process validation schedules.
- ✧ Prepare machine qualification and process validation protocols and reports.
- ✧ Conduct investigations in case of non-conformity during machine qualification and process validation activities.
- ✧ Perform validation studies.
- ✧ Assist the QA Manager in reviewing batch record revisions prepared by the Production Department.

4. QA Supervisor PT. Pyridam Farma – 2012 – 2013

Responsibilities

- ✧ Review the compliance of production batch record documents against established requirements and provide disposition recommendations.
- ✧ Report any non-conformity identified in batch record documents and provide recommendations for deviations.
- ✧ Handle deviations by conducting investigations to identify root causes, implementing follow-up actions, and establishing preventive measures.
- ✧ Follow up on deviations and abnormalities occurring during the production process through investigations, monthly reporting, and trend analysis.
- ✧ Monitor QA Inspectors and ensure the proper implementation of In-Process Control (IPC) activities.
- ✧ Assist the QA Manager in reviewing batch record revisions prepared by the Production Department.

- ✧ Conduct Annual Product Reviews (APR) based on QA/QC testing results and production data, with reports presented in graphical format. Complete the review with trend analysis and necessary comments.
- ✧ Develop and implement risk management related to GMP/CPOB deviations.

5. QA Staff PT.Pyridam Farma - 2010 - 2012

- ✧ Prepare annual calibration schedules and monthly calibration implementation plans.
- ✧ Monitor calibration activities and review calibration reports.

Language Proficiency

Ability					
No	Language	Read	Written	Speak	Listen
1	Bahasa	✓	✓	✓	✓
2	English	✓	✓	✓	✓

Willing to relocate and work under pressure. Committed to maintaining high professional standards, contributing to organizational success, and continuously improving performance.

Regards.



(apt. Gan Gan Ginanjar Mulya Hidayat, S.Farm)