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Working Experiences & Trainings

PT. LANDSON (PERTIWI AGUNG) Cibitung **2004- 2005**
Position Level : R&D/ Quality Control

PT. LANDSON (PERTIWI AGUNG) Cibitung **2007- 2009**
Position Level : Quality Control

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-Penanggung Jawab Registration*

- Planning, organizing, formulating, directing and controlling the day to day factory activities
- Ensuring all implementation of cGMP and ISO 9001:2015 at all level activities
- Supervision of the quality standards including the enforcements of the quality control program.

PT. BINTANG KUPU-KUPU TANGERANG INDONESIA **2022- 2023**
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.

PT. AFI FARMA Pharmaceutical Industries **2024- Now**
Position Level : Head Quality /Plant Manager

- Lead implementation,maintenance,and continuous improvement of the Quality Management system/QMS
- Manage the CAPA system and ensure effective root cause investigations and sustainable corrective actions.
- Coordinate and support regulatory inspection and customer audits.

About Me

I am **Setyo Hartono**, graduate of the Bhachelor 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)**
- **Bhachelor of Pharmacy (2002-2003)**

Soft-Skill

- Leadership
- Enthusiasm
- Cooperative
- Curiosity

Languages

- Indonesia
- English

Skill

- Microsoft Word
- Microsoft Excel
- Microsoft Power Point
- Adobe Photo Shop