

Yashinta Widyaningtyas, S.Farm., Apt.

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OBJECTIVE

My objective is to provide total support to the organization I join by leveraging my experience, skills, and capabilities to help achieve its goals while fostering mutual benefits. I am committed to advancing my career through continuous learning and by utilizing my educational background, technical training, and organizational abilities to contribute meaningfully to the success of the team and the company.

PERSONAL DATA

Name : Yashinta Widyaningtyas, S.Farm.,Apt.

Place / Date of Birth : Kulon Progo, 4 June 1988

Religion : Christian – Catholic

Sex : Female

Health : Good Physical Condition

Nationality : Indonesian

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EDUCATION

2003-2006 SMA Negeri 1 Magelang

2006-Jan 2010 Faculty of Pharmacy Sanata Dharma University GPA 3.31 of 4
Yogyakarta

2010 - 2011 Apothecary Profession Programme GPA 3.94 of 4

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WORKING EXPERIENCE

1. QA QMS (GMP Manager)

PT SKPlasma Core Indonesia (28 Jul 2025 – presents)

Completed six-month intensive training at SK Plasma Andong, South Korea, focusing on plasma-derived product manufacturing processes and preparation for Technology Transfer initiatives.

QA Leader with a key role in the development and establishment of Indonesia's first plasma manufacturing facility, responsible for building and implementing quality systems from the ground up in compliance with GMP, GDP, and international regulatory standards.

Key Responsibilities:

1. QA Responsible Pharmacist for PT SKPlasma Core Indonesia Karawang Site.
2. Lead the establishment of the Quality Management System (QMS) for a greenfield plasma facility
3. Set up and author the Quality Manual and Quality Policies for the new manufacturing facility in alignment with GMP and regulatory requirements
4. Oversaw GMP compliance during commissioning phases
5. Develop and review SOPs, quality risk assessments, and other quality documentation
6. Act as QA and QMS representative for cross-functional teams (Engineering, Production, QC, Regulatory)
7. Handle regulatory inspections and audits
8. Ensure quality culture implementation within plant manufacturing site

2. Quality Assurance – Validation Manager

PT CKD OTTO Pharmaceuticals (Jul 2022 – Jul 2025)

Quality Assurance Manager

PT. CKD Otto Pharmaceuticals (Nov 2023 – Jul 2025)

- a. Responsible for Quality Assurance Process and Quality Management System in Sterile - Oncology Pharmaceutical Manufacturing.
- b. Responsible for Technology Transfer Project in coordination with Production unit and Sending Unit.
- c. Responsible for Packaging Development Team.

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- d. Deputy of QPPV (Qualified Person Responsible for Pharmacovigilance), acts as a backup to the assigned QPPV when the QPPV is not able to perform his/her duties temporarily.
- e. Responsible to establish and maintain Contamination Control Strategy within sterile manufacturing plant.
- f. External Vendor Audit experience:
 - o Huzhou Zhanwang Pharmaceutical Co.,Ltd (China) – API Manufacturer
 - o Kunming Guiyan Pharmaceutical Co., Ltd (China) – API Manufacturer
 - o Hubei Honch Pharmaceutical Co., Ltd. (China) – API manufacturer

Best Achievement: Receive Best Employee Awards PT. CKD OTTO Pharmaceuticals 2025.

Validation Manager

PT. CKD Otto Pharmeceuticals (Jul 2022 – Nov 2023)

Responsible for Validation, Qualification and Calibration , Stability Program Support Regulatory

November 2022 – Nov 2023, in accordance with organizational restructuring, I responsible for Validation Department (new department) under Quality Management. My responsibilities as following:

- a. Validation and Qualification
- b. Calibration Management
- c. Stability for Pharmaceutical Products (Finished Products)

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3. Quality Assurance Associate Manager (Development Center)

PT.Ethica Industri Farmasi Joint Venture with Fresenius Kabi (Feb 2021 – June 2022)

Reporting to Senior Director I&D Centers and Quality System (QM I&D Centers Pharmaceutical – Fresenius Kabi Deutschland GmbH).

Job Purpose :

Quality Assurance at DC Indonesia of PT. Ethica Industri Farmasi Joint Venture with Fresenius Kabi.

Authority :

- a. QA Approval of all documents, requiring local QA approval within DC Indonesia
- b. To stop DC analytical testing activities and contain materials and products with immediate effect where critical deviations from regulatory requirements and/or Fresenius Kabi's Quality Management System are noted
- c. Immediate notification to management on confirmed, reportable quality defects that become known from deviations, complaints, OOX results or other events and when notification to concerned Competent Authorities is required
- d. Immediate notification to management on data integrity issues that become known

4. Quality Management System Jr. Manager

PT.Ethica Industri Farmasi Joint Venture with Fresenius Kabi (September 2017 – May 2021)

Qualified as Global and Local Auditor for Fresenius Kabi.

Audit experience :

- a. Syn-Tech Chem. & Pharm. Co., Ltd (Taiwan) – API Manufacturer
- b. Gerresheimer Pharmaceutical Packaging Mumbai Pvt.Ltd (India) – Primary Packaging Material Manufacturer
- c. Aurobindo Pharma Ltd, Unit XI (India) – API manufacturer
- d. PT. SOHO Industri Pharmasi (Indonesia) – Toll Manufacturer
- e. Pharma Metrics Lab – Contract Laboratory
- f. Other Local Suppliers for Packaging Material, Local Trader, Transporter, Warehouse Facility, Archiving Documents Provider, Calibration Provider, etc

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- g. Qualified as Lead auditor for self-inspection/quality oversight for PT. Ethica Industri Farmasi

Detailed key points as follows:

1. Responsible for Training Management System in PT Ethica Industri Farmasi.

Create training system including: Training Matrix, Training Need Analysis and Annual Training Plan for PT. Ethica Industri farmasi. Currently build and adopt Fresenius Kabi Learning Center localized in PU Jababeka. Detail key functions:

- a. Provides guidance on training in Quality, Occupational Health and Safety and Environmental related matters with considering training methods, roles to be trained, and training content.
- b. Provides guidance on the process of the qualification of personnel by initial and continuous on-going training activities. This is required to ensure employees have been adequately trained for their jobs and to continuously improve their level of qualification.
- c. To ensure knowledge and skills of all employee are always updated and improved by getting annual training.
- d. Develop team for preparing training modules and Standard Operating Procedures

2. Supplier Management and Quality Agreement with External Parties

- a. Responsible in Supplier management including Supplier Qualification, Supplier Maintenance and Development, and Supplier Discontinuation
- b. Collecting all supplier qualification documents, On Site Audit/On Desk Review, create Approved Vendor list, and Maintain Approved Vendor List of PT. Ethica Industri Farmasi joint Venture with Fresenius Kabi
- c. Conduct supplier audit for Local and Global Supplier of RM/PM, Local trader, Service Provider, and other GMP related Supplier
- d. In collaboration with Global Quality Management System and External audits team to arrange audit plan for Fresenius Kabi
- e. Verification and Follow up supplier complaint
- f. Supplier evaluation in coordination with procurement department
- g. Responsible for preparing Quality Agreement within PT. Ethica Industri Farmasi and all external parties: Toll manufacturer, Supplier, etc.

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3. Self-Inspection and quality oversight

- a. Responsible and qualified as Lead auditor for self-inspection and quality oversight in PT. Ethica Industri Farmasi, start from scheduling until reporting (Qualified as Lead auditor for internal inspection)
- b. Follow up CAPA of Self Inspection

4. External audit.

Responsible for planning, coordination and preparation, execution until follow up action after audit of all external audit. Audit Experiences :

- a. BPOM's audit
- b. Global Quality Management Fresenius Kabi's audit
- c. Other external authority (Korean MFDS, etc)

5. CAPA monitoring through Kabitrack System

6. Responsible to create impact assessment and risk assessment required by Global QM of Fresenius kabi once there is any non-compliance i.e warning letter from FDA to approved vendor at Fresenius Kabi.

7. Quality KPI reporting (monthly report).

8. Global Procedure Implementation

Responsible for Implementation of Fresenius Kabi Global Procedure in PT. Ethica Industri Farmasi.

9. Actively involved in Product Transfer and Maintenance (Technology and Site Transfer project in PT. Ethica Industri Farmasi) in collaboration with all other department MU/BU/PU.

5. Sourcing Supervisor

PT.Ethica Industri Farmasi Joint Venture with Fresenius Kabi (October 2015 – September 2017)

Detailed key points as follows:

- 1. Project management in particular dealing with vendor selection. Handle new product development projects, varying from site transfer and technology transfer new plant Jababeka, alternative raw material and packaging material source, change source ie., cost saving project, material shortage issue, etc.

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2. Sourcing supervisor to ensure selection process is comply with EFK Policy. Discover and partner with trustworthy vendors and suppliers.
3. Responsible in delivery material from first trial stages until 1st batch commercial before handed offer to purchasing team.
4. Handling product complaint/product reject in coordination with quality (development stage until first batch commercial).
5. Ensure all supplier/manufacture in EFK are qualified and registered in ERP system.
6. Conduct supplier/manufacture audit as per scheduled. Planning annual vendor audit programme for newly qualified vendors in coordination with quality department
7. All related procurement task.
8. Strategic mapping of all Ethica industri farmasi joint venture with Fresenius Kabi vendors in reference to GMP (regulatory) compliance, environmental situation, and other potential issues affecting material supply continuity.
9. Increase product profitability through material cost reduction programme (alternative sourcing projects).
10. Well acquainted with project management and other department for new product development until launching.

6. Sourcing Executive – Corporate Sourcing of Dexa Group

PT. Dexa Medica (2014 – 2015)

Detailed key points as follows:

1. Sourcing process of new raw materials (API and Excipients), packaging materials, reference and working standards.
2. Maximizing supplier performance and supporting the company's business plan for new product development starting from the first trial (lab scale) until the first batch commercial.
3. Implements plans to assure orders meet specified quality and delivery time.
4. Minimize the total cost of purchases.
5. Oracle transaction of purchasing and maintains a good documentation with dragon infotekna system.

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6. Evaluates current and potential suppliers in coordination with Quality department.
7. Alternative source – sourcing.
8. CDA handling.
9. Quality Questionnaires of approved manufactures.

7. Quality Assurance Supervisor

PT. Kalbe Farma Tbk (2011 – 2014)

Detailed key points as follows:

1. QA Supervisor for Finished Goods
2. QA supervisor for solid dosage form products.

PERSONAL STRENGTH

I am a highly professional individual in both behavior and appearance, with an open-minded attitude and a strong work ethic. I thrive under pressure while maintaining optimism, and I am committed to continuous learning and personal growth. My ability to quickly adapt to new environments and societies allows me to build and nurture positive relationships with ease. I value teamwork and believe that effective communication and adaptability are essential for success in any collaborative setting.