

Agnesia Priyantina Nugraheni Ssi, APT
Mobile: 0816-639597



EDUCATION

- Bachelor of pharmacy – Graduated from University of Indonesia, November 1999 ☐ Pharmacist, Graduated from University of Indonesia, January 2000

PROFESSIONAL PROFILES

- More than 20 years' experience in several related GMP areas: Production, Packaging, Quality Assurance, Quality Control, Quality System & Compliance, Validation and Regulatory
- Highly organized and dedicated with a positive attitude.
- Work well independently and as a team member.
- Excellent ability to handle a multitude of assignment with strict deadlines.
- Excellent written and oral communication skills.
- Fluent in Indonesia and English

TECHNICAL COMPETENCES

- Knowledge of Pharmaceutical Standards and Quality Management Systems
- Technical knowledge of Pharmaceutical Production and other supporting processes
- Understanding of cGMP requirements (Indonesia/ASEAN/company guidelines)
- Detailed understanding of pharmaceutical manufacturing business processes
- Experience in developing Compliance Systems, Training, Audit process, Handle Audits Performed by regulated market authority, Handle Deviation and Changes associated with product quality, perform data analysis and provision of product decisions.
- Experience in developing Quality Risk Management, HIRARC (Hazard Identification, Risk assessment and Risk Control) and IADL (*Identifikasi Aspek Dampak lingkungan / Identification Environmental Impact Aspects*)
- Directly involved in the audit from regulatory authority, such as Indonesian Authority (BPOM), Australian Authority (TGA), United Kingdom Authority (MHRA), and Nigerian Authority.
- Directly involved in the Foreign Site Inspection by Indonesian Authority (BPOM)
- Experience on implementing HALAL Assurance System & HALAL product

CAREER SYNOPSIS

PT. Pfizer Indonesia

01 May 2020 – Now: Site Quality Operations Lead (SQOL)

- Lead Site Quality Operations to ensure highest quality products are supplied to our patient on time and that financial commitment are delivered by owning responsibilities for Quality System and Compliance, Quality Assurance, Quality Control, Validation & Qualification Activities.
- Act as GMP compliance role model for all PGS Jakarta team, with a strong focus on quality system and compliance, QC lab, Quality Assurance and Technical services operations, ensuring that policies and procedures are developed and maintained as per Pfizer Quality Standards, cGMP requirements from Badan POM and other regulatory bodies

Achievement 2021 – 2024

- Strong KPI Performance for quality and compliance consistently in last 3 years (2022, 2023, 2024)
- Successfully support the 3 simultaneous complex projects (semisolid relay out project, new purified water and chemical lab relocation) with No Critical, No repeat observation, No housekeeping observation from BPOM and RQA inspections (2023)
- Complete QO Organization Restructure with no major Supply interruption (2024)

PT. Pfizer Indonesia:**13 Aug 2020 – 30 April 2021: QA Manager**

- Responsible for ensuring that batch record review of products manufactured by PGS Jakarta is done in compliance with Site Procedures and Regulatory Requirements
- Responsible for ensuring that PGS Jakarta delivers on customer expectations of supplying quality of products. Finished product disposition schedule adherence against the Production Plan and shipment Plan is critical
- Manage and coordinate manufacturing investigation and product quality complaint investigation to ensure timely completion of investigation, including the notification to management, batch record evaluation and review and release / rejection of finished goods for distribution activities to ensure timely product supply.
- Drive team engagement and effective communication and the developments of supervisors within the QA team.

Achievement: Overdue QAR reduction to 87 % from total 63 Aging QAR by Dec 2020, and zero aging QAR carried over from 2020 by 30 June 2021

PT. CAPSUGEL INDONESIA – LONZA Company**23 Jan 2017 – 12 Aug 2020: Quality Assurance Senior Manager**

- Responsible for the implementation and adherence to site quality management in compliance all relevant regulatory and certifications requirement (GMP certificates, ISO 9001:2015, ISO 14001:2015, ISO 45001, Halal Assurance System, Halal certificate & Kosher)
- Assures that product is manufactured and released in compliance with the quality management system and GMP Requirement
- Responsible for handling complaint for SOUTHEAST ASIA market & Domestic Market
- Responsible for managing Quality in process control, Quality Control, Quality Compliance and Regulatory in accordance with global direction & guidelines within quality organizations
- Responsible for Quality Environmental Health Safety Management Representative (QEHS MR)

Achievement: Successfully development and implementation of DMS (Documentation Management System) in Lonza – Jakarta (March, 2020)

PT. Ethica Industry Farmasi – Join venture with Fresenius Kabi , Cikarang - Indonesia**1st Feb 2015 – 23 Jan 2017: Quality Operations Senior Manager**

- Responsible for the implementation, maintenance and adherence to site quality management system which us in compliance with Fresenius Kabi corporate procedures and all relevant regulatory and Certification Requirements

- Assures that all products are manufactured and released in compliance with the quality management system, Registration dossiers and GMP requirement.
- Responsible for managing **Quality Control, Quality Assurance & Dossier Management** in accordance with global quality organizations directions & GMP requirement

Achievement

Successfully leading on achievement of GMP Certificate for New Sterile Production Facilities, Cikarang Site within less than 6 months (June, 2016)

PT SOHO GLOBAL HEALTH – JAKARTA - INDONESIA

27th Feb 2014 – 30 Jan 2015: Quality Assurance Manager

- Responsible to initiate, implement and maintain Quality Management System to provide assurance to the products throughout the intended use over the shelf life, and evaluate the effectiveness of the System to advice Management with continuous improvement
- Responsible to conduct external audit (toll manufacturer company, distributors, suppliers)

PT BAYER HEALTH CARE, CIMANGGIS – INDONESIA

March 2013 – Feb 2014 : **Assistant Packaging Manager**

Responsible for ensuring that packaging of bulk products, released by Quality Control for packaging, is done in compliance with the relevant GMP principles, Bayer standard procedures and regulations set forth by the Food and Drug Administration of the Republic of Indonesia (BPOM).

PT FERRON PAR PHARMACEUTICAL, CIKARANG- INDONESIA

May 2010 – 28 Feb 2013 : **PRODUCTION MANAGER**

- Plan, lead and control safe production lines (dispensing, solid 1, solid 2, liquid, sterile 1 (small volume) & semisolid, and sterile 2 (large volume)) activities of Cikarang factory within National and international standard for quality and / or specifications and strict adherence to cGMP rules in order to meet customer requirement in timely and cost effective manner.
- Responsible for Plan, Budget, Manage and develop production human resources, implement HR programs and policies, decide on selection, training, performance review, development and necessary corrective actions of the people
- Responsible for Identify and solve problems and deviation, review and monitor performance of the equipment and other resources in production area to ensure improvement of overall productivity
- Responsible for Review and consolidate production budget, prepare and propose budget, control expenses against budget and prepare periodical report

Achievement

- Successfully leading project Increase Capacity Granulation Solida 1 (Boska – Glucient) up to 33 % (550 to 735 batches/year) through improvement campaign cleaning process from 5 times to be 16 times (December 2012)
- Excellence performance on KPI - Balance Score Card

PT. BOEHRINGER INGELHEIM INDONESIA – BOGOR, INDONESIA

- Jan 2010 – April 2010 Head of Section Production Technologist
- June 2006 – Jan 2010 Head of Section **Packaging**
Responsible for Plan, Lead and Control Safe Primary and Secondary Packaging activities (Solid, Liquid, Suppository, Aerosol and Repacking) within National and Corporate standard for quality/specifications and strict adherence to cGMP rules to meet customer requirement in timely and cost-effective manner.
- Responsible for ensuring the packaging activities are carried out according to the agreed production plan and manage the deviation from defined planning to ensure continuous of quality compliance of products
- Responsible for initiation of investment requirements (Capital Expenditure/CaPex) to improve production effectiveness

Achievement

- Successfully leading Project Scrap of Packaging Materials with tangible saving IDR 459.293.043 (December 4th, 2008)

Jan 2003 – June 2006

HEAD OF SECTION PRODUCTION TECHNOLOGIST

- Responsible for organizing product transfer from Industrial Customer Business (ICB) Customer and / or new product launch in coordination with GMP related departments as outlined in the Production Department organization.
- Responsible for organizing production of trial batches (and scale lab, if required) of the transferred product
- Responsible for planning and coordinate validation studies of the commercial batches of the transferred product
- Responsible for performing Gap Analysis to suggest the requirement for the 'development' or enhancement of the facility to start the needful for managing the changes related to the process at the receiving site.

Achievement

- Successfully coordinating product development activities for new local product: BISOLVON FLU (December 8th, 2005)

Aug 2001 - Jan 2003

QUALITY ASSURANCE SUPERVISOR

- Responsible for managing stability study
- Responsible for organizing Self inspection and monitor effectiveness of Corrective and Preventive Actions (CAPA)
- Responsible for managing GMP training in Bogor Plant
- Responsible for handling artwork development of packaging materials

PT. IKAPHARMINDO PUTRAMAS. PULOGADUNG _ JAKARTA

April 2000-Aug 2001

: VALIDATION STAFF & ISO COORDINATOR

Develop and define design process flow and SOPs of all areas (Production, QA/QC, R&D, PPIC, and Warehouse) to achieved standard of Quality Management System for ISO 9001