



apt. Setyo Hartono, S.Si

PHARMACIST

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About Me

I am **Setyo Hartono**, graduate of the Bachelor of Pharmacy and Apothecary Study Program who is active and contributes to the organizations. I am sure that I will give my best in the word with the experiences and knowledge that i have.

Educations

- **Apothecary Study Program (2004-2005)**
- **Bachelor of Pharmacy (2002-2003)**

Skills

- Analytical Method
- Research and Development
- Quality Management
- Quality by Design (QbD)
- Compendial References
- HPLC, GC, UV-Vis Spectroscopy
- CPOB, CPAKB, CPKB, CDOB
- GMP and GLP Compliance
- Leadership
- Problem Solving
- Team Collaboration
- Communication

Languages

- Indonesian Native
- English Intermediate

Working Experiences & Trainings

PT. LANDSON (PERTIWI AGUNG) Cibitung

2004 - 2009

Position Level : R&D/Quality Control

- Developed and optimized formulations for new pharmaceutical products.
- Assisted in testing preformulation and formulation of pharmaceutical products.
- Supervised with R&D team process validation and technology transfer at production sites.
- Collaborated with the R&D team to identify issues and provide technical solutions.
- Attended internal training on the latest laboratory techniques and equipment.
- Received induction training regarding R&D Analytical Development, QA, QC, and Production guided by the manager.

PT. IMEDCO DJAJA Pharmaceutical Industries

2009 - 2014

Position Level : Quality Assurance Manager

- Follow up CAPA, check and review batch record, lead validation and calibration program, conduct performance qualification of equipment, do and coordinate internal audit, execute performance qualification of water system and air handling unit.

PT. TEMPO SCAN PACIFIK

2014 - 2015

Position Level : R&D Manager-Regristasion/ QA

- Develop and manage product registration strategies in line with company goals and maximizing the competitive advantages of company assets throughout the product lifecycle (coordinate with R&D, QC, Production, and Validation department)
- Interface with the local or global team in order to ensure the regulatory strategies and processes are in line with local business strategy
- Prepare dossiers (CTD) that meet all regulatory requirements in Indonesia and also other countries as per country specific guidelines

PT. ORYZA FARMA INDONESIA

2016 - 2022

Position Level : Quality Assurance Manager-Plant Manager-Penanggujawab Registration

- Planning, organizing, formulating, directing and controlling the day to day factory activities
- Manage all data from another department (QA, QC, R&D, Production and Validation Department) that have relation with registration.
- Ensuring all implementation of cGMP and ISO 9001:2015 at all level activities
- Supervision of the quality standarts including the enforcements of the quality control program.

PT. BINTANG KUPU-KUPU TANGERANG INDONESIA

2022 - 2024

Position Level : Head of Quality

- Manage all data from another department (QA, QC, R&D, Production and Validation Department) that have relation with registration.
- Evaluate the progress and the proses of registration result
- Do Correspondence and consultation with National Agency For Food Drug Control (BPOM) which related with product registration.