freyr™



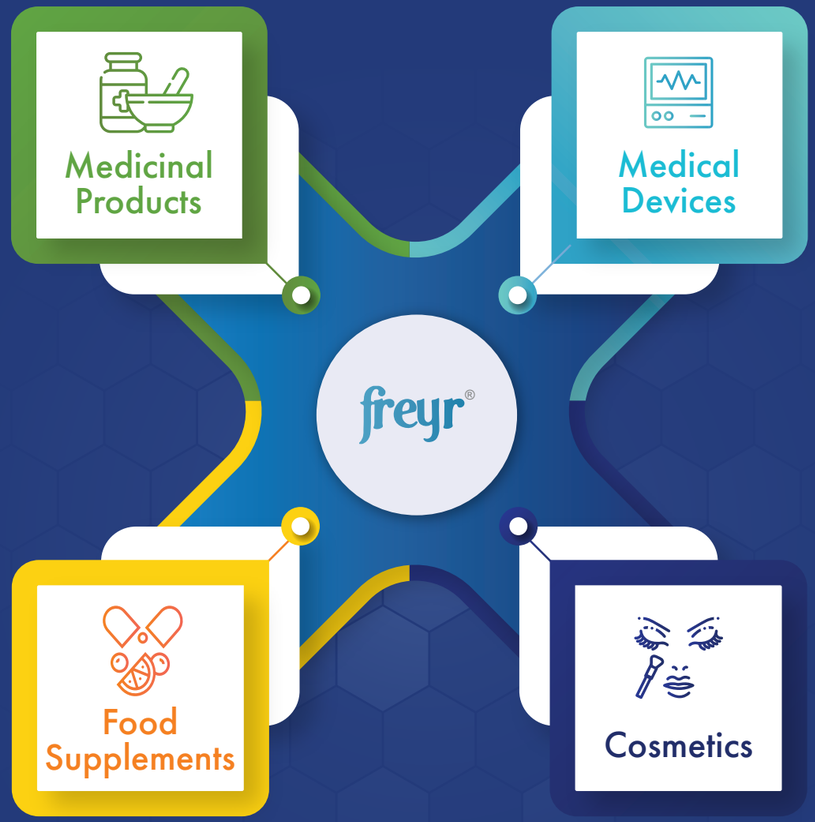

# REGULATORY LANDSCAPE IN Sri Lanka

# Freyr for Sri Lanka

Due to the strict policies of National Medicines Regulatory Authority (NMRA) and region-specific Regulatory complexities, most companies face compliance challenges while entering the Sri Lankan life sciences market. Since the registration of medicinal products in Sri Lanka requires the presence of a local representative, Freyr's strong network of locally authorized agents and a qualified team of experts assist the companies with streamlined and flexible solutions in product registration throughout the product's lifecycle. We provide clients with Regulatory process centralization with local representation, thereby allowing our clients to make informed decisions, along with a good assessment of the market at the time of the product launch. Our Regulatory team identifies, analyzes, and reacts to real-time Regulatory changes and formulates essential mitigation strategies for the upcoming risks. Here are some of the key Regulatory solutions offered in Sri Lanka:

1. Interactions with the NMRA
2. New Product Application
3. Marketing Authorization Holder (MAH)/Local Representation
4. Tailored Regulatory Intelligence (NMRA)
5. Product Maintenance & Compliance
6. Flexible Regulatory Teams

## Our Local Representatives in Sri Lanka are Experienced in





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# Industry Challenges

- Competitive pricing with bigger generic players.
- Ever-changing regulations.
- Heavy investments in acquiring a skilled workforce.
- Packaging compliance with disparate regulations.
- Rise in unregistered drug products plaguing the market.
- Language barriers.



# Freyr Expertise

1. End-to-end product registration.
2. Authorized local representation.
3. NMRA manufacturing site registration RA manufacturing site registration.
4. Sample import license support.
5. Dossier preparation and submission to the NMRA.
6. Preparation of gap analysis report and remediation plan.
7. Query support management till the approval.
8. Lifecycle management support.
9. Artwork management.
10. Ad-hoc Regulatory affairs consultation.
11. Structured and cost-effective approach to ensure compliance.
12. Quick turnarounds and faster time-to-market.

# FREYR DIGITAL

We provide next-generation Regulatory services to help our clients digitally.

Some of them are highlighted below:

**Freyr PRO SUBMIT**

A smart eCTD software for the creation, validation, publishing, reviewing, and reporting of Regulatory documentation to streamline electronic submissions.

**Freyr IMPACT**

An innovative Regulatory Intelligence Platform offering a complete spectrum of Regulatory intelligence, including detailed and customized insights across various product and regulation categories. Freyr IMPACT gathers and analyses publicly available Regulatory information. This includes monitoring the current regulations, guidance documents, policies, and legislation and communicating the same using a systematic approach.

**Freyr rDMS**

An end-to-end electronic Regulatory Document Management (RDM) solution exclusively designed to enable Regulatory groups and departments within life sciences organizations to seamlessly create, capture, manage, organize, connect, deliver, and archive Regulatory data and documents in a compliant, efficient, and intuitive manner.

**Freyr iReady**
Ready-to-use Ingredients Database

An integrated database platform that enables manufacturers and brand owners to understand the Regulatory requirements for the ingredients they use across the global markets. It supports proactive Regulatory compliance observance and management of product formulae in different markets.



**Freyr SPAR**

A Regulatory Information Management (RIM) solution that enables life science organizations to effectively manage the data and generate statistical reports, right from tracking product registration, marketing authorizations life cycle, Regulatory document management, and Health Authority interactions, and correspondence.

**Freyr SPL-SPM**

A software is a robust platform to create, validate, store, and submit complex content structures aligning with SPL and SPM standards control vocabularies and company & product information. Freyr SPL-SPM software is compliant with CFR part 11 criteria and Health Level Seven (HL7) standards.

**Freyr LABEL360**

It is a comprehensive label life cycle management tool through which companies can manage label changes globally in a streamlined and timely manner. The overarching principle of Freyr LABEL 360 is to integrate industry best practices by bridging the gaps within the global and regional labelling processes and to control the flow of labelling information.

# SUCCESS
# FREYR IN SRI LANKA

## Medicinal Products

**Client**
A private US-based Healthcare company.

**Project Scope**
Regulatory Intelligence report services required for General Cosmetics.

### Business Challenges

- No clear guidelines were available since National Medicines Regulatory Authority (NMRA) proposed updating the guidelines with major changes including fee structure.

### Freyr Solutions and Services

- Comprehensive Regulatory Intelligence reports were created by primary and secondary research.
- With Freyr's local presence in Sri Lanka, some practical nuances were also included that usually occurs while registering the products.

### Client Benefits

- Client was able to gain explicit knowledge on regulations of cosmetics in Sri Lanka and were able to launch their product successfully in Sri Lanka.
- Time and cost-effective service.



## Medical Devices

**Client**
US-based leading Medical Devices Manufacturer.

**Project Scope/ Client's Requirement**
Local representation and device registration.

### Business Challenges

- The device had lot of accessories and each accessory was available in multiple variants.
- The grouping of accessories and variants was challenging.
- The client was not aware of NMRA regulations, device registration process and procedures.

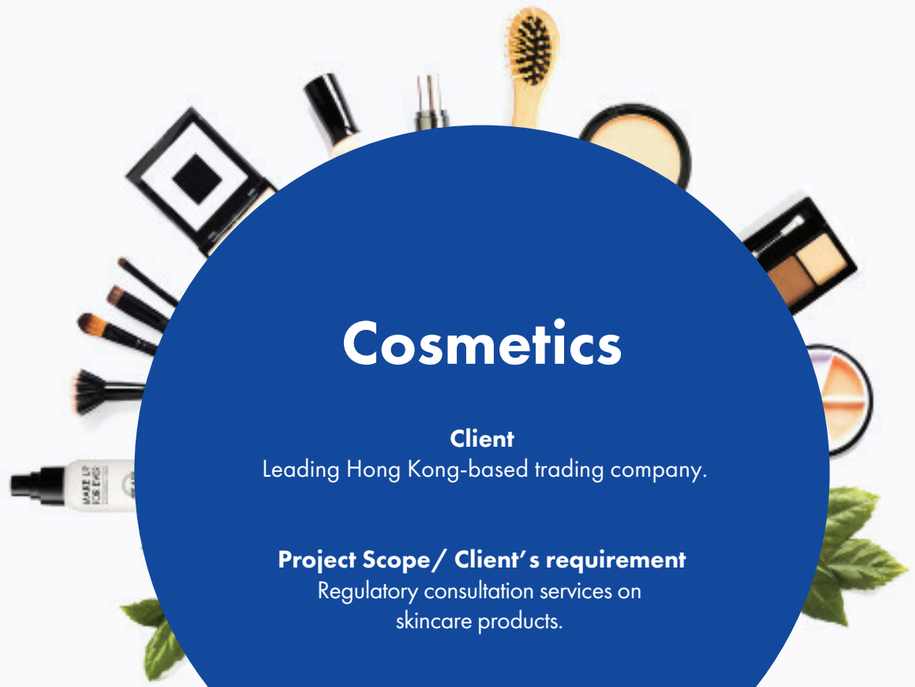
### Freyr Solutions and Services

- Freyr has carried out detailed evaluation to identify the products regulated as medical devices.
- The grouping of medical devices has been done and no. of applications to be submitted has been finalized.
- The device registration was carried out in a phase-wise manner.
- Freyr acted as an authorized representative for the client in Sri Lanka.

### Client Benefits

- Hassle-free registration of device in Sri Lanka.
- Successful market access to Sri Lanka.
- Cost-effective services.
- Single partner for end-to-end Regulatory activities.

# SUCCESS STORIES OF FREYR IN SRI LANKA



## Cosmetics

**Client**
Leading Hong Kong-based trading company.

**Project Scope/ Client's requirement**
Regulatory consultation services on skincare products.

### Business Challenges

- Client had issues with Labeling.
- The challenge here was that Sri Lanka regulations are not very straighforward. The client gave different scenarios and based on them, labelling regulations had to be suggested.

### Freyr Solutions and Services

- Freyr gave customized solutions based on the specific cases mentioned by the client.
- Coordination and consultation with the Health Agency was the key highlight of this project.

### Client Benefits

- The client queries were addressed which included reference links wherever applicable, thus enabling the client to develop the necessary Regulatory strategy in order to launch their products and remain compliant in Sri Lanka.



## Food and Food Supplements

**Client**
A leading Infant Food manufacturer from India.

**Project Scope/ Client's requirement**
Product registration of an infant powder containing a new ingredient in Sri Lanka.

### Business Challenges

- The client required Freyr's Regulatory compliance support for a new ingredient in their infant food product.
- The project primarily focused on whether the ingredient is acceptable in that geography and submission of dossier to the Sri Lanka Authority.

### Freyr Solutions and Services

- The project primarily focused on checking whether that ingredient is acceptable or not. Freyr compiled scientific documents available and submitted it to the Authority.

### Client Benefits

- Great rapport between the Freyr local partner and local HA.
- Suggestions were provided to the client before dossier compilation
- Received approval from the Authority to use the ingredients in infant powder and launched the product in the market.

# About Freyr

Freyr is the largest, global, Regulatory solutions and services company that offers end-to-end Regulatory solutions to life sciences industries. The services include Regulatory affairs, pharmacovigilance, clinical research, quality management, and technology solutions such as Regulatory information management systems and Regulatory data integration. Freyr's expertise in Regulatory affairs makes it a trusted partner for life sciences companies seeking to navigate the complex Regulatory landscape.

USA | UK | Germany | UAE | India | Canada | Mexico | Malaysia | South Africa | Singapore

Sri Lanka | Australia | Poland | France | Switzerland | China | Japan | Brazil | Colombia | South Korea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