

Kong Weng Yip

**Assistant Manager,
Regulatory Affairs**



About me

Registered Pharmacist with 13 years of working experience in various pharmaceutical area, include pharmaceutical production, formulation, regulatory affairs and in-licensing.

Personal Info

Address: 18, Jalan Elektron
U16/54G, Denai Alam, 40160
Shah Alam, Selangor.

Phone : +6012-5269869
Email :
fred_ace786@yahoo.com

Language:

- English
- Bahasa Malaysia
- Cantonese (spoken)
- Mandarin (spoken)

PROFESSIONAL EXPERIENCE

June 2021 – **Assistant Manager, Regulatory Affairs**

Present Duopharma (M) Sdn Bhd

- Timely submission of new pharmaceutical products registration, inclusive of generics, biosimilar and vaccine, in Malaysia and export countries in ASEAN, Middle East and Africa regions.
- Provide support for regulatory strategy and regulatory consultation for internal and external stakeholders.
- Management of correspondences/queries from regulatory authorities and customers.
- Liaison person with government officers from State and Federal Pharmacy Enforcement, Pharmaceutical Services Division and National Pharmaceutical Regulatory Agency (NPRA) for all matters pertaining product registration and regulations.
- Project lead for NPRA's e-labelling pilot project.

Sep 2018 – **Assistant Manager, In-Licensing**

June 2021 Duopharma Innovation Sdn Bhd

- Source, coordinate and negotiate with potential licensing partners for new products for technology transfer and trading.
- Review dossiers with technical team to assess the suitability of the licensing partner's product.
- Coordinate contract negotiation that involves various parties from internal stakeholders and licensing partner.
- Source for external laboratories to support R&D testing.
- Successfully sourced products from Spain and Netherlands for registration in Malaysia.

Sep 2015 – **Assistant Manager, Technical Operations**

Jun 2018 InQpharm Group Sdn Bhd

- Key personnel for operations, supply chain and technical for new market launches.
- Lead formulation development, technology transfer and formulation improvements for new products.
- Source for suitable contract manufacturers across Europe and USA.
- Successfully launched products into USA and Canada.

Mar 2014 – **Production Pharmacist/Manager**

Aug 2015 Scanlab Sdn Bhd

- Lead Production Department in ensuring all production output are met without compromising quality.
- Poison A holder in ensuring compliance to pharmacy law at all times.
- Conduct investigation and suggest solutions for product out-of-specifications during manufacturing.
- Ensure compliance with GMP requirements at all times.
- Key personnel for NPRA GMP plant audit
- Review Batch Manufacturing Records, validation reports and other relevant reports.
- Handle all regulatory submission to NPRA.

Apr 2013 – **Production Pharmacist**

Mar 2014 Royce Pharma Manufacturing Sdn Bhd

- Lead Production Department in ensuring all production output are met without compromising quality.
- Poison A holder in ensuring compliance to pharmacy law at all times.
- Conduct investigation and suggest solutions for product out-of-specifications during manufacturing.
- Ensure compliance with GMP requirements at all times.
- Key personnel for NPRA GMP plant audit
- Review Batch Manufacturing Records, validation reports and other relevant reports.

Jul 2010 – **Fully Registered Pharmacist**

Mar 2013 Ministry of Health (Government Hospital)

- Served as a fully registered pharmacist in Ministry of Health hospital.
- Completed compulsory pharmacy housemanship with Ministry of Health

EDUCATION

2016 - 2017 – **Master of Business Administration**

HELP – Anglia Ruskin University

2006 - 2010 – **Bachelor of Pharmacy (Hons.)**

International Medical University (IMU)

CERTIFICATES

- Registered Pharmacist (Registration No. 8204)
- The 7 Habits of Highly Effective People
- Kepner Tregoe Problem Solving Skills
- Life Science QbD Specialist Training

SPECIALIZED TRAINING

- Problem Solving Skills
- Good Manufacturing Practice Training (GMP)
- CRO Selection for BE Study and Workshop on Review of BE Data
- Life Science QbD Specialist Training
- Seminar on BCS-Based Biowaiver and SUPAC Guidelines
- Good Submission Practice Workshop

REFEREES

• Puen Kian Yong (Assistant Director Operations, INQPHARM)
016 – 2739986 Years known: 3 years

• Suzanne Tan (Manager Technical Operations, INQPHARM)
012 – 6507014 Years known: 3 years