Reynard Aw

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Highly skilled registered pharmacist with a track record of success in hospital, community, and industrial settings. Proficient in preparing and submitting regulatory submissions, conducting product assessment, and collaborating with cross-functional teams to navigate regulatory requirements. Adept at staying abreast of evolving regulatory landscapes to support the organization's adherence to quality and compliance standards.

Education

2015- 2019 Bachelor of Pharmacy (HONS)
Taylor's University, Malaysia, *First Class Honours*
Recipient: Pharmaceutical Industry Student Adoption (PISA) Scholarship

Courses

- **ICH Q12 PACMP Workshop** - National Pharmaceutical Regulatory Agency (NPRA), Malaysia (September 2022)
- **Seer Pharma Good Manufacturing Practice (GMP) Training** - Seer Pharma, Malaysia (October 2022)
- **International Medical Device Regulatory Initiatives Towards Harmonisation, Regulatory Convergence and Reliance Workshop** - Medical Device Authority (MDA), Malaysia (October 2022)
- **Bioequivalence: The Basics and Beyond Workshop** - Taylor's University, Malaysia (November 2022)
- **Bioequivalence Desktop Evaluation (BEDE) Workshop** - National Pharmaceutical Regulatory Agency (NPRA), Malaysia (February 2023)
- **Stakeholders Engagement for Active Ingredients Regulation** - Health Science Authority (HSA), Singapore (March 2023)
- **Pharmacovigilance: For Safer Use of Medicine Workshop** - National Pharmaceutical Regulatory Agency (NPRA), Malaysia (April 2023)
- **eCTD Industry Briefing** - Health Science Authority (HSA), Singapore (May 2023)
- **National Regulatory Conference 2023** - NationalPharmaceutical Regulatory Agency (NPRA), Malaysia (August 2023)

Work Experience

Oct 2023 – Present **Sandoz Products Malaysia Sdn Bhd**
Drug Regulatory Affairs Specialist

Key Responsibilities

Regulatory Planning

- •Collaborate with global and regional functions to ensure timely and clear dossier requirements for local submissions.
- •Maintain submission plan in systems and update on monthly basis based on regulatory activities.
- •Support implementation of the regulatory plan by global RA function and global business plans.

Dossier Management

- •Conduct gap assessment and ensure submission for product registrations and variations are carried out in timely manner in compliance with internal and external regulatory requirements.
- •Manage and respond to product regulatory questions.
- •Liaise with local regulatory authorities and regional regulatory affairs to deliver timely and commercially advantageous license approvals.
- •Build effective working relationships with regulatory authorities and follow-up closely on approvals.

Artwork Management

- •Manage labelling text and packaging components to ensure compliance with local registered details and prescribing information, as well as maximizing the commercial value of the label.
- •Ensure new/artworks are readily available in line with launch and supply timeline.

Project Involvements

- •Project ORBIT (Market Authorization Transfer)
- •Project Flying Dragon (Site Transfer)
- •Project Loquat (Site Transfer)
- •Project Rose (Product Owner Change)

Jan 2022 – Oct 2023 **Xepa-Soul Pattinson (Malaysia) Sdn Bhd**
Regulatory Affairs Pharmacist

Key Responsibilities

- Primary country custodian for APAC (Hong Kong, Singapore, Taiwan) and MEA (Iraq).
- Main contributor for CTX/CTIL/Import Permit Application and Active Pharmaceutical Ingredient (API) quality assessment and submission.
- Liaised with local and international regulatory authorities for product registration and life cycle management in multiple countries.
- Reviewed registered product dossiers and prepared applications in accordance with local and overseas regulatory requirements (CTD, ACTD, PIF, CSTD formats).
- Implemented and maintained adherence to regulatory submission plan for new product registration and product license maintenance, including variations.
- Provided input to commercial team on marketing materials, and ensured compliance with Medical Advertisement Board (MAB) regulations for product advertising.
- Conducted routine meetings with International Business Team and distributors to monitor new product registration and regulatory intelligence.
- Proactively monitored and analyzed regulatory changes in custodian countries, and advised management on necessary updates to ensure compliance.
- Developed product safety data sheets for non-poison products in accordance with the GHS.

Achievements

- Successfully registered 3 GDAs in Hong Kong, 1 GDA and 5 Cosmetics Notification in Singapore, 1 GDA in Iraq.
- Initiated variation activity trackers for RA department for operational monitoring and process improvement.
- Met all product submission milestones with 100% on-time delivery, and ensured timely preparation of required dossiers for custodian countries.
- Streamline the regulatory control requirements by developed a master listing for finished product specification which facilitates the issuance of certificate of analysis (CoA) for every shipment to other countries.

Jan 2020 – Dec 2021 **Thomson Hospital Kota Damansara**
Fully and Registered Pharmacist

Key Responsibilities

- Handle daily outpatient, inpatient and store operation.
- Collaborated with prescribers as part of the Antimicrobial Stewardship Team to manage hospital antimicrobial usage in compliance with diagnostic outcomes and local antimicrobial resistance data.
- Accountable for drug adverse reaction reporting to local health authorities and performed patient medication safety reviews.
- Produced pharmacy newsletters, bulletins, and educational videos to ensure high standards of medication knowledge for all departments.
- Managed the "Auto-Top Up" ward supply system for COVID-19 wards and oversaw stock inventory for both outpatient and inpatient pharmacies, including Cytotoxic Drug Reconstitution (CDR) pharmacy operations.
- Covered ad-hoc oncology drug preparation and delivery as needed.

Achievements

- Awarded with top achiever by scoring more than 90% during provisionally registration period.
- Awarded with perfect attendance award.
- Managed "Auto-Top Up" ward supply system for COVID-19 wards that successfully reduces physical contact between health care personnel during pandemic period.

Aug 2019 – Dec 2019 **Marketing Assistant**
Blackmores (Malaysia) Sdn Bhd

Key Responsibilities

- Coordinated, implemented, and monitored daily marketing activities, including competitor surveys and point-of-sale material preparation.
- Served as a liaison with sales team, Key Opinion Leaders (KOLs), and other stakeholders in the marketing process.
- Assisted in new product launch campaigns, such as shopping mall events and social media influencer launches.
- Coordinated with eCommerce partners, media and creative agencies to oversee company social media platforms.

Dec 2017 – Mar 2018 **Student Internship**
Dec 2018 – Mar 2019 Blackmores (Malaysia) Sdn Bhd

Key Responsibilities

- Regulatory Affairs Department
  - Registered new products and conducted post-marketing surveillance activities, including label inspection and complaint screening, in compliance with Malaysia Health Authority (NPRA) requirements.
  - Provided regulatory input to marketing team for new product development and promotional materials.

- Education & Training Department
  - Served as part of the health advisory team, answering daily health enquiries online and performing on-site bone density screenings for customers.
  - Prepared product-related materials, such as fact sheets, leaflets, and labels. ○ Conducted internal training on updated product information for relevant stakeholders.
  - Reviewed learning materials for online education modules (CMEd Masterclass).

Dec 2015 – Mar 2016 **Student Internship**
Dec 2016 – Mar 2017 Pfizer (Malaysia) Sdn Bhd

Key Responsibilities

- Medical Affairs Department
  - Assisted in product complaint investigations and provided supporting documents from customers.
  - Participated in the approval process for promotional activities, including screening of product gimmicks, leaflets, and patient information.
  - Handled daily administrative tasks for the medical affairs department.

- Education & Training Department
  - Created promotional materials, including digital and print materials, for new and existing products.
  - Collaborate with advertising agencies and vendors to ensure timely and effective production of materials.
  - Contributed in training sales representatives on product information and features.

Languages

- English – written and spoken (Good)
- Chinese – written and spoken (Good)
- Bahasa Malaysia – written and spoken (good)

References will be provided upon request.