freyr™

REGULATORY LANDSCAPE IN INDIA

Medical Devices

Medical Products

Comestics

Food Supplements

company / freyrsolutions

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Freyr for India

The life sciences industry in India has recorded rapid growth over the past three (03) decades and continues to move towards a promising future. The total market size of the Indian pharmaceutical Industry is expected to reach USD 130 billion by 2030. One of the main reasons for the expansion of the industry is Regulatory reforms. The availability of affordable drugs and highly qualified manpower in India has led to a lot of manufacturing units shifting their bases here.

India has the largest number of United States Food and Drug Administration (USFDA)-approved pharmaceutical manufacturing sites outside the US. In recent years, the Regulatory process in the country has become much more structured and stringent, involving separate regulations for various categories of products. Companies often face challenges in comprehending region-specific Regulatory requirements and staying compliant with the latest norms. In the face of such challenges, a foreign company with no local presence must have an authorized agent in place.

Freyr's strong network of local authorized agents and a qualified team of experts supports companies with streamlined and flexible solutions for product registration throughout the product life cycle.

Freyr offers Regulatory Intelligence (RI) solutions to help clients make informed decisions about their products and carry out proper assessments of the market at the time of product launch.

Freyr's Regulatory team identifies, analyzes, and reacts to real-time Regulatory changes and formulates essential mitigation strategies for upcoming risks.

KEY
REGULATORY SERVICES OFFERED

1. Interactions with the Central Drugs Standard Control Organization (CDSCO)
2. New product application
3. Marketing Authorization Holder (MAH)/Local Representation (LR)
4. Tailored RI (CDSCO)
5. Product maintenance and compliance
6. Flexible Regulatory teams

Industry
Challenges

Stringent and ever-evolving regulations.

Increasing competition among companies to provide affordable products.

Heavy investment in acquiring a skilled workforce.

Lack of supply chain visibility.

Complex market intelligence.

FREYR
EXPERTISE

1. End-to-end registration support.
2. Authorized local agent support.
3. Marketing Authorization Application (MAA).
4. Support with manufacturing site approval.
5. Support with import registration.
6. Support with sample import license.
7. Regulatory Affairs (RA) consulting.
8. Gap analysis of dossiers as per the CDSCO's Regulatory requirements.
9. Preparation of the gap analysis report and the remediation plan.
10. Preparation and submission of the pharmaceutical dossier to the CDSCO.
11. Query support management till approval.
12. Pharmaceutical artwork management.
13. Pharmaceutical market access strategy.
14. Artwork pharmaceutical packaging.
15. Pharmaceutical Life Cycle Management (LCM) support.
16. Ad hoc Regulatory consultation.

FREYR DIGITAL

Freyr SUBMIT PRO

Freyr SUBMIT PRO is a smart electronic Common Technical Document (eCTD) software used for the creation, validation, publishing, reviewing, and reporting of Regulatory documentation; its main purpose is to streamline electronic submissions.

Freyr IMPACT

Freyr IMPACT is an innovative RI platform offering a complete spectrum of RI services, including detailed and customized insights into various product and regulation categories. Freyr IMPACT gathers and examines publicly available Regulatory information. This includes monitoring current regulations, guidance documents, policies, and legislations, and communicating the same using a systematic approach.

Freyr rDMS

Freyr rDMS is 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

Freyr iREADY is an ingredient database platform that enables manufacturers and brand owners to understand the ever-evolving regulations for ingredients across the globe. It supports proactive observance of Regulatory compliance and management of product formulae in different markets.

Freyr SPAR is a Regulatory Information Management (RIM) solution that enables life sciences organizations to effectively manage data and generate statistical reports, from tracking product registration and marketing authorization life cycle, up to Regulatory document management and Health Authority (HA) interactions and correspondences.

Freyr SPL-SPM is a software and a robust platform used to create, validate, store, and submit complex content structures that align with control vocabularies adhering to SPL and SPM standards and company and product information. The Freyr SPL-SPM software is compliant with the Code of Federal Regulations (CFR) Part 11 Criteria and the Health Level Seven (HL7) standards.

Freyr LABEL 360 is a comprehensive label LCM 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 the industry's best practices by bridging the gaps between global and regional labeling processes and to control the flow of labeling information.

Freyr and the

Indian Success Stories

Medicinal Products

Client

An India-based Active Pharmaceutical Ingredients (API) manufacturer.

Project Scope/Client Requirement

Preparation of cover letters for Active Substance Master File (ASMF) for European Union (EU) countries.

Buisness Challenges

- Lack of understanding of the formats for requirements w.r.t EU requirements/Guidelines.

Freyr's Solutions

- Prepared the cover letters and shared with client for signature.
- After receiving the signed documents from client, published ASMF annual reports in eCTD format and uploaded through CESP within agreed timelines.

Client Benefits

- Preparation of cover letters and necessary guidance provided for completion of ASMF.
- ASMF publishing activity completed on time and submitted to health authority.

Freyr and the

Indian Success Stories

Medicinal Devices

Client

Large-sized manufacturer of dental products, with presence in multiple nations.

Project Scope/Client Requirement

Grouping of devices in scope and end-to-end Regulatory services for obtaining import license.

Buisness Challenges

- The client was not aware of the target market requirements.
- The devices in scope was a mix of diversified device categories falling into different regulations and had to follow different pathways.

Freyr's Solutions

- Freyr performed classification, variation grouping, technical evaluation of document and gap analysis with suggested remediation for identified gaps.
- Freyr acted as an Indian Authorized Agent (IAA) and supported for all the Regulatory requirements

Client Benefits

- Detailed understanding of medical devices regulatios in India.
- Timely and accurate classification, grouping and registration of different devices which led to cost optimization.
- Techinical document evaluation support.

Freyr and the

Indian Success Stories

Food and Food Supplements

Client

China-based manufacturer of a gastrointestinal capsule.

Project Scope/Client Requirement

Product compliance, ingredient analysis, and label and claims review.

Buisness Challenges

- One of the Chinese manufacturer of a gastrointestinal capsule wanted to know if they can ship their capsule to India and required product compilance services in India.

Freyr's Solutions

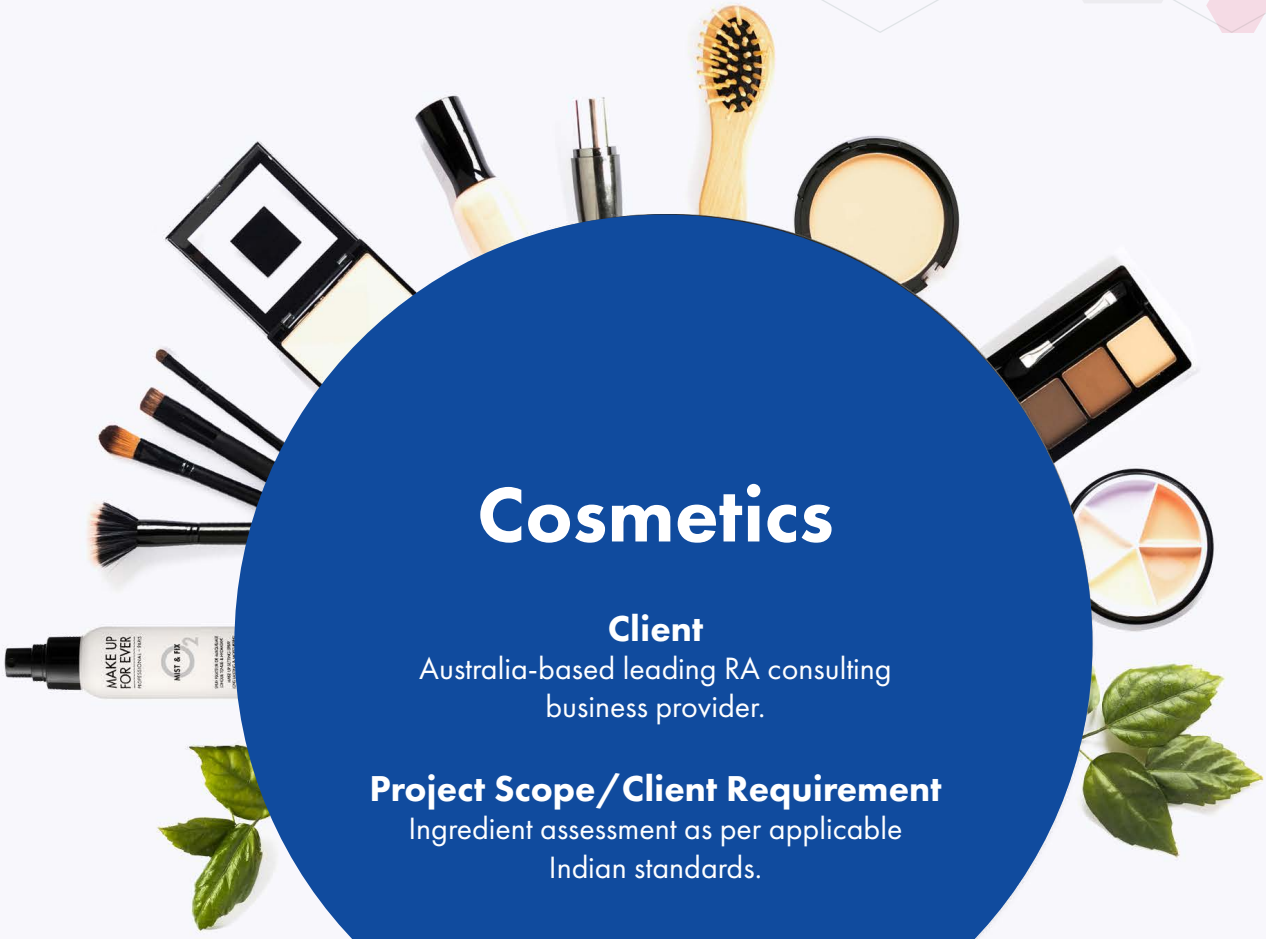
- Product classification
- Formula review
- Complete Product compliance
- Label assessment
- Claims review

Client Benefits

- Due to the expertise of Freyr SME, the product was categorized into the appropriate category and it was also ensured that critical purity parameters for nutraceuticals as laid down by FSSAI are met along with sufficient documentation that should be available with client.

Freyr and the

Indian Success Stories



Cosmetics

Client

Australia-based leading RA consulting business provider.

Project Scope/Client Requirement

Ingredient assessment as per applicable Indian standards.

Buisness Challenges

- The client was not aware of the underlying comestic regulations but considering the huge market potential, the company was keen to launch its prodcuts in India.

Freyr's Solutions

- Freyr suggested the changes with respect to the acceptable CAS numbers and safety levels of the ingredients to be used in the hair cleansers as per the Indian standards.
- Freyr was able to provide the complete approval status of each ingredient

Client Benefits

- With Freyr's assistance, the client was able to identify the Regulatory status of around one hundered (100) ingredients and also assisted the client by adjusting the formulation as per the restrictions to make the formulation compliant as per Indian standards.

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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