



KONG MIEN YUH

CONTACT

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SKILLS

Microsoft Excel ●●●●●

Microsoft Words ●●●●●

Microsoft Point ●●●●●

Adobe ●●●●●

LANGUAGES

Mandarin ●●●●●

English ●●●●●

Malay ●●●●●

Cantonese ●●●●●

PROFESSIONAL SUMMARY

A registered pharmacist (RPh 12578) with Pharmacy Board Malaysia, to manage product registration and post approval activities to assist in product registration approval successfully within the stipulated timeline.

WORK EXPERIENCE

Aug 2023– Current

Senior Associate Manager, Novugen Pharma Sdn. Bhd.

- Involve in company set up of pharmacovigilance (PV) system and to ensure the system fulfil as per requirement in Malaysian Pharmacovigilance Guideline (GPV).
- Responsible person for PV (RPPV), to ensure that a company's pharmacovigilance activities are conducted in compliance with regulatory requirements and the safety of marketed medicinal products is effectively monitored and managed.
- Ensure the company's products and operations comply with all applicable regulations and laws. Stay updated on regulatory changes and communicate the impact of these changes to relevant stakeholders.
- Develop and implement regulatory strategies for new product approvals and market expansion. Provide strategic input to product development teams.
- Provide and identify potential regulatory risks and propose solutions to mitigate these risks.
- Prepare for and participate in regulatory audits. Collaborate with auditors and ensure compliance with regulatory standards.

Jan 2022 – July 2023

Associate Manager, Novugen Pharma Sdn. Bhd.

- In-charge of Oncology and Non-Oncology portfolio in regulatory strategies and submission
- Manage regulatory affairs activities for assigned products, including regulatory submissions and regulatory compliance according to Drug Registration Guidance Document (DRGD)
- Ensure that all regulatory submissions are completed accurately and on time by appropriate tracking system
- Serve as a subject matter expert on regulatory requirements for assigned products and provide regulatory guidance to cross-functional teams
- Collaborate with cross-functional teams to develop and execute regulatory strategies for new product development and post-approval changes
- Conduct regulatory assessments of promotional materials to ensure compliance with regulatory requirements
- Liaise with regulatory authority pertaining to matters related to regulatory queries
- Handling for overseas filing for products (cover for Brunei, Vietnam, Saudi Arabia with product dossiers in compliance with local regulatory requirements.

PERSONAL STRENGTH

- Willing to learn attitude
- Good analytical and able to work independently.
- Strong attention to details and ability to manage multiple projects simultaneously
- Responding promptly to problems
- Self-management.
- Teamwork and interpersonal skills

- Monitor regulatory developments and updates and assess their impact on assigned products

Jan 2021 – Dec 2021

Assistant Manager, Novugen Pharma Sdn. Bhd.

- Review of documents and comment if any before dossier submission to ensure smooth submission without screening remarks and reduce the number of correspondences
- Maintain good rapport with the local authorities
- Involve in post-approval activities such as variation application to ensure the correct variation type is submitted to NPRA and hence variation approval within 6 months

Jan 2019 – Dec 2020

Senior Executive, Novugen Pharma Sdn. Bhd.

- Manage poison check and maintain appropriate poison tracking and record to ensure zero finding from enforcement officer during yearly enforcement inspection
- Product artwork review and comment before submission in compliance with regulatory requirements
- Worked closely and coordinate with cross-functional teams to ensure that all regulatory submissions were completed on time
- Involved in new product development such as provide product presentation to the team for better understanding before product development
- Ensure licenses (such as import license, manufacturing license) were applied and renewed yearly
- Import permit application for unregistered products from overseas to Malaysia for product development purpose and ensure import permit approval with zero queries from authority

Jan 2017 – Dec 2018

Registered Pharmacist U44, Hospital Selayang

- Work in pharmacy satellite for inpatient
- Answer to doctors' queries during dispensing and preparation of trolley
- Work in MTAC Respiratory by giving counselling to patient on how to use the medical device such as inhaler appropriately

Apr 2015 – Dec 2016

Registered Pharmacist U41, Hospital Selayang

- work in Farmasi Logistik (Store pharmacy) and dealing with procurement of medication, applying kpk for medications not stated in bluebook, reports form JKNS and dealing with sales representatives and drug companies and distributors. I'm also involved in application of import permit for items which are not available in Malaysia. Reports for internal and external audit purposes were also prepared
- Work for night shifts (able to multitask as night shifts cover inpatient and also outpatient)
- Dispensing methadone in AADK, Gombak
- Involve in research development as one of the requirements for the pharmacists in Hospital Selayang. (involved in NMRR registration, and the use of SPSS

- software in statistical analysis of the data in the research)
- Qualified to involve in research as I've passed the Good Clinical Practice (GCP) Certification examination held by National Pharmaceutical Regulatory Agency (NPRA)

Dec 2013 – Mar 2015

Provisionally Registered Pharmacist (PRP), Hospital Tengku Ampuan Afzan

- Attached in all the departments such as CDR, TPN, Clinical, Inpatient, Outpatient, Drug Information Centre, Store pharmacy

Jan 2016- Jan 2019

Locum Pharmacist. Caring Pharmacy

- Work as a locum pharmacist in Fahrenheit 88, Pavilion and Avenue K
- Management of prescriptions and dispensing medications
- Keeping of financial records
- Provide professional advises to the customers in response to their enquiries

EDUCATION/ PUBLICATION

2016

- Published paper “ A Retrospective Study on the Outcome of Deferasirox in Pediatric Thalassemia Patients in Selayang Hospital”

Jan 2010

- MPharm (2 ½ + 1) Programme in IMU and partner university in University of Strathclyde, Glasgow, Scotland.
- Semester 1 modules include Physiology 1, Mathematics, Bioscience 1, Biopharmacy and Foundation Chemistry.
- Semester 2 modules include Physiology 2, Statistic, Bioscience 2, Bahasa Malaysia and English.
- Semester 3 modules include Physical Pharmacy, Foundation Pharmacy, Pharmaceutical Microbiology, Fundamentals of Pharmacology, Biopharmacy 2 and Malaysian Studies.
- Semester 4 modules include Health Promotion, Drug and Disease 1, Pharmacy Practice 1 and Biopharmacy 3.
- Semester 5 modules include Biopharmacy 4, Drug and Disease 2, Drug and Disease 3 and Pharmacy Practice 2.
- Semester 6 modules include Formulation, Manufacture and Testing 1, Formulation, Manufacture and Testing 2 and Pharmacy Practice 3.
- Semester 7 and semester 8 modules include Advance Drug Delivery, Biopharmacy 5, Drug Delivery System, Pharmaceutical Care and final year research project.

July 2007- July 2009

- Graduated from International Education Centre(INTEC) UiTM, Shah Alam.
- Completed Edexcel A -Level with 3As.
- IELTS result: Band 6
- MUET result: Band 4

Jan 2002- Dec 2006

- Graduated from Sekolah Menengah Kebangsaan Tengku Afzan, Kuantan, Pahang and completed SPM with 11As.

ACHIEVEMENTS

- 2012: Awarded with Gold Medal in IMU for completion of part A of the pharmacy programme and completed the course of Master in Pharmacy in University of Strathclyde with Merit. (Dean list in all semesters)
- 2008: Passed Grade 8 piano examination of Associated Board of the Royal Schools of Music with merit.
- 2019-2023: Managed to register at least 20 products (SKU: 35 products) in Novugen Pharma Sdn. Bhd.

REFERENCES

References available upon request