



BAGUS IRAWAN

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EXPERTISE

- *16 years extensive experience in Quality Management System, Good Manufacturing Practice (PIC/S GMP, EU GMP Annex 1, WHO GMP), ICH Guidelines (Q8, Q9, Q10, Q12), GAMP 5 and Data Integrity (ALCOA+) principles.*
- *Subject Matter Expert (SME) in Process Validation, Cleaning Validation, Equipment-Utilities Qualification and Computer System Validation while managing departmental KPIs, project timelines, and resource optimization.*
- *Strong cross-functional leadership with Production, Engineering, Quality Assurance, QC, Regulatory Affairs, Supply Chain, and Management to successfully execute complex pharmaceutical projects.*

LANGUAGE

Indonesia	
English	

PROFESSIONAL EXPERIENCE

PT. ERELA

Validation Manager

- Project (New Plant Start Up, Eyedrop Production Line, Effervescent Production Line, Traditional Medicine Production Line, Betalactame Decontamination, Syrup Line Expansion, Eye Ointment Line Expansion)
- Manage utility and equipment qualification activities
- Manage computer system validation activities
- Manage cleaning validation activities
- Manage validation process activities
- KPIs
- Continuous Improvement

Feb 2020 - Now

PT. DION FARMA ABADI

Production Assistant Manager

- Planning, managing and executing production operation to meet Supply Chain order
- Coordinate and plan production priorities, workflow and schedule
- Identify and report operational and maintenance problems to prevent production delays
- Develop or update standard operating procedures and best practices for production operations
- Ensure safety measures are procedures are followed to reduce unexpected incidents and hazards
- Ensure that all equipment, materials and supplies are readily and continuously available to carry out production processes
- Continuous improvement

**August 2017 – Jan
2020**

PT. GLOBAL MULTI PHARMALAB

QA Manager

- Preparing, approving and monitoring the implementation of key documents based on CPOB / GMP and ISO 9001:2015 (Quality Policy, Quality Manual, VMP, PQR, QRM, and SMF etc.).
- Review and approve Batch Record to release finished product that meet company and regulatory requirement.
- Review and approve calibration, qualification, and validation, as well as critical utilities qualification report (HVAC, water systems, etc.).
- Ensuring that planned/unplanned changes or deviations are documented, reviewed and analyzed, or validation activities to be performed.
- Responding to customer complaints and recalls, supervising the investigation into the cause of issue, providing an investigation report to the customer, etc.
- Leading the internal audit team for all department, interacting with auditors during external, internal and customer inspections.

**May 2015 – August
2017**

PT. SANBE FARMA-West Java

Production Manager of Biologicals Plant

- Supervise project activities within time limits
- Initiate cGMP, SOP and Work Instruction training program for new personnel
- Create Batch Record, SOP and Working Instruction

**Nov 2013 – April
2015**

Validation and Qualification Supervisor

- Supervise qualification and validation activities
- Perform qualification and validation documentation

**May 2011 – October
2013**

PT. SIMEX PHARMACEUTICAL-West Java

QA Supervisor

- Prepare Annual Product Quality Review to drive product quality improvement.
- Handle site Change Control Management to comply with Quality System.
- As an Internal Audit coordinator (GMP) and participate in External & Supplier Audit.

**May 2010 – April
2011**

Achievement and Key Contribution

- PT. Erela
 - Reduce EM from weekly to monthly using QRM
 - Chief of Betalactam decontamination project
 - Certification of New Eye Drop Facility
 - Certification for Syrup Line Expansion
 - Certification of New Low RH Facility
 - Certification for Traditional Medicine Expansion
 - Extension of Eye Ointment AHU PQ from Annually to every 3 years (2023)
- PT. Dion Farma Abadi
 - Successful for ISO 45001 Occupational Health & Safety Management System Certification
 - Halal line certification for Halal Product Assurance
 - Improvement from offline process to inline direct from filling to secondary packing
- PT. Global Multi Pharmalab
 - Develop 5R Management
 - Complete documentation for sharing facilities drug and health supplement
 - Reduce sterilization cycle from 30 minutes to 20 minutes
- PT. Sanbe Farma
 - The biological plant facility was successfully approved by BPOM in March 2015
 - The oncology plant facility was successfully approved by BPOM in January 2012.

EDUCATION AND ACTIVITIES

Apothecary :

- Apothecary Profession Study Program Faculty of Science, Indonesia Islamic University, Yogyakarta (2009-2010) GPA 3.65.

Bachelor Degree of Pharmacy :

- Pharmacy Study Program Faculty of Science, Indonesia Islamic University, Yogyakarta (2004-2008) GPA 3.06.

OTHER EXPERIENCES

- FAT of Inline Machines for Granulation, Drying, Lubrication, and Tablet Compression (Ex GEA India)
- FAT of Inline Machines for Vial Washing, Depyrogenation, Mixing, and Filling (Ex Steriline Italy)

REFERENCE PERSON

Bp. Wahyu Prabowo – Plant Manager of Konimex Plant

*Reference's contact no/email are available upon request.

I hereby declare that the above written particulars are best of my knowledge and belief.