freyr™

YOUR **REGULATORY** PARTNER IN **Brazil**

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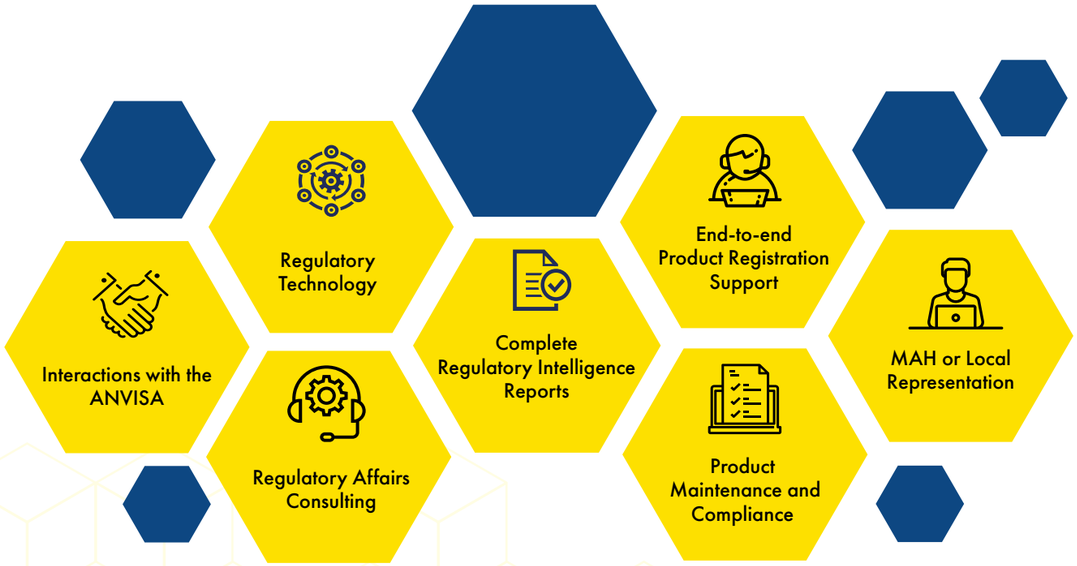
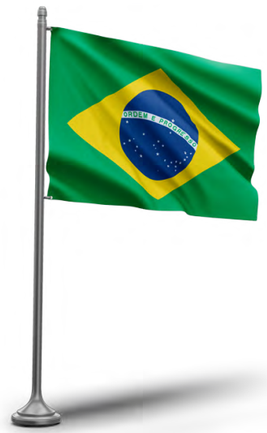
FREYR FOR BRAZIL

Brazil is Latin America's (LATAM's) largest pharmaceutical market and offers significant opportunities for investments in pharmaceuticals and medical technology. As both domestic and multinational enterprises play an important role in meeting the medicinal demands in the nation, the government is keen on standardizing the regulations. This keeps the nature of Regulatory requirements in Brazil highly dynamic.

ANVISA (Agência Nacional de Vigilância Sanitária), the Regulatory Authority responsible in Brazil, is constantly evolving, and it's prime to always keep up with the process changes. Entering the Brazilian market may pose significant challenges, from finding the authorized representatives, ANVISA applications, and submission approvals to time-bound license maintenance. Freyr provides Regulatory solutions to aid global clients in making informed decisions coupled with a sound assessment of the market for their product launch. Our on-ground Regulatory team identifies, evaluates, and responds to current Regulatory updates and develops critical risk mitigation plans. Following are some essential Regulatory services:



Our **Brazilian Regulatory Experts** are **Experienced** in



INDUSTRY CHALLENGES

- Ever-changing Stringent Regulations
- Highly Price-Controlled Market
- High Competition Between Generic Players
- High Product Development Costs
- Complex Regulatory Submissions and Strict Deadlines
- Heavy Investment in Acquiring Skilled Workforce
- Language Barrier

FREYR EXPERTISE

1. End-To-End Product Registration Support
2. Authorized Local Representation
3. Product Classification Services as per the ANVISA
4. Authoring, Reviewing, and Submitting Dossier to the ANVISA
5. Preparing Gap Analysis Reports and Remediation Plan
6. Strategic Guidance During Product Development and Regulatory Affairs Support
7. ANVISA Site Registration Support
8. Import and Export Licence 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 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™

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™

It is a robust platform to create, validate, store, and submit complex content structures aligning with SPL and SPM standards control vocabularies and company and 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 best practices by bridging the gaps within the global and regional labeling processes and to controlling the flow of labeling information.

Freyr & the Brazilian

SUCCESS STORIES

Medicinal Products

Client
A Germany-Based Multinational Pharmaceutical Company

Client Requirement
Topical product-Brazil switch application

Buisness Challenges

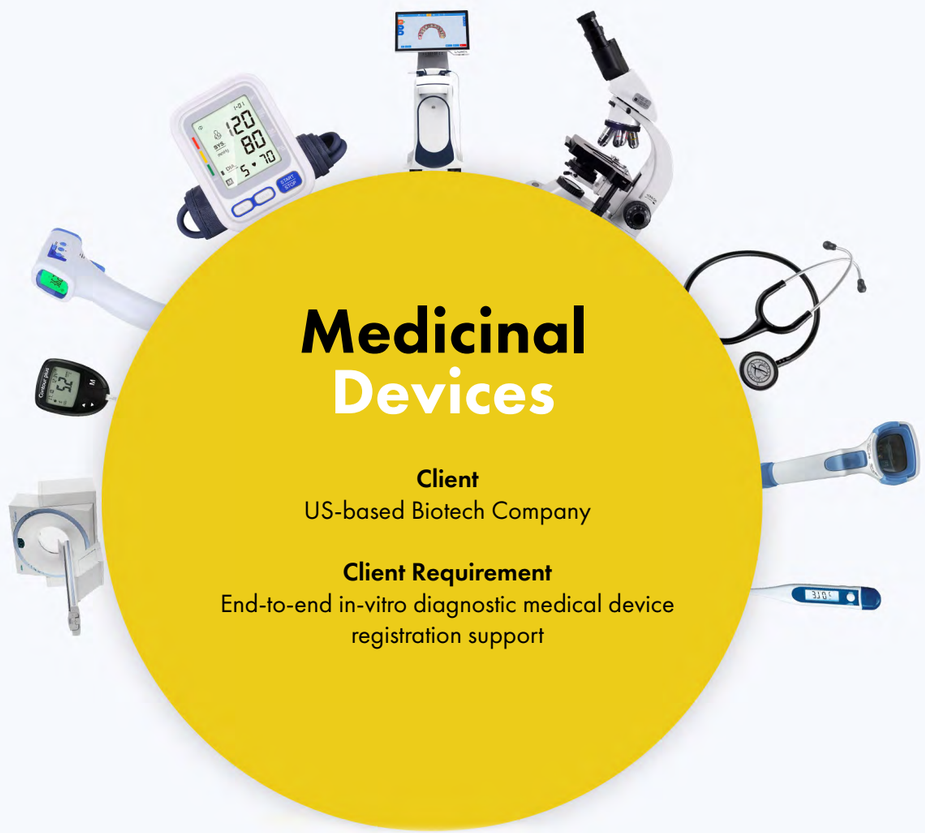
- Gap analysis and Regulatory intelligence
- Compilation and dossier submission to ANVISA
- Stringent Regulatory requirements for labeling

Freyr's Solutions

- Documents prepartion and compilation
- Authoring, reviewing and submission of dossier
- Safety data evaluation
- Labeling evaluation as per ANVISA
- Response to HA queries with proper justification and documentation

Client Benefits

- Effective pre-assesment of the application
- Timely dossier prepartion and submission to ANVISA
- Meeting complex product labeling requirements for OTC product as per ANVISA
- Post-submission follow-up and HA queries resolution



Medicinal Devices

Client
US-based Biotech Company

Client Requirement
End-to-end in-vitro diagnostic medical device registration support

Buisness Challenges

- Evaluation of vendors for product registration support in Brazil
- Selection of local representative for marketing authorization approval of medical device
- Overcoming complex Regulatory guidlines of ANVISA
- Documents translation in Portugese

Freyr's Solutions

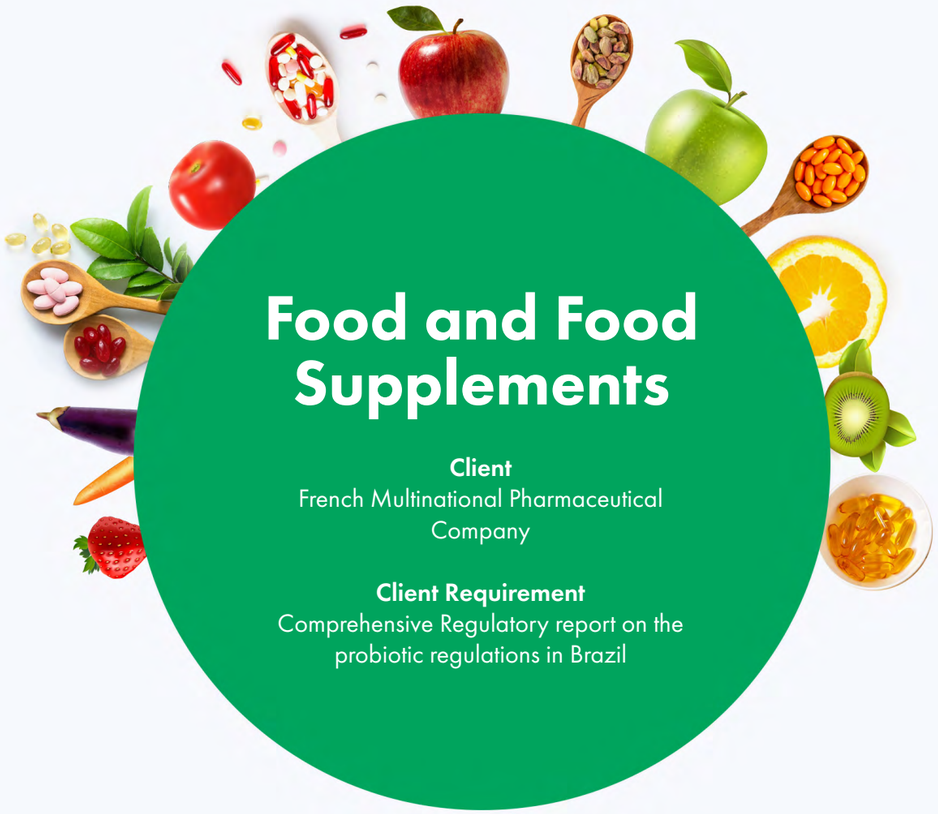
- Classification of product as per ANVISA
- Gap identification in existing QMS and meeting BGMP requirements
- Authoring, reviewing and submission of dossier and response to HA queries
- Supported with local represtative services
- Translation services of documents in Portugese language

Client Benefits

- Timely compilation and submission of technical dossier along with label and the legal documents
- Right classification and Regulatory process provided to timely registration of the product
- Post-submission follow-up and HA queries resolution with proper justification and necessary documentation

Freyr & the Brazilian

SUCCESS STORIES



Food and Food Supplements

Client
French Multinational Pharmaceutical Company

Client Requirement
Comprehensive Regulatory report on the probiotic regulations in Brazil

Buisness Challenges

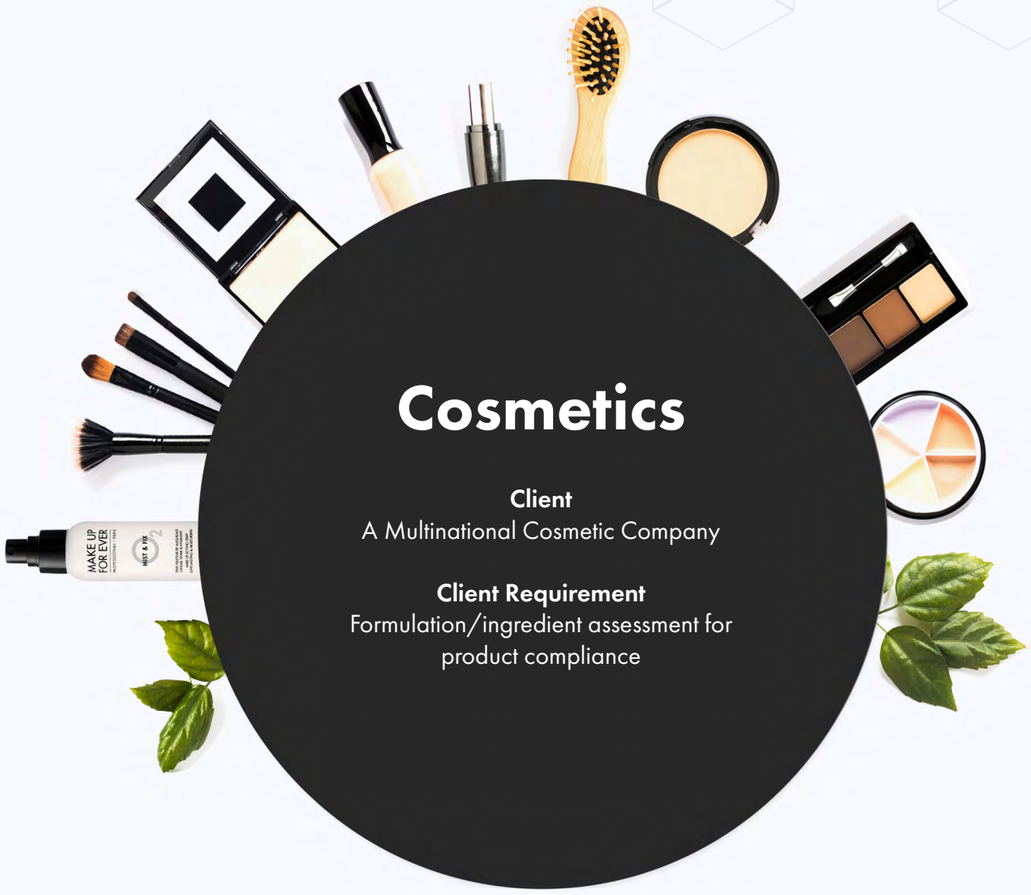
- Comprehensive Regulatory intelligence report
- Technical documentation
- Import requirements
- Labeling requirements
- Regulations for ingredients limits and clamis approval process

Freyr's Solutions

- Comprehensive Regulatory report for probiotics including but not limited to classification, product registration, import requirements, labeling requirements, ingredients and limits, permitted claims, new claim approval process, etc.

Client Benefits

- Enabled client to make an informed decision for entering the market by providing the comprehensive report of Regulatory requirements
- Helped them obtain more clarity on probiotic regulations as to what can be used in the formulations as per respective country regulations



Cosmetics

Client
A Multinational Cosmetic Company

Client Requirement
Formulation/ingredient assessment for product compliance

Buisness Challenges

- Assesment, review, and approval of raw materials under the "Guidelines and Restrictions (GnR) for their skin care, baby care, wound care, and oral care products
- Identifying gaps in the process, control requirements and documenting 'ToBe' processes

Freyr's Solutions

- Highly rational and technically sound review of the raw materials of the client's products
- Assessement of various products of the client for raw materials and their limits as per Regulatory guidelines
- Identifying gaps in the process, control requirement and documenting 'To-Be' processes

Client Benefits

- Freyr's Regulatory experts followed up with suppliers/vendors for the required documents as per HA regulations
- Compiled supplier/vendor Regulatory data in standard format
- Maintained a raw material database for all the products

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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