CURRICULUM VITAE

JULIET CHU LEE HEOK

PERSONAL INFORMATION:

Birth Date: 24 November 1973
Birth Place: Malaysia
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EDUCATION:

July 1995 **Bachelor Degree in Pharmacy (Hons) 1995**
UNIVERSITY OF NOTTINGHAM UNITED KINGDOM
Second Class Upper

Sept 1996 **Advanced Diploma in Marketing**
UNIVERSITY SWANSEA
1st Class (Distinction)

EXPERIENCE:

July 2023 – Present

PHARMACOVIGILANCE CONSULTANT, BLOOMS AGENT PTY LTD

1. Act as Local Person for Pharmacovigilance (LPPV) for Malaysia
2. Local Literature Search
3. Regulatory Intelligence
4. Regulatory Affairs Consultant

September 2021 – July 2023

REGULATORY AFFAIRS MANAGER, YTB HEALTHCARE SDN BHD

1. To lead and drive the development of the company's regulatory affairs strategy, compliances and documentations – set up Quality Management System for Quality Assurance and Pharmacovigilance
2. Managing the entire process for regulatory approval of drugs from pre-market submissions to post-market surveillance activities

3. To execute all regulatory activities including submission of new products or renewals until post-approval monitoring
4. To initiate respective steps or changes upon request of updates or news which may affect existing or planned regulatory submissions to ensure continuity of business
5. To represent the company as the primary communication point with the local regulatory activities, industry groups and relevant stakeholders
6. To develop, implement and maintain the required regulatory standards, standard operation procedures and resource documents
7. To ensure that Business Continuity Plan has been put in place for the Healthcare division
8. Appointed as Committee member of the Emergency Response Team for YTB Occupational & Health Committee

March 2021 – August 2021

PHARMACOVIGILANCE AND REGULATORY AFFAIRS ASSISTANT MANAGER, MITSUBISHI TANABE PHARMA MALAYSIA SDN BHD

Responsible for all pharmacovigilance (PV) and regulatory affairs (RA) matters, including but not limited to establishment and maintenance of local pharmacovigilance system, submission of new drug application of new products and maintenance of existing products.

Pharmacovigilance

• To manage safety queries and other significant safety information locally, inclusive of crisis
management
• To prepare, maintain and implement the necessary SOPs that meet the requirements of the regulations with respect to drug safety.
• To ensure the proper and timely collection, reporting and managing of safety information of
the products of the Company in accordance with the regulatory requirements.
• To ensure sufficient management of safety information to enable head office to perform a
comprehensive and accurate assessment.
• To conduct local literature search and ensure any other safety data deemed fit for inclusion in the PSUR/PBRER or signal management process.
• To provide non-safety staff with the regular training to ensure that they are aware of their Drug safety responsibilities.
• To review and finalise the relevant agreement, including Pharmacovigilance Agreements with third parties (e.g., distributor) to ensure appropriate safety reporting processes are in place.
• To ensure company is ready for pharmacovigilance audits and inspections.
• Continual risk assessment of local PV operations, including early notification of any risks.

Regulatory Affairs

• To ensure proper submission of NDA to the health authority (NPRA), including but not limited to, compilation of dossiers and preparation of product information (e.g., package insert and artwork of package materials)
• To ensure accurate reporting and compliance to the regulatory requirements.
• To be responsible for all regulatory affairs matters after NDAs, including but not limited to, new indications, variations and registration renewals.

April 2019 – March 2021

REGULATORY PHARMACIST, SMART MEDICINE SDN BHD

1) Pharmacovigilance –

- To manage safety queries and other significant information locally, including execution of local Risk Management Plan requirements
- To prepare, maintain and implement the necessary SOPs that meet the requirements of the regulation with respect to drug safety
- To ensure the proper and timely collection, reporting and managing of safety information of the products of the Company in accordance with regulatory requirements (Filling of CIOMS form to be submitted to corporate clients and NPRA)
- To ensure sufficient management of safety information to enable head office to perform a comprehensive and accurate assessment, and follow-up of safety information
- To provide staff with regular training to ensure that they are aware of their Drug Safety responsibilities (with assessment test to see the level of understanding)
- To review and finalise the relevant agreement, including Pharmacovigilance Agreement with third parties (e.g., distributors) to ensure appropriate safety reporting processes are in place.
- As the local pharmacovigilance contact person/ representative for the local health authorities and stakeholders.

2) Quality Assurance –

- To prepare, maintain and implement the necessary SOPs and oversee the quality management system that meet the requirements of the regulations with respect to product quality and GDP
- Participated as observer for external audit on distributor and followed the whole process of the Audit.
- To assist corporate clients that requires to be audited for GDP and to provide services to help with the audit report and requirements of NPRA.

3) Regulatory Affairs –

- To ensure proper submission of New Drug Approval to the health authority (NPRA), including compilation of dossiers and preparation of product information.
- To ensure accurate reporting and compliance to the regulatory requirements

- To be responsible for all regulatory affairs matter after NDAs, including new indications, variations and registration renewals.

4) Import and Wholesale License –

- To prepare and submit an application for Import License and Wholesale License for principal company/corporate clients.

5) Others –

- Provide training (internal and external) on proper usage of products, SOPs, PV system
- Regulatory consultant to 3 corporate clients on matters pertaining to PV, RA and QA.
- Management of Local Medical Inquiries

January 2011 – February 2019

DEPUTY GENERAL MANAGER, LUYE PHARMA (MALAYSIA) SDN BHD

1) Planning marketing strategy for the products –

a) to position the product A as market leader for the herbal/natural supplement for cholesterol management in consumer market

b) to position product B as the herbal/natural alternative for cholesterol management in ethical market

c) to develop from scratch an Herbal drink for control of blood sugar, from manufacturing to market

2) Execute the marketing plans – identify different markets segments and customize different plans to target the marketing segments

3) Expand the sales of products overseas in Asean region

a) Expand the sales of product A into Hong Kong – looked for distributors, manage the distribution agreement, provide training and prepare training materials for the local agent in Hong Kong, as well as do market visits to Manning and negotiate with Manning for exclusive distribution in 2014.

b) On-going process to register ad launch into Indonesia market

- Preparation of dossiers/documents for BPOM Indonesia and working closely with local partners in Indonesia

c) Exploring other Asean markets like Cambodia, Myanmar and Vietnam by setting up booths in respective countries' health exhibition.

4) Ensure all the regulatory requirements are adhered to by working on the Quest 3+ to do the product variation, product re-registration and working alongside MOH to ensure that KKLIU certificate is obtained for various advertisement

a) Successfully completed the Good Distribution Practice Audit by the MOH for 2018/2019 – obtained GOOD

b) Preparation of SOP for the Audit and ensure that SOP are being complied to

5) Preparation of updated information and product development to be presented for product training to distributor's sales team, community pharmacists, sales assistant and even the public.

a) To do quarterly training to sales team of distributors to update the latest progress

b) Giving talks to the public on health awareness and to visit doctors to disseminate information
c) Transferred to Luye International Division and was responsible to initiate the contract agreement with business partners to ensure the transition of product and information is done smoothly
d) Oversee general operational duties such as Administration, Human Resource and Accounts and Audit
e) Successfully implemented GST compliant system in the company 2015

January 2008 – December 2010

ASSISTANT GENERAL MANAGER, SMART MEDICINE SDN BHD

1) Manage marketing plans for products – from preparation of detailing aids, product information, media plan and budget
2) Work alongside distributor's sales team to ensure marketing plans are being executed
effectively
3) Work with key accounts on trading terms and marketing plans
4) Brand awareness programme – roadshows, product training in factories, MPSJ resident day, pharmacies, health centers and clinics
5) Market intelligence – checking out competitors' brand and development and planning strategically to overcome the situation

January 1999 – December 2007

PHARMACIST CUM DIRECTOR, FARMASI ALYCHEM SDN BHD

1) Branch manager – Daily operations
2) Central purchase of drugs for the whole group
3) Set-up Point of Sales system for the company – 5 outlets linked together and manage as well as maintain the databases
4) Daily counselling to customers and keeps a database of the regulars with their health conditions
5) Organise talks from companies for continuing education programme

September 1997 – November 1998

COMMUNITY PHARMACIST, CAMDEN SDN BHD

1) Daily operations
2) Mainly counselling patients

October 1996 – July 1997

REGULATORY AFFAIRS EXECUTIVE, WYETH (M) SDN BHD

1) Set-up the regulatory department of Wyeth (M) Sdn Bhd
2) Register new products – oral contraceptive pills with MOH (NPRA)
3) Maintain the existing products by renewing the product license and update DCA on the variation

4) Provide time-line for the registration of products to facilitate marketing plans (launching of new products) by Marketing department
5) Fast-track vaccines that were needed by the Department of Pediatric in GHKL
6) Sent to Philippines to learn more about the clinical trials conducted there

SKILLS:

- Excellent organisational skills established through professional experience
- Sound understanding of timelines with regards to case processing and reporting
- Attention to detail and good team working skills
- Ability to prioritise multiple tasks and meet deadlines
- Time management and problem- solving abilities
- Proficient in Microsoft Office, internet researching and IT skills for PV related skills

LANGUAGE:

English Language – Fluent (verbal and writing)
Bahasa Malaysia – Fluent (verbal and writing)

ACTIVITIES:

Volunteer for medical mission trips to
1) Bethesda Hospital in Serukam, Indonesia
2) Orang Asli village in Grik, Perak
3) School Of Joy in Siem Riep, Cambodia
4) Rohingya Centre, Cheras
5) Jalan Chin Chin, Kuala Lumpur

-Lead the team to get the Award for Most Resourceful Team 2009 in SmartMedicine Sdn Bhd.
-Malaysian Pharmaceutical Society – did a nationwide survey and reported the results and went on to prepare a handbook for Disease Management Protocol Group for Malaysian Pharmaceutical Society
-Award for Excellence for an essay written on globalization in 2014 in Asiapharm Biotech Sdn Bhd
- Public speech to create awareness on Cholesterol in Subang Jaya
- Invited to give lectures on overview of Pharmacy Industry to University Students – IMU and Segi University
- Train the Pharmacy Department and Nursing School in Bethesda Hospital in Serukam, Indonesia (Voluntary basis)
- Award for MOST ARTICULATE INDIVIDUAL in 2008 in SmartMedicine Sdn Bhd
- Grade 4 for Gu Zheng instrument
- Grade 1 for Belly Dancing
- Volunteer at Malaysian Pharmaceutical Society in the Election SOP committee

TRAINING/SEMINARS:

2022	ASEAN-Japan Risk Management Plan (RMP) Symposium
2022	28th Federation of Asian Pharmaceutical Association (FAPA) Congress and National Pharmacists Convention
2022	ASEAN-Japan Risk Management Plan (RMP) Symposium
2022	ASPIRE Educational Scientific Pharmacist Congress CMEd
2022	Complementary Medicine Education
2021	Asian Pacific Society of Cardiology – Dapagliflozin et.al. The growing therapeutic spectrum of SGLT2i
2021	Asian Pacific Society of Cardiology – Evolocumab (PCSK9i): A bride for the old faithful statin?
2019	Internal Audit – A key to your Quality System (MOPI)
2018	51st Annual Seminar – Leveraging Collaboration for Better Patient Outcomes Seminar by MPS
2018	Transitioning from GST to SST Seminar
2017	Corporate Director's Training Programme Fundamental 1.0
2015	Seminar on the Introduction of the New Guideline for Medicines Advertisement – Pharmaceutical Services Division, MOH
2014	Malaysian GST Mechanism, Its Impact on Business and Financial Planning
2013	National Regulatory Conference 2013
2013	Budget 2013 – Tax implications on Employers and Employees
2012	Mastering Negotiation Skills
2012	45th MPS Annual Seminar – Focus on Non-communicable Diseases