freyr®

celebrating a decade of success!

ONE OF THE LARGEST, GLOBAL,

REGULATORY-FOCUSED SOLUTIONS AND SERVICES COMPANIES

OVERVIEW

Freyr is a leading Regulatory solutions & services company with an exclusive focus on the end-to-end Regulatory value chain of Pharmaceuticals (Innovators / Generics), Consumer Healthcare and Medical Device companies, globally. Headquartered in New Jersey, US, and with exclusive delivery centers dotted across the UK, USA, Canada, Germany, UAE, Mexico, Singapore, Malaysia, South Africa, Slovenia, Srilanka, Australia, Poland, France, Switzerland, China, Japan & India; Freyr caters to over 1000+ consumers globally. Freyr has been diligent in delivering excellence to its clients since its inception. Freyr believes in proactive contribution towards clients' Regulatory requirements to enable them build a credibility among industry peers. Freyr is certified with ISO 9001 and 27001.

YOUR GLOBAL STRATEGIC REGULATORY PARTNER

1300+
Strong Global Regulatory Team

1000+
Global Consumer and Growing

120+
Countries Global Affiliate Network

1400+
Global Brands/Products Supported Across Markets Worldwide

QUICK FACTS

320+ Consumer Companies (Cosmetics / Food and Food Supplements / Chemicals)

08 Forbes Global Top 10 Drugs & Biotechnology Companies

180+ Generic Companies / API Manufacturers

04 Forbes Global Top 10 Health Care Equipment & Services

125+ CROs / Consulting Companies

03 Forbes Global Top 10 Household & Personal Product Companies

120+ Innovator Pharma Companies

02 Forbes Global Top 10 Chemicals Companies

230+ Medical Device Companies

02 Forbes Global Top 10 Food & Drink Companies

50+ Bio-Tech / Bio-Similar Companies

INDUSTRIES

Radically redefining the global Regulatory solutions and services landscape for Pharmaceuticals (Innovators / Generics), Consumer Healthcare and Medical Device companies.

Center of Excellence
Global Pharmaceutical Regulatory Services

Center of Excellence
Global Consumer Healthcare Regulatory Services

Center of Excellence
Global Generics Regulatory Services

Center of Excellence
Global Cosmetics Regulatory Services

Center of Excellence
Global Medical Device Regulatory Services

Center of Excellence
Global Food and Food Supplements Regulatory Services

Center of Excellence
Global Biologics Regulatory Services

Center of Excellence
Global OTC Healthcare Regulatory Services

Center of Excellence
Chemicals Safety and Regulatory Affairs

Center of Excellence
Global Innovator Drugs Regulatory Services

FREYR REGULATORY CENTERS OF EXCELLENCE

Center of Excellence Publishing & Submissions

- Submission Publishing & Management (Electronic, Paper, eCTD, NeeS)
- Submissions Document Development and Publishing
- Dossier Compilation
- PMO & QC Services
- XML Validation, Metdata Verification

Center of Excellence Regulatory Medical Writing

- Clinical/Non-clinical Overviews
- Clinical Study Reports
- Clinical Protocols
- Investigator's Brochure
- Medical Expert Review
- Publication Writing

Center of Excellence Regulatory Labeling

- Global Labeling Management
  - CCDS/CCSI
  - Tracking and Compliance
- Regional Labeling Management
  - Regional Prescribing Information (RPI) & Patient Information Leaflet (PIL)
  - Core to Local Label Alignment
  - Deviation Management and HA Query Management

Center of Excellence Regulatory Intelligence

- Primary and Secondary Regulatory Intelligence
- New Product Development & Launch Strategy
- New Market and Geography Strategy
- Actionable Interpretation & Analysis
- Data Driven, Technology Enabled Decision Support

Center of Excellence Pharmacovigilance

- Pharmacovigilance Database, System Setup and Strategic Services
- Aggregate Report Services/Periodic Safety Report Services
- ICSR services
- Signal detection

Center of Excellence Regulatory Strategy

- Product Market Regulatory Pathway Strategy
- Evaluation of Regulatory Impact to Products regarding Safety
- Verification of Trade Name, Manufacture INCI(s),
- Evaluation of Potential Impact of New Guideline

FREYR REGULATORY ARTWORK SERVICES

- Artwork Process Consulting & Lifecycle Coordination
- World-class Design Studio
- Content to Carton Capabilities
- Artwork Staffing Management
- Dedicated Artwork Support for Life Sciences Industries

Center of Excellence Global Consumer Healthcare Regulatory Services

- Product Registration and Notification
- Ingredient Review
- Pre-formulation Assessment
- Safety Assessment
- Claims and Substantiation

Center of Excellence Regulatory Affairs

- New Product Authorizations - Finished Products
- New Market Authorizations - APIs
- Post Approval - CMC and Life Cycle Management
- Regulatory Assessment / Gap Analysis
- Regulatory Consulting and Strategy
- Health Authority Queries - Response / Interactions

Center of Excellence Regulatory Contract Staffing

- 700+ Qualified Regulatory Professionals
- Exposure to All Life Sciences Industries
- Expertise in End-to-End Regulatory Functions
- Resource Deployment Across the Globe

Center of Excellence Compliance, Audit and Validation

- End-to-end Training Process, Training Automation, Training System Validation
- GDP, GAMP
- End-to-end Validation
- Audit and Compliance Services
- CSV, GxP, ERES and HIPAA

freyrX Go Global

- Strategic And Tactical Regulatory Support
- Expert Consultant Network In Over 120+ Countries
- Localized Regional Services
- Centralized Project Management

FREYR REGULATORY SOFTWARE SOLUTIONS

Freyr SUBMIT PRO

Freyr SUBMIT PRO is a smart eCTD software for the creation, validation, publishing, viewing, and reporting of Regulatory documentation to streamline electronic submissions.

Freyr rDMS

Freyr rDMS is 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 compliant, efficient and intuitive manner.

Freyr iREADY

Freyr iREADY is an ingredient 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 IMPACT

Freyr IMPACT is 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 analyzes publicly available Regulatory information. This includes monitoring the current regulations, guidance documents, policies and legislation and communicating the same using a systematic approach.

Freyr SPAR

Freyr SPAR is a Regulatory Information Management (RIM) solution that enables life science organizations to effectively manage the data and to generate statistical reports; right from tracking product registrations, marketing authorization life cycles, Regulatory document management and Health Authority interactions and correspondence.

Freyr LABEL360

Freyr LABEL 360 is a comprehensive label life cycle management tool through which companies can manage the 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 to control the flow of labeling information.

Freyr IDMP

Freyr IDMP 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 SPL-SPM

Freyr SPL-SPM software is a robust platform to create, validate, store and submit complex content structures aligning with SPL and SPM standard control vocabularies and company & product information. Freyr SPL-SPM software is compliant with 21 CFR Part 11 criteria and Health Level Seven (HL7) standard.

Freyr IDENTITY

Freyr IDENTITY leverages the Plan, Process and Training methodology to offer an end-to-end UDI compliance solution. Suitable for a company of any size with any 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 the FDA regulated UDI mandates.

Freyr XEVMPD

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

FREYR
AWARDS & RECOGNITIONS

ELEMED Featured Freyr as the “Best Supplier to the Industry”

GHP Awards 2021 Honored Freyr for ‘Innovative Global Regulatory Services and Solutions for Life Sciences’

AI Awards 2019 has recognized Freyr As the ‘Best Labeling and Artwork Solutions and Services Provider - Lifesciences 2019’

USA-9 Technology Magazine Listed Freyr in the “10 Best Technology Solution Providers of 2021”

Freyr Has Been Recognized As One of The 10 Most Innovative Pharma & Life Sciences Solutions Providers 2019

Excellence in Pharma Regulatory Procedures & Compliance Award 2018

Sunitha Anumula: Driving Strategic Business Opportunities with Advanced Regulatory Solutions

Freyr Bagged the Excellence Award At the GHP International Life Sciences Awards 2018

Freyr Wins The Best Pharma Contract Services Award at the 2018 IAE

Freyr Receives ACQ5 Gamechangers 2021 Awards In Three Niche Categories

Freyr Listed in Top 20 Most Promising Pharma and Lifesciences Tech Solutions Providers List - 2017

Freyr Bags ‘2016 India Knowledge Process Services for Pharmaceutical Life Sciences Growth Excellence Award’

About Freyr

Freyr is a leading, niche, end-to-end global Regulatory solutions and services company supporting large, mid, and small global organizations across different life sciences verticals - Pharmaceuticals | Medical Devices | Biotechnology | Biosimilars | Consumer Healthcare | Cosmetics | Food and Food Supplements | Generics | Chemicals. Freyr supports life sciences organizations in their entire Regulatory value chain-Intelligence Driven Submissions/Product Registrations | Labeling | Artwork | Post-Approval Change Management | Regulatory Software and other related services.

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

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

+1 908 483 7958

sales@freyrsolutions.com

www.freyrsolutions.com

/company/freyrsolutions

/Freyrsolutions

/Freyrsolutions

/user/FreyrInc

/freyrsolutions