RIZA ANNISA DW

REGULATORY AFFAIRS AND QUALITY ASSURANCE EXPERTISE **JAKARTA PUSAT, INDONESIA** **085364294471**

DETAILS

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LINKS

LinkedIn

SKILLS

- Creative Problem Solving
- Multitasking Skills
- Creative Thinking
- Interpersonal Communication
- Public Speaking
- Detail Oriented
- Flexibility and Adaptability Problem
- Solving Skills Critical
- Thinking Skills Detail
- Oriented

LANGUAGES

English

PROFILE

Experienced in Regulatory Affairs and Quality Assurance with over five years of experience in the multinational pharmaceutical industry. Proven track record of successfully managing internal audit, external audit and registered more than ten imported products for Indonesian state-owned enterprises.

EMPLOYMENT HISTORY

Regulatory Affairs Supervisor at PT Etana Biotechnologies Indonesia

November 2023 — Current

- Supervise High-Priority Etapidi Project “Tislelizumab" for Imported Product **Etapidi is a product of collaboration between PT Etana Biotechnologies Indonesia and BeiGene Guangzhou Biologics Manufacturing Co., Ltd for immunotherapy drugs Cancer (Tislelizumab). This collaboration is supported by the government where the cooperation agreement was signed on January 29 2024, which was attended directly by the Minister of Health of the Republic of Indonesia.**
- Supervise the product registration and ensure to achieve the target
- Communicate with the plant team and the principle for a list of documents needed to apply for a license (drug registration for local and imported or other licensing)) based on the regulation.
- Develop and maintain good and professional relationship with appropriate government agencies to ensure smooth and efficient registration process
- Oversee the registration process for new products with regulatory agencies, ensuring all necessary documentation and approvals are obtained before products are introduced to the market
- Ensure timely approvals of new products registration, variations and renewals
- Stay updated of all relevant regulations, guidelines, and standards set by regulatory bodies such as BPOM and other local, national, and international regulatory agencies.

Regulatory Affairs Supervisor at PT Kimia Farma Holding, Jakarta

November 2019 — October 2023

- Developed and implemented policies and procedures to ensure product compliance with BPOM and MOH requirements
- Researched and analyzed regulatory requirements to ensure compliance with applicable regulations
- Identified and reported additional required documents to importer country to ensure quality products complies with applicable regulations
- Lead discussion with BPOM and MOH to ensure product compliance with applicable regulations
- Lead discussion with importer countries (China, Germany, France, India, Spain, Egypt) to fulfill the additional required documents for product registration

Quality Assurance Compliance at Actavis Indonesia (Teva Pharmaceutical), Jakarta

August 2018 — October 2019

- Developed and implemented a quality assurance program that ensured compliance with BPOM regulations
- Developed and maintained quality assurance processes that improved product quality and customer satisfaction.
- Developed a comprehensive quality assurance program that ensured all deliverables met the highest standards of quality
- Lead Halal Project for Paracetamol Tablet
- Lead External Audit for Packaging suppliers and Raw Materials suppliers

EDUCATION

Pharmacist (Industrial Specialization), University of Indonesia, Depok

July 2017 — July 2018

Cum Laude