freyr™

Your **Regulatory** Partner In **Japan**

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Freyr For **Japan**

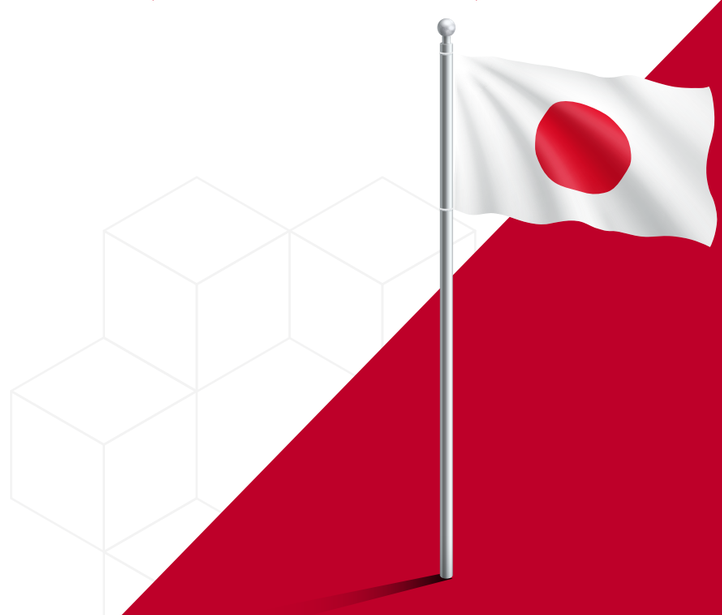
The Japanese Pharma infrastructure is one of the world's most dynamic and ever-expanding market spaces. Japan's aging population and government incentives present a lucrative opportunity for companies wishing to expand in the country.

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 **Core Competencies** in **Japan** are

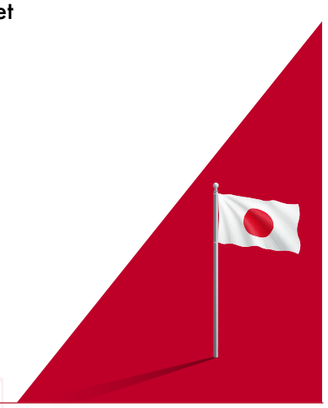


Industry Challenges

- 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

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

Some of them are highlighted below:

Freyr SUBMIT PRO

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 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 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)

Business 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

Business 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

Project Scope
Product classification services in Japan

Business 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

Business 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 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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