



apt. Aryo Bimo Bayu Aji, S.Farm.

Pharmacist | Pharmaceutical Product Management | Product Lifecycle Management

Licensed Pharmacist with 4+ years of experience in the pharmaceutical industry, combining hands-on experience in Product Executive, Quality Assurance, GMP Compliance, product lifecycle monitoring, scientific documentation, and cross-functional project management. Seeking to transition into Product Management, leveraging strong pharmaceutical knowledge, product experience, and understanding of quality and regulatory requirements to support product growth and business success.

PROFESSIONAL EXPERIENCE

PT. PESONA NATASHA GEMILANG

Person in Charge of Quality Assurance (Jun 2025 - Present)

Led the establishment of the Pharmaceutical Quality System (PQS) for a greenfield stem cell manufacturing facility to achieve CPOB certification readiness and compliance with PIC/S GMP and EU GMP Annex 1.

Key Achievement

- Led cross-functional projects involving 5 departments, ensuring project milestones and deliverables were achieved according to timelines.
- Managed technical evaluation and supplier qualification for 15+ critical GMP equipment packages, strengthening experience in supplier and product evaluation.
- Established the complete Pharmaceutical Quality System (PQS) from ground zero by developing 150+ GMP documents, including the Quality Manual, Validation Master Plan (VMP), SOPs, risk assessments, and validation protocols.
- Successfully supported Indonesian Ministry of Health certification** for an Autologous Stem Cell Processing Laboratory through regulatory inspection readiness and QA oversight.
- Led qualification of **45+ GMP systems and equipment** from URS through PQ, **achieving 100% on-time completion** while supporting facility operational readiness and regulatory compliance.

PT. NOVELL PHARMACEUTICAL LABORATORIES

Product Executive (Dec 2024 - Feb 2025)

Supported product lifecycle management, scientific documentation, product training, and cross-functional coordination for new product commercialization.

Key Achievement

- Supported product lifecycle management and new product commercialization**, including preparation of scientific documentation and coordination with cross-functional teams.
- Developed scientific and product-related documentation** to support new product launches and regulatory compliance.
- Delivered product knowledge** training to Field Force, strengthening scientific understanding and product portfolio knowledge.
- Coordinated with relevant internal functions** to support product readiness, commercialization activities, and launch requirements.
- Utilized pharmaceutical scientific knowledge to **translate technical product information into materials and explanations** that could be effectively communicated to commercial teams.

PT. FONKO INTERNATIONAL PHARMACEUTICALS (DEXAGROUP)

Quality Assurance Specialist - Compliance (Mar 2022 - Sep 2024)

Managed Quality Assurance Compliance activities to ensure pharmaceutical manufacturing processes consistently complied with PIC/S GMP and EU GMP requirements while supporting continuous improvement initiatives and production efficiency.

Key Achievement

- Managed pharmaceutical quality and compliance activities while supporting **product lifecycle monitoring and continuous improvement**.
- Collaborated** with Production, QC, Engineering, Procurement, and other functions to deliver pharmaceutical projects and improvement initiatives.
- Led procurement, qualification, and commissioning of 100% IPC laboratory instruments, including preparation of URS, supplier evaluation, IQ, OQ, and PQ documentation for New Project Oral Oncology Solid Dossage Line
- Reviewed and approved **30+ Batch Manufacturing Records (BMRs) per month**, maintaining an average batch release lead time of **less than 14 working days**.
- Investigated **100+ deviations, incidents, and material complaints annually** using **5 Why and Ishikawa methodologies**, resulting in effective CAPA implementation and reduced recurrence.
- Conducted **5+ internal GMP audits across manufacturing departments** and monitored CAPA effectiveness to improve inspection readiness.

PT. NOVELL PHARMACEUTICAL LABORATORIES

Production Supervisor (Oct 2021 - Mar 2022)

Supervised daily production operations to ensure GMP compliance, production efficiency, and quality performance.

Key Achievement

- Supervised **daily production operations while ensuring GMP compliance**, manpower utilization, production efficiency, and on-time batch execution.

SELECTED PROFESSIONAL ACHIEVEMENT

- Successfully supported Indonesian Ministry of Health Certification of Autologous Stem Cell Processing Laboratory
- Achieved 100% on-time procurement, qualification of laboratory instruments of New Project Oral Solid Dossage.
- Reduced lyophilized product particle rejection by 65% through process optimization.
- Reduced IPC sampling downtime by 50% through workflow redesign.
- Led cross-functional project teams involving Engineering, QA, QC, Production, and Procurement to successfully deliver qualification and regulatory readiness milestones.



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Aryo Bimo Bayu Aji

ACADEMIC BACKGROUND

- Professional Pharmacist / Apoteker** (GPA 3.97/4.00) - Gadjah Mada University - 2021
- Bachelor of Pharmacy** (GPA 3.03/4.00) - Gadjah Mada University - 2020

TECHNICAL EXPERTISE

- Product Knowledge & Scientific Training
- Scientific Documentation
- Product Presentation
- Cross-functional Leadership & Project Management
- GMP / CPOB Compliance
- Validation & Qualification
- Contamination Control Strategy (CCS)
- Internal & Supplier Audit
- Regulatory Inspection Readiness
- Data Integrity & Documentation Control

TRAINING

- Sistem Manajemen Mutu ISO 9001:2015 (2026)
- Desk Konsultasi CAPA-CPOB & Diskusi Interaktif BPOM (Jun 2026)
- Leadership League - Dexa Manufacturing Academy (Aug 2023 - Aug 2024)
- GxP Auditor Training (Jul 2024)
- Adaptive Communication Skills (Jun 2024)
- Design Thinking (Oct 2022 & May 2023)
- Root Cause Analysis (May 2022; May 2023; May 2024)
- Pharmacovigilance (Mar 2023)

SOFTWARE

- Microsoft Office (Word, Excel, PowerPoint)
- Microsoft Visio
- Oracle ERP
- Laboratory Information Management System (LIMS)
- Corel Draw; Photoshop
- Adobe Premiere Video