



Yant Noviana Tias Fajar Saroh

Profile

Experienced regulatory manager with expertise on pharmaceuticals product (copy drug, NCE, biological product, medical devices, cosmetics) and consumer product.

Employment History

Regulatory Manager at PT Etana Biotechnologies Indonesia

July 2021 — Present

- Manage the activities of Regulatory Affairs within the field of responsibility ensuring the implementation of appropriate and effective regulatory strategies
- Provide expert regulatory input to strategic decision making; including prioritization, and external communications
- Provide advice about regulations to all stakeholders
- Coordinate successful submissions and approval of all applications
- Keep up-to-date with changes in regulatory legislation and guidelines
- Liaise and negotiate with regulatory authorities (BPOM, MoH)

Regulatory Manager at PT SOHO Industri Pharmasi, Jakarta, Indonesia

January 2020 — July 2021

- Manage the activities of Regulatory Affairs within the field of responsibility ensuring the implementation of appropriate and effective regulatory strategies
- Provide expert regulatory input to strategic decision making; including prioritization, and external communications
- Provide advice about regulations to all stakeholders
- Coordinate successful submissions and approval of all applications
- Keep up-to-date with changes in regulatory legislation and guidelines
- Liaise and negotiate with regulatory authorities (BPOM, MoH)

Regulatory Affairs Officer at PT Daewoong Pharmaceutical Company Indonesia, Jakarta, Indonesia

September 2013 — January 2020

- Review, prepare and submit all registration dossier to authority (including drug, medical devices, health supplement and cosmetics)
- Maintain and follow up post registration
- Keep up-to-date with changes in regulatory legislation and guidelines
- Liaise and negotiate with regulatory authorities (BPOM, MoH)

Details

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Date / Place of birth

9 November 1989

Jakarta

Links

linkedin.com/in/yant-noviana

Skills

Ability to Work in a Team

Effective Time Management

Ability to Work Under Pressure

Communication Skills

Analytical Thinking

Languages

English

Hobbies

Travelling, watching movie, culinary

Education

Pharmacist Profession Program, Universitas Pancasila, Jakarta

May 2012 — May 2013

Bachelor degree Pharmacy, Universitas Pancasila, Jakarta

August 2007 — May 2012

Senior High School, 62 , Jakarta

June 2004 — June 2007

References

Irma from PT Daewoong Pharmaceutical Company Indonesia

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