



SITI FATIMAH MOHD MUSTAFA

SCIENTIFIC -TECHNICAL PROFESSIONAL



EXPERIENCE

Regulatory Affair Officer 30 Maple Sdn Bhd (FVG Group/ dUCk brand) - Damansara, Kuala Lumpur
02/2019 - 10/2022

- Lead in the coordination of multiple facets of regulatory procedures and operations within the Regulatory Affairs service function and across the company's product portfolio
- Compiled information and maintained regulatory documentation databases and information management in compliance with regulatory requirements
- Provided administrative support for the activities conducted by the Brand Department
- Ensured all regulatory documentation was compliant with Standard Operating Procedures (SOP's) for format, content, and storage
- Managed Cosmetic-Personal care product Regulatory affair Formulation/INCI, Scientific review prior product development, Notification and Compliance with Control of Drugs and Cosmetic Regulations
- Key person to liaise with manufacturers/supplier (local and international), regulatory agency National Pharmaceutical Regulatory Agency, JAKIM, CUSTOMS and other (freight forwarder), SIRIM & KPDNK etc
- Halal Executive for Halal Certification application and renewal as well for product compliance
- Liaised with retail channel, supply chain management such as Watson and Sephora Malaysia and Singapore), in house store, collaborator for technical aspect and administration for shipment-logistic (local, International)
- Assisted in Operational Database/B2B Online Platform for Watson Retail Business' Transaction process

Sr Exec, Research & Regulatory Affairs Natural Wellness Pharmaceutical Sdn Bhd - Cheras, K.Lumpur
12/2018 - 01/2019

- Lead in quality, research and regulatory team across the company's product portfolio.
- Lead in the preparation of regulatory dossiers, audit/inspection by NPRA and SIRIM for new product / GMP license renewal purposes
- Prepared and submitted new product registration and renewal process
- Provided meeting minutes or dashboard updates for related activities resulting in an increase in communication efficiency within the department
- Advised in production daily meeting, tracked expenses, and submitted purchase orders resulting in efficient financial management of the department
- Verified QC/QA work/report and the finished product COA

📍 Putrajaya, Malaysia

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Diligent professional with extensive knowledge of government regulations and best practices. Comprehensive in investigating organizations and reporting findings. Offers 8 years plus in regulatory affair, research and quality. Detail-focused in quality, research and regulatory affair process and policy, well-versed in government regulatory affairs and stakeholder managements. Respectfully communicates problems and recommends solutions to consistently provide first-class results in line with stringent targets and deadlines.

SKILLS

- Microsoft Office (Word, Excel, Power point) & SPSS
- Scientific-Instrumental Analysis (AAS-ICP, GC-MS, LC-MS, HPLC, NMR etc)
- Product Certification and Registration/Notification (Food, Cosmetic-Personal care, TCM, OTC)
- Food and Cosmetic-Personal care Halal Certification
- Premise Certification (MESTI, GMP & HACCP)
- SIRIM and KPDNKK Product Safety-Certification Mark
- Clinical Trial/ Research

- Project Management & Quality Management System
- Research & Product Development
- Analytical laboratory tests and Foundation study
- Product Quality, Safety and Complaints
- Laboratory Safety Procedures

STRENGTHS

- Project Management- Successfully managed and coordinated multiple regulatory projects, ensuring adherence to timelines and budgets.
- Attention to Detail- Demonstrated meticulous attention to detail while reviewing and preparing regulatory documents and submissions.
- Communication-Proven ability to communicate effectively and build positive relationships with cross-functional teams, regulatory agencies, and stakeholders.
- Problem Solving-Effectively resolved complex regulatory issues by analyzing and synthesizing information from multiple sources and proposing innovative solutions.
- Multi-Talented Professional- Over 10 years of diverse work experience with successful deal making and leadership.
- Regulatory Affairs Expert- Extensive knowledge in product regulations, halal compliance, and product development.

ACCOMPLISHMENTS

- Managed the supply chain issue -logistic with relevant stakeholder and resulted smooth customs clearance process
- Lead the regulatory submission and follow up for approval process resulting in revenue savings
- Improved compliance by implementing a regulatory compliance checklist and updated current regulations

Assistant Manager, Scientific & Regulatory Affair FELDA Wellness Corporation Sdn Bhd (Subsidiary of FELDA) - WP Kuala Lumpur, Kuala Lumpur
01/2014 - 07/2018

- Supervised and delegated tasks to employees to meet key productivity targets and assisted senior management plan and carry out daily operations
- A subject matter expert for company product and services (foods, beauty-personal care, health and wellness products, R&D Project and services)
- Provided summaries of complex communication and follow-up to ensure proper and timely action was taken in regulatory affair function
- Ensured project are reviewed and approved by top management in a timely manner and report are appropriately maintained and updated
- Lead in the preparation of product dossier for registration /compliance and Halal certification to relevant authority, resulted the product launch according to schedule
- Reviewed and advised for product formulation, label, packaging and claim, as well for promotional material /A&P related
- Supported on customer complaint handling related to product formulation, quality and safety
- Collaborated with other department such brand and communication, sales and marketing, production, QC/QA and Strategic planning team
- Engaged with authorities (Food Safety and Quality Department, National Pharmaceutical Regulatory Agency, JAKIM, SIRIM, CUSTOMS KPDNK, PBT etc.), manufacturer, supplier, partner, research collaborator etc.

Clinical Study Coordinator Clinical Investigation Centre (CIC), University Malaya Medical Centre (UMMC) - WP Kuala Lumpur, Kuala Lumpur
02/2011 - 12/2013

- Coordinated the overall clinical operations related to trial process (i.e., patient's screening selection, recruitment, consent, blood sampling processing, visit scheduling, dispense of medication, safety update, study report, site initiation, monitoring and audit, closure of study and documents archive etc.)
- Assisted Principal Investigator and other Investigator throughout the trial process (based on study protocol)
- Served as focal point for communication between Site Doctor, Nurse, Pharmacist, and other healthcare personnel) MEC and sponsor
- Assisted other administration task such payment, claim and cheque deposit under department research fund
- Handled 3 different Clinical Trial project (Diabetics, Hypertension and Nephrology) at one time with 3 different Study Protocol, Investigational Brochure product and Sponsor
- Ensured study protocols, investigator brochure, study consent, study data, safety info, test kits, medications etc approved by relevant authority in timely manner and appropriately maintained and updated
- Prepared a full checklist prior a patient visit, documents readiness and data entry updated, inquiry response in timely manner and ready for site audit

- Prepared and coordinated company's research project grant resulting for shortlisted for Industry Smart Fund application under Ministry office
- Streamlined workflow by consolidating lengthy processes and redundant documentation which resulted in more effective and timely regulatory approvals.
- Recognized by management for special projects delivering an outstanding output

TRAINING

- ISO 22000- Food Safety Management System
- Food Handler & Good Hygiene Practise
- MS 2400-2:2019 Halal Supply Chain Management System
- MS 1500:2019 Halal Food Standard
- ISO 9001 - Quality Management Systems
- Halal Assurance Management System
- Halal Warehousing & Sertu Compliances
- GMP & HACCP



ADDITIONAL INFORMATION

- Career Break -Family Health -2023
- Freelance Jobs during the break-2023



EDUCATION

Master of Science: (Full Research)

University Malaya - Kuala Lumpur, 01/2013

Bachelor of Science: (Hons) Applied Chemistry

University Technology Mara - Selangor, 01/2006



CERTIFICATIONS

- Certified Good Clinical Practices (GCP), MOH-UMMC
- Certified Halal Executive by Halal Professional Board (HPB), JAKIM



LANGUAGES

Malay: First Language

Malay: C2
Proficient

English: C1
Advanced

Japanese: B1
Intermediate



REFERENCES

- Upon Request