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Personal Data

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Mobile Phone	085694502831
E-mail Address	rionaldo_oo@yahoo.co.id
Place/Birth Date	Padang, May 25 th 1990
Nationality	Indonesian
Religion	Islam
Marital Status	Single
Height	167 cm



Personal Description

I am graduate from Institute Technology of Bandung (ITB) with a honours degree in magister pharmacy industry. I am currently working in PT. LAPI Laboratories as QA Manager. My first experience at PT. Dankos Farma. During placement with Dankos Farma, I worked in production division. In production division, I worked to management production that consider cGMP, stage of each process for steril or nonsteril dosage form, work in process, batch staging, lead time, equipment capacity. After that, I was mutation to the QC department as a QC supervisor who handled the release of raw materials, packaging materials, finished products and stability. Nearly 5 years at Dankos Farma, I was promote to corporate QA PT. Kalbe Farma as Corporate QA Asisstant Manager and after that working as QA Line Managet at PT. Dankos Farma and now working in PT LAPI Laboratories as QA Manager.

Educational Background

2021-2023	Institute Technology of Bandung (ITB), Magister Pharmacy Industry, GPA 3.89 of 4.00
2012-2013	University of Indonesia (UI), apothecary profession degree, GPA 3.50 of 4.00
2008-20012	Pharmacy Faculty, University of Indonesia (UI), pharmacy bachelor degree, GPA 3.37 of 4.00
2005-2008	SMAN 12 Jakarta
2002-2005	SMPN 139 Jakarta

2001-2002	SDN 05 Malaka Sari Jakarta
1996-2001	SD Kartika 1-10 Padang
1994-1996	Taman Kanak-kanak Pertiwi Kotamadya Padang

Organizational Experience

2003-2004	Scientific Group of Young Junior High School 139 as Chairman of extracurricular
2003-2004	The board ekstrakurikuler SMP 139 as Chairman
2005-2006	Class Representative Assembly SMAN 12 years as amember of the commission
2006-2007	Class Representative Assembly SMAN 12 as general treasurer
2013- present	The member of TPM Pillar at Dankos Farma

Committee Experience

2007	Basic Training Student Leadership Committee SMAN 12
2008	Student Orientation Committee SMAN 12
2010	Mathematics and Science Committee Cup
2010	Committee Oliampiadde Pertamina
2011	Excursion Study Committee of Pharmacy class of 2008
2012	Training Committee for Biotechnology

Achievements

1999	Participants Quiz PT. Semen Padang in West Sumatra elementary level
1999	Representatives of elementary school students in the West Sumatra reception Command Chief of the Army
2002	Best Graduate Students of SDN 05 Malaka Sari Jakarta
2005	Best Graduate Student SMP 139 Jakarta
2008	Representatives of the high school Quiz competition Ministry of marine
2005-2008	Scholarship of PT.Enseval Megatrading
2014	The majority of A3 Report in Dankos Farma

2014	Increase Capacity in Line Capsule
2015	Make QRM for injectable product, hardcapsule dan softcapsule
2015	Reduce Spec in product tested impurity
2016	Validate mobile phase and reference standar for pareto product
2016	Doing skip lot testing for pareto packaging material

Work Experience

2012	Assistant to the analysis of Pharmaceutical Chemistry Laboratory, University of Indonesia
2012	Assistant Chemical Raw Materials Analysis Laboratory, Pharmacy, University of Indonesia
2012	Training tool microplate reader at Faculty of Pharmaceutical Biotechnology
January , 2013	Pharmacists Professional Practice (PKPA) in East Jakarta Health Sub- Department
February , 2013	Pharmacists Professional Practice (PKPA) in PT. Taisho Pharmaceutical Indonesia Tbk
April , 2013	Pharmacists Professional Practice (PKPA) in Keselamatan Apotec
July 2013 - Juni 2015	Production Supervisor in PT. Dankos Farma
Juni 2015- March 2018	Quality Control Supervisor in PT.Dankos Farma
March 2018- December 2019	Corporate Quality Assurance PT.Kalbe Farma
January 2020 – December 2021	Corporate QA Assistant Manager PT. Kalbe Farma
January 2022 – Mar 2024	QA Line Manager PT. Dankos Farma
Apr 2024 – Now	QA Manager PT LAPI Laboratories

PT Dankos Farma, Jakarta **July 2013 – Juni 2015**

Occupation or position held: **Production Supervisor**

Responsibilities:

- a. Supervise all activity of production operator from the beginning until the end of working hour.
- b. Supervise the realization of GMP pratices in production area through supervising the activities,building, production utilities, production equipment, hygiene and sanitation, production processes and

documentations.

- c. Generate deviation report for any deviation that occur during manufacturing and implement Correction Action and Prevention Action to avoid deviation recurrences.
- d. Continuously improve efficiency and effectivity of manufacturing process
- e. Coordinate weekly production planning with other section : QA/QC, PPIC, and Logistic
Control execution of daily production planning done effectively
- f. To organize and synchronize all of the jobs for Coordinator , to make the production process works in a safe, effective, and efficient way, appropriate with the working plan and the existing procedure.
- g. To organize and supervise the implementation of each step in production process and to guarantee that product manufacturing process is comply with batch manufacturing and batch packaging procedures.
- h. Manage training program in production area
- i. Review and Control OEE and Productivity

PT Dankos Farma, Jakarta

Juni 2015 – Maret 2018

Occupation or position held:

Quality Control Finish Good Supervisor

- a. Ensure ongoing operational activities and stabilize QC to timely and accurately in accordance with the applicable procedures, with :
 - 1. To examine the results of the analysis done by the Analyst
 - 2. Approval process bulk products via the system oracle
 - 3. Report to their superiors when discovered irregularities in analyzing and reviewing the Forms Out of Specification (OOS) that was created by Analysts
 - 4. investigate the causes of OOS and make improvements that does not reoccur
 - 5. Coordinate the transfer schedule Analytical Methods (MA) of R&D
 - 6. Make a monthly report on all activities related to the analysis that has been done.
 - 7. Make a monthly report on all activities related to the analysis that has been done.
 - 8. Coordination with the production of the sampling stabilize
 - 9. Checking the results of the analysis and make a recap OOS stabilize
 - 10. Report the results of the analysis of the TMS stabilize to QC Manager
- b. Ensure the competence of the subordinate in its parts:
 - 1. Creating a competency matrix for subordinates
 - 2. Ensuring sub-ordinate to meet the competencies required for the job
 - 3. Ensure all sub-ordinate been given training on the procedures that exist in the QC Department

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- c. Ensuring a tool or instrument is ready for use in the analysis process, with
 - 1. Overcoming / follow up if there is a tool or instrument obstacles in the field.
 - 2. In cooperation with QA to perform calibration of the means of the needs analysis.
 - d. Operational guarantees QC run without any occupational accidents, by working with QHSE section to identify risk, plan preventive measures, as well as monitoring the implementation of K3 (Health and Safety at work) and the environment
 - e. Contribute to the implementation of best practice in the department, to carry out improvement works to the area in particular and the company in general.

Occupation or position held

Quality Control Raw Material and Packaging Supervisor

- a. Responsibility to sampling, analyze and make disposition raw material and packaging material
- b. Audit our vendor such as raw material , packaging material, distribution and also toll out vendor
- c. Do qualification vendor with purchasing and QA to ensure all supplier is comply to our standar
- d. Join many project like zero failure line and increase capacity in production area

PT. Kalbe Farma, Jakarta

April 2018 - Present

Occupation or position held

Corporate Quality Assurance Audit and Compliance PT.Kalbe Farma

- a. Support Kalbe affiliate in regulatory inspection and Monitoring CAPA Implementation Progress from Regulatory inspection on all Kalbe affiliates during Corporate audit
- b. Make risk assessment for vendor audit and execute Vendor Audit (RM, PM and Toll Manufacturing)
- c. Ontime vendor audit report (RM, PM and Toll Manufacturing)
- d. No Overdue CAPA critical finding (RM/PM Distributors)
- e. Ensure Audit Close Out (CAPA Closing) for Audit performed by CQA: 80% audited vendor (RM/PM and Toll Manufacturing)
- f. Support Quality Agreement Assurance for Toll Manufacturing and RM PM distributor/manufacture and Service Provider
- g. Perform qualification vendor (RM/PM)
- h. Perform QA Supplai Chan to Toll Manufacturing and moniroring KPI quality for Toll Manufacturing

PT. Kalbe Farma, Jakarta

April 2018 - Present

Occupation or position held

Corporate Quality Assurance Assitant Manager PT.Kalbe Farma

- a. Prepare the operational budget of the Corporate QA department
- b. Support and Assist Kalbe Group Project, including Audit for Certification new facility
- c. Develop Corporate Manual for Laboratory and Assist integration of Quality Manual into SOP and system
- d. Conduct Corporate Quality Audit to each Kalbe Company, Toll Manufacturer, Principal FG, Distributor/Sub Dis and Vendo
- e. Collect and Analyze KPI Quality Compliance in Kalbe Group through Monthly Report
- f. Develop Module training for personnel QA specialized in Pharma

PT. Dankos Farma, Jakarta

January 2022- March 2024

Occupation or position held

QA Line Manager PT. Dankos Farma

- a. Ensuring manufacturing process evaluation prior to batch disposition.
- b. Ensure that operational expenses are in accordance with the budget, by identifying needs, calculating, planning the budget, and checking the use of the budget.
- c. Minimize the long-term risks & financial impacts that arise in the operations of the relevant departments, by identifying risk, analyzing and taking preventative action.
- d. Ensuring the quality system runs according to applicable regulations, by Establish a quality system
- e. Initiating and participating in the formation of company quality manuals.
- f. Review and check batch rework, after identifying CAPA
- g. Reviewing product risk assesement
- h. Review proposal for procurement of new equipment or plan for modification of equipment or systems needed for the manufacture of transferred product to ensure the best possible technology that have any impact on GMP implementation.
- i. Ensure correct labeling on product containers
- j. Review and approve proposed changes that have the potential tmpact on process and product quality (change control management)
- k. Define procedure and monitor hygiene and sanitation program.
- l. Ensuring process validation and media fill (aseptic process) validation are conducted in

accordance with Validation Master Plan (VMP)

- m. Managing Deviation Handling include investigation until a decision is obtained that ensure product quality, documentation, making trends and maintaining compliance status
- n. Ensure operational runs without work accidents, in coordination with the HSE
- o. Contribute in development and implementation of best practices in its department operations
- p. Develop human resources which related to the productivity at department, through identify the organizational needs and human resources, organize the team
- q. Contribute in Project Parametric Release and New Facility : Ready To Fill and Blow Fill Seal

PT. LAPI Laboratories

Banten, April 2024 – Present

Occupation or position held

QA Manager PT. LAPI

- a. Carrying out finished product release
- b. Ensuring validation, qualification and calibration is carried out in accordance with the Validation Master Plan
- c. Managing Deviation Handling include investigation until a decision is obtained that ensure product quality, documentation, making trends and maintaining compliance status
- d. Managing retur, recall and complaint include investigation and decision
- e. Ensure that operational expenses are in accordance with the budget, by identifying needs, calculating, planning the budget, and checking the use of the budget.
- f. Monitor and ensure that the QA program is running according to the standards and regulations applicable in the pharmaceutical industry
- g. Ensure that the implementation of CPOB/CPOTB, ISO 9001:2015 and other regulations are running well
- h. Manage product renewal and provide data for product renewal to BPOM
- i. Ensure product compliance as submitted to BPOM

Training

2013	Basic Training CPOB 2012
2014	Interpersonal Communication Skill
2014	Technical Presentation skill
2014	Total Productive Maintenance
2015	Quality Risk Management
2015	Konsep Pemastian Mutu
2016	Drug Inspection and Quality Audit
2016	GMP Internal and External Auditor
2016	Personel Effectiveness Program
2016	Leadership Development Program
2016	How to be a great trainer
2018	Halal, Good Distribution Practice, Risk Management, Quality by Desain
2021	Computer System Validation, Continuous Process Verification
2022	Parametric Release and PAT
2024	Contaminant Control Strategy

Language

Language	Speaking	Listening	Writing
English	Fair	Good	Good
Bahasa Indonesia	Good	Good	Good

I hereby certify that the information I have provided is accurate and true to the best of my knowledge and belief.

Sincerely yours,

Rionaldo Sarano