NOR SHAFEEZA BINTI SAIFOL

QUALITY & REGULATORY AFFAIR MANAGER

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PROFILE

A highly responsible and target-oriented person with good interpersonal skills in handling tasks given. As a resourceful problem solver, always demonstrated high professionalism and shows ability to carry out big amount of work while ensuring work are completed according to timeline

EDUCATION

BACHELOR OF BIOMEDICAL SCIENCE (HONS)

School of Science (2012 - 2015) Management and Science University

Focus on biological and the medical sciences through extensive theoretical knowledge and advanced laboratory skills.

CGPA - 3.33

DIPLOMA OF MEDICAL LABORATORY TECHNOLOGY

School of Science (2008 - 2010) Pusat Teknologi dan Pengurusan Lanjutan

Focus on all laboratory testing and skills. Advance understanding on theoretical knowledge

CGPA - 3.08

EXPERIENCE

QUALITY & REGULATORY AFFAIR MANAGER **(Oct 2022- Current) - OWI LAB (M) SDN BHD**

Quality Assurance & Quality Control

- Handling, checking and approving all quality testing and including microbiology
- Monitor production in-process and QC processes to ensure all processes are carried out in accordance with SOP set by Management and compliance with GMP standards
- Approve bulk materials, in-process goods, and finished goods to proceed to the next stage; or hold such products that deviate from specifications
- Prepare and review quality complaint trends. Report serious or repeated non-conforming products and make informed judgement to recommend corrective actions and/or improvement plans or programs for overall reduction of detected products
- Lead and continuously improve quality management system i. audit management ii. Quality manual and site master file
- Enforce all SOPs, policies and documentation.

Regulatory Affairs and Halal

New Product Registration

- Responsible to prepare, compile and submit of documents for application of new product registration
- Consult and liaise with respective unit, department manufacturer and/or principal should additional information required for preparation of product dossiers and during evaluation of product registration, as and when necessary

- Responsible to follow-through and monitor the registration process for all new product registration submission, as well as all other applications from NPRA, HALAL and to tackle any queries or problems arise, as and when necessary
- Successfully managed registered 15 cosmetics product per month and Halal every 3 months of the year
    - Document Controller : SOP, Work Instructions, Job Description to ensure they are in line with Regulation Standards (ISO, GMP, Halal etc)
    - Maintain and update Product Information File (PIF) and ensure ready accessibility for Authorities or for internal Audit purposes.
    - Conduct Product Safety Assessment (PSA) for all product, ensuring safety and compliance to regulatory requirements.
    - Conduct packaging assessments for all products, ensuring compliance with regulatory requirements.
    - Oversee Production Notification and Halal submissions and renewals for all products and answer correspondence from related authorities.
    - Coordinate Export product registration in providing necessary documentation to support export markets.
    - Keep up to date with applicable regulatory and enforcement changes and amendments (including both local and international regulations) - either via official notifications, announcements, meetings, or trainings -and notify necessary departments and management.
    - Work with R&D and Marketing Teams to provide regulatory advice
    - Coordinate and lead internal audits to ensure compliance with all applicable standards including but not limited to ISO, GMP, Halal
    - Coordinate with and act as Liaison to applicable authorities (NPRA, JAKIM/JAIS, CUSTOMS etc)
    - Coordinate and liaise on any other matters related to NPRA (GMP), ISO, HALAL
    - Coordinate and lead barcode system
    - Coordinate and lead packaging testing
    - Lead Packaging team and technical team

ASSISTANT MANAGER REGULATORY AFFAIR **(Feb 2021 – Oct 2022) – OWI LAB (M) SDN BHD**

New Product Registration

- Responsible to prepare, compile and submit of documents for application of new product registration
- Consult and liaise with respective unit, department manufacturer and/or principal should additional information required for preparation of product dossiers and during evaluation of product registration, as and when necessary
- Responsible to follow-through and monitor the registration process for all new product registration submission, as well as all other applications from NPRA, HALAL and to tackle any queries or problems arise, as and when necessary
- Successfully managed registered 15 cosmetics product per month and Halal every 3 months of the year
- Document Controller : SOP, Work Instructions, Job Description to ensure they are in line with Regulation Standards (ISO, GMP, Halal etc)
- Maintain and update Product Information File (PIF) and ensure ready accessibility for Authorities or for internal Audit purposes.
- Conduct Product Safety Assessment (PSA) for all product, ensuring safety and compliance to regulatory requirements.
- Conduct packaging assessments for all products, ensuring compliance with regulatory requirements.
- Oversee Production Notification and Halal submissions and renewals for all products and answer correspondence from related authorities.
- Coordinate Export product registration in providing necessary documentation to support export markets.
- Keep up to date with applicable regulatory and enforcement changes and amendments (including both local and international regulations) - either via official notifications, announcements, meetings, or trainings -and notify necessary departments and management.

- Work with R&D and Marketing Teams to provide regulatory advice
- Coordinate and lead internal audits to ensure compliance with all applicable standards including but not limited to ISO, GMP, Halal
- Coordinate with and act as Liaison to applicable authorities (NPRA, JAKIM/JAIS, CUSTOMS etc)
- Coordinate and liaise on any other matters related to NPRA (GMP), ISO, HALAL
- Coordinate and lead barcode system
- Coordinate and lead packaging testing
- Lead Packaging team and technical team

REGULATORY AFFAIR SPECIALIST

(2014 -2021, Feb) - DUOPHARMA INNOVATION SDN BHD (FORMERLY KNOWN AS INNOVAX SDN BHD

New Product Registration

- Responsible to prepare, compile and submit of documents for application of new product registration
- Consult and liaise with respective unit, department manufacturer and/or principal should additional information required for preparation of product dossiers and during evaluation of product registration, as and when necessary
- Responsible to follow-through and monitor the registration process for all new product registration submission, as well as all other applications from NPRA, MDA and to tackle any queries or problems arise, as and when necessary
- Successfully managed registered 4-5 new product per year Poison/Non-Poison, OTC, THMS, Biologics and Medical Devices

Regional Product Registration

- Responsible to prepare, compile and submit of documents for application of regional product registration
- Consult and liaise with respective unit, department manufacturer and/or principal should additional information required for preparation of product dossiers and during evaluation of product registration, as and when necessary
- Responsible to follow-through and monitor the registration process for all regional product registration submission, as well as all other applications with the authority and to tackle any queries or problems arise, as and when necessary
- Successfully managed registered 2-3 regional product per year Poison/Non-Poison to Singapore, Philippine, Thailand, Vietnam and Indonesia

Maintenance of Product Registration
Variation (inclusive change of holder (COH) and change of Site (COH)

- Responsible to notify NPRA on any changes or amendments of registered pharmaceutical products for in-house, contract manufacture and imported product (through manual or Quest On-line System application) progressively and timely
- Consult with other unit, department and manufacturer should additional information require for variation submission as when necessary
- Follow through and monitor the variation approval of products submitted to authority and to tackle any queries or problems arise as and when necessary

Product Registration File and List

- Responsible for maintaining the Product Registration Files for all respective product by ensuring all relevant documents (e.g correspondence
- Responsible for updating product list related to respective manufacturer/principal assigned
- Responsible for monthly report on the local registration status and update plants or relevant divisions or departments accordingly

Renewal of Products Registration

- Responsible for the product that is due for registration renewal comply with the current regulatory requirement such as Bioequivalence (BE Study), Stability Study for Zone IVB, Drug Master File and etc, prior to renewal application
- Responsible for the product re-registration /renewal to be done on time

Surveillance (Internal and Post - Market)

- Responsible for checking all artwork of existing registered products and to ensure all information in the artwork are as per registered info and comply with the registration requirement
- Co-ordinate, verify and ensure that the documents in the product file (Technical Specification, Certificate of Analysis, Batch Manufacturing Record, Packaging Material etc.is up to date

Product Complaint
Upon received the product complaint from NPRA: Responsible

- to acknowledge receipt of complaint to NPRA
- Responsible to notify respective Manufacturer/ Principal/Marketing team accordingly

Notify NPRA upon received the product complaints from private clinic, customers etc

License

- Responsible for maintenance and renew of manufacturing import, wholesale license and other license related to respective manufacturer and/or principal assigned

Regulatory Updates

- Responsible to share current registration requirements (circulars and directives) and update plans or relevant divisions or departments accordingly

Bioequivalence (BE Study) Documents and Monitoring

- Responsible to deal with the Clinical Research Organization Malaysia and oversea for BE Study
- Review and liaise with CRO for the Protocol Report preparation, Bioanalytical report and protocol,
- Consult and liaise with respective unit, department manufacturer and/or principal should additional information required for preparation of product dossiers and during BE Study process as and when necessary
- Responsible to monitor the timeline of product during BE Study process
- Responsible to assist the BE Study correspondence from NPRA and other country (Treading Product, In-Licensing and Out-source Product)
- Monitoring the dosing period at Clinical Research Organization (BE Study) and provide the monitoring report for evaluation
- Manage to handle 2-3 BE Studies per year and 2-3 BE Study passed per year

To undertake any other duties as directed by the Immediate Supervisor and Management as and when required

SKILLS

Technical Documents

- Review the Specifications, Test Methods and Certificate of Analysis for submission
- Review the Analytical Method Validation for submission
- Review the Manufacturing's document and Protocol Validation for submission
- Prepare and submit the package insert and Rimup for all products category
- Consult and liaise with the respective unit, department manufacturer and /or principal should additional information required for preparation of product dossiers as and when necessary

SAP System

- Handling PR PO for BE Studies and Purchasing Innovator product

Drug Master File (DMF) and Certificate of Suitability (CEP)

- Review and share with a team the gap
- Consult and assist a team to request supplier the information required as per requirement before proceed

AWARD

PNB INNOVATION & QUALITY 2016

Played an immense role in adopting various OE tools including Lean Six Sigma Methodology as well as PDCA (Plan-Do-Check-Act) Cycle, Fishbone Diagram and Root Cause Analysis towards enhancing quality control efficiency leading to the 2014 PNB Innovation & Quality Award

WINNER OF PNB INNOVATION CHALLENGE 2016

Cost Saving in Bioequivalence Study - 1st prize

CERTIFICATIONS

GOOD CLINICAL PRACTISE (GCP) 2016	Passed GCP in year 2016 at University Malaya
PDCA & OE TOOL 2016	Passed PDCA & OE Tool Training in year 2016 at Duopharma Innovation Sdn Bhd (In- House Training)
GDPMD 2016	ISO 13485
2021	Halal Executive Certified
2023	License B Holder (Poison Act 1952) ISO certified

LANGUAGES

- English
- Malay