

# Andy Setiawan

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## Work Experience

### Regulatory Affairs Associate – Regulatory Department // Feb 2023 – Present

PT. Bayer Indonesia – Jakarta

- Maintaining product license and develop submission strategy for Oncology and established product portfolio, including prescription & non prescription drug
- Leading APAC editorial board with 3 team members looking after monthly newsletter and RA website for information exchange and sharing with regional and global audience
- Leading serialization & site transfer implementation project in Indonesia (Jan 2020 – Present)
- As an expert and main focal point at the country for adoption of new cloud-based regulatory management system (Nov 2020 – Present)
- Regional RA for oncology products oversee Asia Pacific countries (Apr 2023 – Present)

### Regulatory Affairs Associate – Regulatory Department // Sep 2019 – Jan 2023

PT. Bayer Indonesia – Jakarta

- Maintaining product license and develop submission strategy for Radiology & Intervention (R&I) and Men's health product portfolio
- Contributing for business insight and strategy from regulatory point of view
- Editorial Board Member for global RA website representing Asia Pacific Region

### Regulatory Affairs Executive – Regulatory Department // Dec 2018 – Aug 2019

PT. Sanofi Indonesia – Jakarta

- Manage end-to-end lifecycle management for Pharma and Vaccine product portfolio

### Regulatory Site Officer – Quality Department // Jul 2016 – Nov 2018

PT. Sanofi Indonesia – Jakarta

- Prepare registration document prior submission, both for local and export countries, including most of ASEAN countries
- Make periodic gap analysis review between dossier and corresponding quality documentation of the site to ensure regulatory compliance practice
- Maintain excellent documentation and perform document review of the site
- As an expert reviewer in the change control system and provide regulatory assessment for any regulatory related issue raised by the site
- Support product transfer project with both internal company and Contract Manufacturing Organization

### Formulation Officer - R&D Department // May – Nov 2015

PT. Kalbe Farma – Bekasi, Jawa Barat

## Education

2014-2015

### Apothecary Professional Degree

Bandung Institute of Technology – Indonesia  
Production and Quality Control Program

2011-2013

### Master of Science

Bandung Institute of Technology – Indonesia  
Pharmacology and Clinical Pharmacy Program

2008-2012

### Bachelor of Pharmacy

Bandung Institute of Technology – Indonesia  
Science and Pharmaceutical Technology Program



## PROFILE

As a young professional, I am a highly motivated person who is willing to learn and to challenge myself with new experience. With my background career at manufacturing site, it allows me to have a broader view not just from regulatory but also from quality and technical perspective which always come hand in hand during the product lifecycle. My current position has enabled me to develop not only the knowledge on drug regulation itself, but also cross-functional coordination and collaboration with more diverse function, formulate strategy and solution to overcome any obstacles in the business to achieve goals while keep maintaining high level of compliance.

## PROFESSIONAL SKILLS

Regulatory Compliance



Regulatory Affairs



Cross-functional Coordination



Project Management



Quality Management System

