freyr®

YOUR **REGULATORY** PARTNER IN **JAPAN**

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FREYR FOR JAPAN

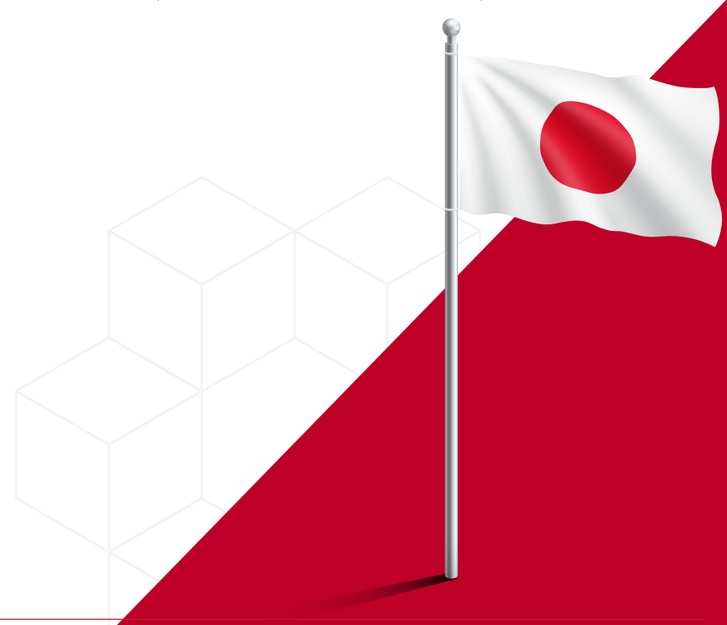
The Japanese Pharma infrastructure is one of the world's most dynamic and ever-expanding market spaces. Japan's aging population and government incentives present a lucrative opportunity for companies wishing to expand in the country.

The Pharmaceutical and Medical Devices Agency's (PMDA's) product review and approval processes are stringent and lengthy processes with multiple challenges, including translation, filing, and quality standards.

Freyr provides Regulatory intelligence solutions to aid customers in making informed decisions coupled with a sound assessment of the market at the time of product launch.

Our Regulatory team identifies and evaluates current Regulatory updates and develops critical risk mitigation plans. Following are Freyr's essential Regulatory services:

OUR **REGULATORY EXPERTS** IN **JAPAN** ARE **EXPERIENCED** IN THE FOLLOWING

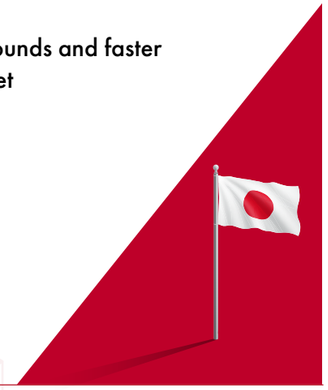


INDUSTRY CHALLENGES

- Extensive drug review and approval process
- Complex Regulatory submissions and strict deadlines
- Language barrier
- Patent and Intellectual Property Rights permits
- Harmonized regulation of medical Products

FREYR EXPERTISE

1. End-to-end product registration support
2. Authorized Local representation
3. Product classification services as per the PMDA
4. Authoring, reviewing, and submitting a dossier to the PMDA
5. Preparing Gap analysis reports and remediation plan
6. Strategic guidance during product development and Regulatory affairs support
7. PMDA site registration support
8. Import and export license application
9. Regulatory Affairs Consulting
10. Lifecycle Management Support
11. Strategically handling HA queries and preparing response packages
12. Product maintenance and compliance support
13. Product labeling and Artwork management
14. Quick turnarounds and faster time-to-market



FREYR DIGITAL

Freyr PRO SUBMIT

A smart eCTD software for 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 solution exclusively designed to enable Regulatory groups and departments within a life sciences organization to seamlessly create, capture, manage, organize, connect, deliver, and archive Regulatory data and documents in a complaint, efficient and intuitive manner.

Freyr iREADY

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 IDENTITY

Leverages the plan, process, and training methodology to offer end-to-end UDI compliance solutions. Suitable for a company of any size with number of devices, Freyr IDENTITY is exclusively designed to streamline the complete compliance process by connecting disparate internal functions and integrating data sources and formatted information with a centralized database for automated XML generation and submission that meets all FDA regulated UDI mandates.

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) standard.

Freyr XEVMPD

Freyr's Extended Medicinal Product Dictionary (EVMPD) is a ready-to-use, web-based, on-demand solution that offers end-to-end Extended EudraVigilance Product Report Message (EVPRM) lifecycle management right from creation, preview, and till submissions. It enables an automated validation process to verify submission accuracy and provides custom dashboards and reports to identify post-submission data changes in the products.

Freyr IDMP

It is an intuitive, user-friendly, and on-demand web-based solution with state-of-the-art navigation that supports consolidating, cleaning up, updating, authoring, approving, publishing, and archival of information in a standardized and structured format. Freyr IDMP efficiently monitors, tracks, updates, and creates XML files that are compliant with EMA's IDMP requirements.

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 labeling processes and controlling the flow of labeling information.

SUCCESS STORIES
FREYR IN JAPAN

Medicinal Products

Client
US-based biotech company headquartered in Maryland is a producer of vaccines

Project Scope
Gap analysis, dossier writing, translation, submission, in-country caretaking (ICC)

Buisness Challenges

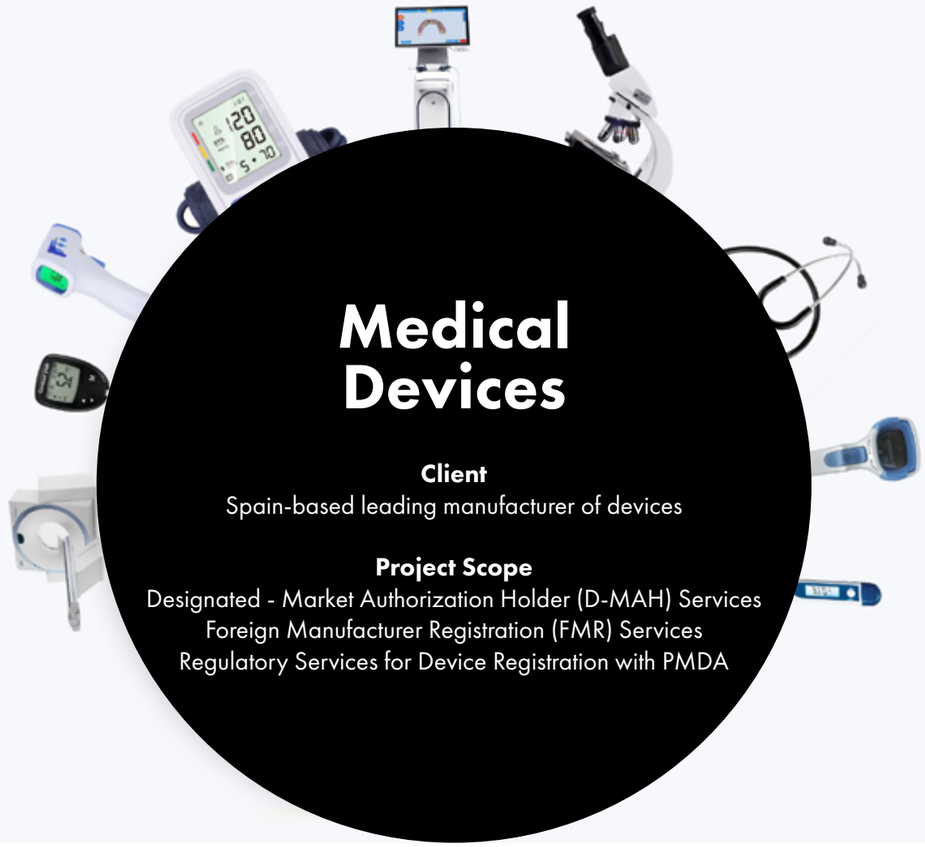
- The project primarily focuses in identifying the gaps, dossier writing in accordance with Japanese regulations.
- Translation of the DMF followed by submission.

Freyr Solutions and Services

- Gap Assessment
- DMF Writing
- Translation to Japanese
- Submission to PMDA
- ICC services

Client Benefits

- Supported client by providing strategic consultation where client can register the DMF of a vaccine adjuvant in Japan



Medical Devices

Client
Spain-based leading manufacturer of devices

Project Scope
Designated - Market Authorization Holder (D-MAH) Services
Foreign Manufacturer Registration (FMR) Services
Regulatory Services for Device Registration with PMDA

Buisness Challenges

- The client has minimal knowledge of Regulatory pathway and classification for bringing Medical Devices into Japan
- Local presence is highly required to frequently interact with PMDA

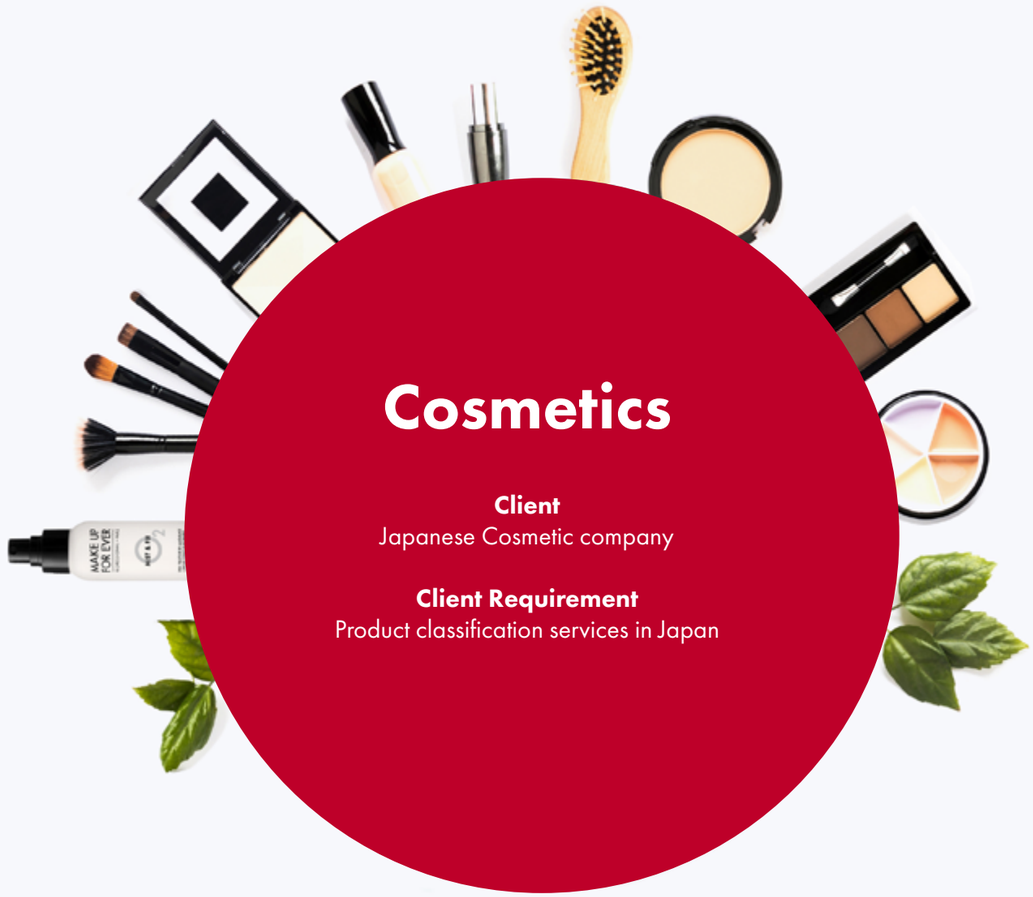
Freyr Solutions and Services

- Device classfication according to PMDA regulations for registration
- Freyr has registered the manufacturing site as per Foreign Manufacturer Registration (FMR) requirements

Client Benefits

- The client secured detailed knowledge of Regulatory process to market the product in Japan
- Cost-effective and right Regulatory strategic approach for device registration with PMDA.

SUCCESS STORIES
FREYR IN JAPAN



Cosmetics

Client
Japanese Cosmetic company

Client Requirement
Product classification services in Japan

Buisness Challenges

- Regulations for the market in scope are not easily available and there are language barriers to assess the product category
- The classification of the product was challenging due to product complexity in the formula and label claims

Freyr Solutions and Services

- Freyr has submitted the request for the product classification of Hand Sanitizer to Japan Health Authority and confirmed the category of the product as 'Quasi Drug'

Client Benefits

- With Freyr's assistance, the client was able to identify the category of the product in the target country
- The classification report provided by Freyr helped the client to understand the product category to proceed further in Japan

Food and Food Supplements

Client
UK-based Multinational consumer goods company headquartered in Slough, England, and is a producer of health, hygiene, and home products

Project Scope
Classification, product compliance, ingredient analysis, label, and claims review

Buisness Challenges

- British multinational consumer goods company required product compliance services for Japan
- The project primarily focused in classifying the products, checking the ingredients, label and claims compliance with Japanese regulations

Freyr Solutions and Services

- Product Classification
- Product Compliance
- Ingredient Assessment
- Label Assessment
- Claims Review

Client Benefits

- With our experience, we helped client by providing high level strategic conclusion where client can categorize the products and proceed with registering their products as FNFC

ABOUT FREYR

Freyr is one of the largest, global, Regulatory-focused solutions and services companies for the Life Sciences industry, supporting Large, Medium, and Small size global Life Sciences companies (Pharmaceutical | Generics | Medical Device | Biotechnology | Biosimilar | Consumer Healthcare | Cosmetics) in their entire Regulatory value-chain, ranging from Regulatory Strategy, Intelligence, Dossiers, Submissions, etc. to Post-approval/Legacy Product Maintenance, Labeling, Artwork Change Management, and other related functions. Freyr is also expanding its footprints into other key areas like Pharmacovigilance.

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

Slovenia | Sri Lanka | Australia | Poland | France | Switzerland | China | Japan | Brazil

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