SARUN GEORGE

Regional Regulatory Affairs / Pharmacist-in-Charge
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Summary

Accomplished Regulatory Affairs professional with over 12 years of expertise in the pharmaceutical industry, specializing in regulatory strategy, product lifecycle management, and cross-functional leadership across the GCC region. Proficient in regulatory submissions, product classification, and compliance with local and international health authorities. Adept at navigating complex regulations to streamline product approvals and ensure business continuity. Recognized for strong project management, regulatory intelligence, and driving results in high-stakes environments.

Experience

Arabian Medical Enterprises — Dubai, UAE

Regional Regulatory Affairs / Pharmacist-in-Charge — 04/2019 - 02/2024

- Led Regulatory Affairs, managing product lifecycle and approvals across GCC markets (UAE, Oman, Qatar, Bahrain, Kuwait, and KSA).
- Accomplished registration of a diverse range of products, including surgical and non-surgical medical devices, injectables, skincare products, and cosmetics.
- Managed (6) manufacturing site and marketing authorization holder registrations with the Ministry of Health and Prevention (MOHAP).
- Conducted product classification (32) and pricing (11)in collaboration with MOHAP.
- Facilitated (32) product registrations via the Dubai Municipality Montaji portal.
- Ensured 100% compliance with ESMA (Ministry of Industry and Advanced Technology) regulations for product registration in the UAE.
- Collaborated with principal companies on Quality Management Systems (QMS), risk management, and pharmacovigilance.
- **Artwork & Labelling:** Reviewed artwork and labeling, collaborated on marketing material reviews for new and existing (18) products.
- **Pharmacovigilance:** Managed pharmacovigilance activities, including the review and reporting of ADR's (03)to health authorities. Ensuring contracts with marketing authorization holders (MAH) were current and compliant.
- **Quality management system:** Developed and maintained QMS documentation and Standard Operating Procedures (SOPs) for the Regulatory Affairs department and drug store, including CAPA for reported incidents (2).
- **Supply chain:** Coordinated with the logistics team to secure (100+) import permits from MOHAP and Dubai Municipality, facilitating the clearance of goods to warehouses in both mainland and Free Zone store.
- Collaborated with the supply chain team to implement QMS and maintain Good Storage and Distribution Practices (GSDP) standards.
- **Warehouse management:** Ensured compliance with regulatory agencies and developed regional logistics strategies to enhance distribution oversight.
- Introduced tracking system for temperature-controlled shipments to the UAE and for exported products, including a cloud-based security system for continuous monitoring.
- **Auditing:** Served as the primary contact for internal and external audits, conducting periodic internal audits of the drug store to ensure adherence to QMS and GSDP requirements.
- **Inspection:** Assisted government inspectors during facility inspections (15) and provided necessary follow-up information post-inspection.

Al Razi Pharmacy Co — Abu Dhabi, UAE

Regulatory Affairs Associate — 06/2015 - 01/2019

- Managed product registration and life cycle for conventional medicines (32) and medical devices(8).
- Prepared and submitted electronic Common Technical Document (eCTD) applications, handled renewal processes, and conducted product pricing with MOHAP(9)
- Registered skincare products (11)with the Dubai Municipality and coordinated quality control laboratory analysis and certification
- GSL registration of products and classification of products in compliance with MOHAP regulations
- Engaged in pricing with MOHAP, including appeals for price(1) increases on registered products
- Submitted and obtained approvals for Dubai Drug Codes (DDC) for medicinal products(12).
- Compiled and submitted Periodic Safety Update Reports (06) (PSUR) and PBRER on behalf of principal companies.

Shasun Strides — Puducherry, India

Quality Assurance Executive — 05/2014 - 03/2015

- Served as an in-process Quality Assurance Executive at a pharmaceutical manufacturing site compliant with USFDA, MHRA, CGMP, and TGA regulations
- Focused on formulations including tablets and capsules to international markets, designated to the US, Canada, and the UK.
- Reviewed and validated manufacturing process batch records, ensuring adherence from raw material dispensing to batch release

Aravind Remedies — Chennai, India

Quality Assurance Associate — 07/2011 - 05/2014

- In-process quality control, process validation, and cleaning validation for pharmaceutical products
- Managed a variety of formulations, including tablets, capsules, oral reconstituted syrups, ointments, creams, and liquids
- Reviewed artwork, patient information leaflets (PIL), and batch manufacturing records to ensure compliance with regulatory standards

Key Achievements

Best Regulatory Performance Award in the year 2020 from Teoxane, Switzerland.

Achieved other GCC registrations 11 products(Oman and Qatar) within a timeframe of 06 months to sustain the business continuity.

Successfully priced 11 products with the concerned authorities (MOHAP- UAE & MOPH- Qatar).

Successfully accomplished Insurance claim release (1)in liaise with logistic department, worth 0.5M AED of the temperature-impacted shipments from Switzerland.

Found and rectified printing error in the batch manufacturing record (BMR-USFDA document) with necessary ratification.

Education

KM College of Pharmacy
Madurai, India

Master of Pharmacy - Pharmaceutical Chemistry
08/2009 - 05/2011

- Research Project: Anti-cancer activity of Pyrimidine derivatives in rats

Pushpagiri College of Pharmacy
Thiruvalla, India

Bachelor of Pharmacy
07/2005 - 07/2009

- Research Project: DNA-assisted organic synthesis

Skills

Regulatory Intelligence & Documentation · Problem-Solving & Decision-Making · Strategic Planning & Implementation · Critical Thinking · Quality Auditing & Compliance · Attention to Detail · Team Leadership & Mentorship · MS Office Suite Proficiency · Training and Development · Supply Chain Management

Certification

MOHAP licensed Pharmacist.

Certified Lean six-sigma green.

Certified ISO lead auditor.

Personal Information

Date of Birth
10/07/1984

Visa Status
Residence

Gender
Male

Driving License
LMV