

Hoirul Fikri Mubarak

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EDUCATION

Universitas Airlangga

Bachelor of Pharmacy (GPA: 3.26)

Pharmacist Education Program (GPA: 3.60)

Surabaya, Indonesia

August 2019

November 2020

PROFESSIONAL EXPERIENCE

PT. Novell Pharmaceutical Laboratories

Quality Assurance Qualification Staff

Bogor, Jawa Barat

January 2021 – February 2022

- Compiling Installation, Operational, and Performance Qualification Protocol for Sterile Equipment (Washing Machine, Oven/Tunnel Depyrogenation, Autoclave Preparation, Mixing Tank, Holding Tank, Filling Machine, Autoclave loads for Non Aseptic Product).
- Compiling Installation, Operational, and Performance Qualification Protocol for Non Sterile Equipment (Super Mixer, Double Cone Blender, Fluid Bed Dryer, Compressing Machine, Coating Machine, Stripping/Blistering Machine, Labelling and Cartoning Machine) Monitor CAPA for deviations.
- Compiling Installation and Operational Qualification Protocol for Support System such as HVAC System for Grade D, C, and B Area, Water for Injection (WFI), Compressed Air, and Industrial Steam based on cGMP, ISO, CPOB, and other regulation.
- Perform Particle Examination, Integrity Test, Velocity Test and Study Air Direction (Smoke Test) for Unidirectional Airflow (UDAF), Isolator, and Laminar Airflow (LAF).
- Perform Particle Examination, Integrity Test, Velocity Test and Study Air Direction (Smoke Test) for Unidirectional Airflow (UDAF), Isolator, and Laminar Airflow (LAF).
- CAPA Handling related to Qualified Equipment and Support System.
- Create URS (User Requirement Specification) for Machines that will be procured.
- Perform the Qualification Process (IQ, OQ) for Buildings.

PT. Dankos Farma

Quality Assurance Line Supervisor

Jakarta Timur

February 2022 – Present

- Oversee production process to assure its compliance with guidelines and standard operating procedures in production facility.
- Monitoring of implementation Secondary Packaging IPC in production area.
- Handle deviations occurs during production process, from GENBA with related department, data collection for investigation and also lead investigation process until possible root cause discovered.
- Perform batch record reviews to ensure product quality and regulatory conformity and release batch production by Oracle system.
- Handling and Monitoring of validation by providing schedule, review protocol and report of execution.
- Review and proceed to approval process for site master batch record, include change control implementation and periodic review with Technical Support department.
- Monitoring weekly open and closed CAPA, manage CAPA verification and effectiveness derived from deviation and quality oversight.
- Conduct quality oversight daily and internal audit for manufacturing according to fixed schedule.
- Provide quality training to production staff related compliance practice.
- Reviewing Protocol and Mediafill Process Validation Reports.
- Conduct quality improvement to enhance quality awareness to shopfloor and also collaborate with other department.
- Perform investigation related products complaints include batch record review, deviation history and GENBA with related department
- Monthly report related Quality achievements to Site and Corporate Quality

ORGANIZATION EXPERIENCE

BEM Fakultas Farmasi

PSDM Staff

Universitas Airlangga
February 2017 – January 2018

HMI Komisariat Farmasi UNAIR

Chief of the Organization

Universitas Airlangga
February 2017 – March 2018

HMI Komisariat UNAIR

Head of Development Division

Universitas Airlangga
March 2018 – April 2019

PROJECT & ACHIEVEMENT

Auditee Badan Pengawasan Obat dan Makanan (BPOM) (2021)

- PIC QA Qualification for Certification of Production Facilities Antiviral NBL-3 PT Novell Pharmaceutical Labs

Zero Environmental Monitoring NMS (2022)

- This project aimed to reduce environmental monitoring related growth of microbiology on aseptic process.

Increase QA Cycle Time (2022)

- This project aimed to increase QA time for reviewing batch record after complete production process

Increase BRFT BD by Zero Failure Line Project (2023)

- This project aimed to increase BRFT (Batch Right First Time) from the amount of Batch Deviation during production process by Zero Failure Line Product based on Top 3 deviation category per month.

Reduce Particle Contamination in Sterile Product (2023)

- This project aimed to reduce contamination from black particle, white particle and fibers from utility and machine during aseptic filling production process

Trainer of KUALIMA Basic GMP (2023)

- This program aimed to trained shopfloor related compliance issue, updated guidance related GDOCP, aseptic behaviour and GMP

Increased Yield Product Ketorolac with Two Stage Inspection “ICONIC 2024” at PT Dankos Farma (2024) **Silver Medal of Dankos CONIM Award 2024**

- This project aimed to implementation two stage inspection method to increased yield and reduce reject, in response to high levels of deviation due to the discovery of black particles during the product Ketorolac inspection process and this project collaboration with engineering, production, qualification and calibration.

QCP Advance Fogging Solutions for Isopropyl Alcohol Desinfection “ICONIC 2024” at PT Dankos Farma (2024) **Finalist Grand Convention in Orchestra Category**

- This project aimed to improve quality by obtaining disinfectants and other sanitation equipment that are effective in killing bacteria and fungi in the weighing area. This project collaboration with QC and logistic.

Reduce Deviation Related Documentation (2025)

- This program aimed to reduce finding on batch record for data creation from productions personnel, include batch record simplification ideas.

SKILLS

- GMP, Sterile Manufacturing
- Risk Management/Assessment
- GAP Analysis/Assessment
- Deviation Handling
- Qualification and Validation
- People Management
- Effective Communication
- Continuous Improvement
- CAPA Monitoring/Management
- Quality Oversight
- Batch Record Review and Product Release

COURSE

- Pharma 4.0
- Good Documentation Practice
- Data Integrity
- Contamination Control Strategy
- Problem Solving Report
- Personal Effectiveness Program
- Parametric Release
- Quality Risk Management
- GMP Auditor