freyr®

Your **Regulatory Success Partner** in **Mexico**

company | freyrsolutions

www.freyrsolutions.com | Sales@freyrsolutions.com

FREYR FOR MEXICO

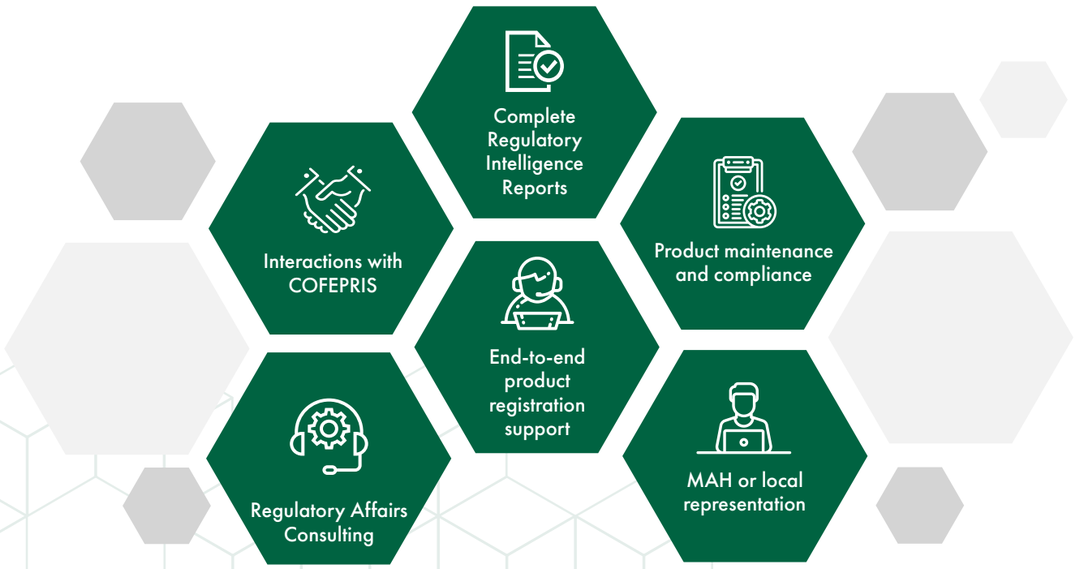
The Mexican pharma market is one of the largest markets in the world. It is among the leading markets in Latin America. This market is highly driven by better healthcare services and increasing population, ageing population.

COFEPRIS is the national health Regulatory authority in Mexico. It is a decentralised body that regulates the drug registration process in Mexico. It is substantially making constant efforts to contribute to the growth of pharmaceuticals.

However, the Mexican pharma market poses certain challenges towards the pharma drug manufacturers. The Regulatory requirements for approval of a drug are stringent, legal representation, delay in market entry and language barrier are few of them.

Freyr provides Regulatory solutions to aid global clients in both understanding the regulations and aligning with them in a streamlined manner with a focussed strategy for compliance. With our local presence in Mexico, we ensure cost-effective and time critical approaches for all processes. Following are some essential Regulatory services:

Highlights of some of the comprehensive set of Freyr's Regulatory services is given below:



FREYR MEXICO SPECIALIZES IN

INDUSTRY CHALLENGES

- Stringent regulations
- Tedious drug approval process
- Involvement of various Regulatory bodies
- Time-consuming application review process
- Linguistic barrier
- Legal representation

FREYR EXPERTISE

1. End-to-end product registration support
2. Authorized Local representation
3. Product classification services as per COFEPRIS
4. Authoring, reviewing, and submitting dossier to COFEPRIS
5. Preparing gap analysis reports and remediation plan
6. Strategic guidance during product development and Regulatory affairs support
7. COFEPRIS site registration support
8. Import and export licence application
9. Regulatory Affairs Consulting
10. Lifecycle Management Support
11. Strategically handling Health Authority 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 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 OF FREYR IN MEXICO

Medicinal Products

Client
Korea based biotechnology manufacturer

Project scope/ Client's requirement
Preparation of complete Biological License Application

Business Challenges

- CTD preparation for BLA submission for USFDA and using same CTD for global registrations.
- Strategy and submission support for biological product in LATAM and APAC.
- CMC data generation as per USFDA.

Freyr's Solutions

- Supported CTD and BLA submisssion. Product registered in LATAM and APAC.
- Assessment of CMC data and prepared gap analysis.
- Dossier submission strategy Detailed tracker creation.

Client Benefits

- Successful submission of BLA to USFDA.
- Product registeration dossiers submitted in LATAM and APAC countries.
- On-time delivery of the project.

Medical Devices

Client
Innovator of AI based diagnostic imaging techniques company

Project scope/ Client's requirement
End-to-end Regulatory support for ultrasound device registration in Mexico

Business Challenges

- Mandatory MRH.
- Translationa nd notarization of documents.
- Document translation into Spanish
- End-to-end Regulatory support.

Freyr's Solutions

- Notice of operation with COFEPRIS for initiating the submission.
- Mexico registration holder (MRH) service.
- Internal device classification and gap analysis.
- Technical file compilation, submission and follow up with COFEPRIS.
- Obtaining IFETEL / NOM-208 radio type approval.

Client Benefits

- Regulatory support for Notice of Operation with COFEPRIS.
- MRH support.
- Technical file compilation and submission to COFEPRIS.
- Documents reviewed, gap analysis performed and remediation suggested.
- Translation support and notarizartion of documents.

SUCCESS STORIES OF FREYR IN MEXICO

Food and Food Supplements

Client
British MNC consumer goods company

Project scope/ Client's requirement
Product compliance services for food supplements in India and Mexico

Business Challenges

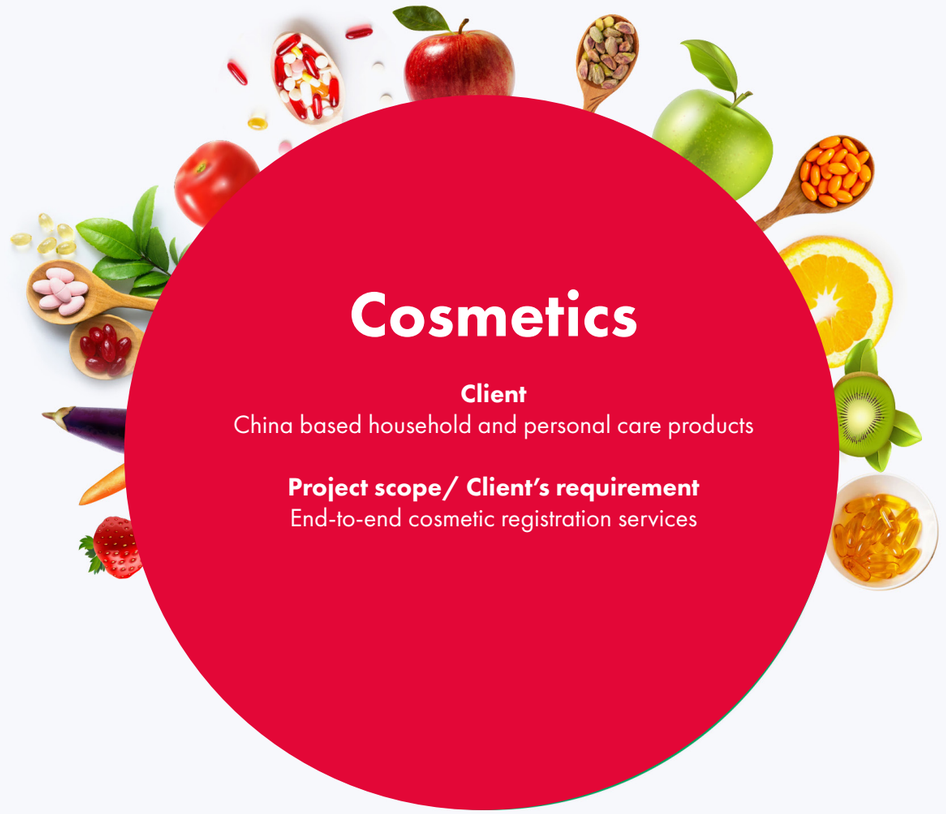
- Required product compliance services for India.
- Product classification, ingredient analysis, labels and claims compliance with Indian FSSAI regulations.

Freyr's Solutions

- Product classification
- Product compliance
- Ingredient assessment
- Label assessment
- Claims review

Client Benefits

- Provided high-level strategic conclusion where client can reformulate the products as per Freyr's suggestion or proceed with registering their products as drugs with CDSCO as their products are exceeding the RDA.



Cosmetics

Client
China based household and personal care products

Project scope/ Client's requirement
End-to-end cosmetic registration services

Business Challenges

- Most labels on the claim were unacceptable and thus, were rephrased.
- Document provided were not compliant and thus, were reformatted.
- Labels were non-compliant and hence, were updated from the core.

Freyr Solutions and Services

- Labels were assessed for label compliance and formulation compliance.
- A detailed report for label assessment, claims review and formulation assessment was provided for individual product.

Client Benefits

- Client incorporated all the suggested claims and change in product identity.
- End-to-end cosmetic services were provided for all the cosmetic products in all three regions as per country-specific regulations.

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

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

www.freyrsolutions.com.mx

+ 1 908 483 7958

sales@freyrsolutions.com

www.freyrsolutions.com

/company/freyrsolutions

/Freyrsolutions

/Freyrsolutions

/user/FreyrInc

/freyrsolutions