freyr

GLOBAL REGULATORY SOLUTIONS & SERVICES

AN ISO 9001 & 27001 COMPANY

Radically Redefining the Global Regulatory Solutions and Services

A Fast-Growing, End-to-End, Regulatory Solutions & Services Partner for Global Top 20 and Fast Growing Small/Medium Life Sciences Companies

Freyr is a leading global Regulatory consulting services and solutions provider with an exclusive focus on entire Regulatory value-chain of Global Life Sciences industry. Freyr, with a deeper understanding of regional/local Regulatory requirements of 120+ countries, caters specialized Regulatory services to over 60+ clients across the globe availing support from rapidly growing 400+ Regulatory experts virtually situated in the US, UK, Germany and India. Freyr is a certified member of NASSCOMM and is ISO 9001 and 270001 certified. Freyr has been diligent in delivering excellence to its clients since its inception and strongly believes in highly attentive customer service. The philosophy has consistently helped Freyr build a credibility among the industry peers.

Your Global Strategic Regulatory Partner

400+
Strong Global Regulatory Team

60+
Global Brands/Products Supported across Markets Worldwide in 12 months

120+
Countries Covered Through Global Affiliate Network

Quick Facts

- Headquartered in New Jersey, USA.
- A Global Regulatory Operations & Development Center in Hyderabad, India, Asia's leading bio-tech hub
- Rapidly growing, strong 400+ team of Regulatory, scientific, technology and consulting professionals
- Multi-year, successful engagements with Top 20 global brands for 6 of the Forbes* Global Top 10 Fortune 500 Healthcare / Life Sciences, Mid-market $1+ Billion Bio Pharma, and several Small-Medium, Fast Growing Life Sciences companies, CROs and Standards agencies
- Management team with a rich background and global experience in Regulatory, life sciences, business operations, and information technology, driving global vision and innovation
- Strong Process and Quality Management System – ISO 9001 Certified. State-of-the-art Infrastructure with ISO 27001 Certified Information Security Management, and Robust BCP & DR site. Freyr is a Certified NASSCOM member.
- Management focus to embrace and seriously contribute to going green and in Corporate Social Responsibility initiatives

Freyr Regulatory Solutions & Services Portfolio

Regulatory Submissions & Publishing Services

Regulatory Affairs & Operations

Regulatory Intelligence Services

Regulatory Labeling & Artwork Services

Regulatory Outsourcing Services

Regulatory Strategy & Business Consulting

Regulatory Information Management

Health Authority Directives

Freyr Regulatory Competencies

Regulatory Operations

- Submission Publishing & Management (Electronic, Paper, eCTD, NeeS)
- Regulatory Dossier Life Cycle Management
- Labeling & Artwork Management
- CCDS | Clinical Trial Applications | SPL Submissions
- Regulatory Data and Document Management
- Medical Translation Services

Regulatory Software

- FREYR SOFTWARE: LABEL | SUBMIT | IDENTITY | INSIGHTS | eTMF | IDMP | rDMS
- THIRD PARTY SOFTWARE: Aris Register, Open Text, Documentum, Liquent Insight Publisher, Lorenz Docubridge, ISI Publisher, eCTD Express, etc..

Regulatory Strategy & Business Consulting

- Regulatory Business Strategy & Consulting
- Regulatory Centralization
- Regulatory Process Standardization
- Regulatory Product & Market Strategy
- Regulatory Pathways

Regulatory Labeling & Artwork

- Company Core Data Sheet (CDS) / Local Product Labels – Authoring
- CDS Content & Process Management
- Clinical and Non-Clinical Overviews
- Artwork Services & Proof Reading
- Manuscript Development

Freyr X

- Strategic and tactical regulatory support
- Expert consultant network in over 120 countries
- Localized, regional services
- Centralized project management
- Integrated within Freyr systems

Regulatory Writing & Safety Services

- Clinical Documents (Clinical Overview, CSR, Protocols, IB etc.)
- PV (PSUR, PBRER etc..)
- Medical Information (Publications, Claims Justifications..)
- Case Processing, REMS, Safety IT, PV Program Management

Legacy Products : Lifecycle Management

- End to End Product Lifecycle Management
- New market registrations,
- MAA renewals, transfers
- Site transfers, CMC variations, publishing
- Label & Artwork change management & deviations
- Regional support, submissions

Regulatory Information Management & IDMP

- Product Registration Management
- Quality Data Management
- Submissions Data Management
- Product Classifications
- IDMP – Strategy, Data Management, Data Governance & IDMP Software

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

Regulatory Affairs

- New Product Introductions & Rollouts
- CMC Support and Change Control
- Gap Analysis, MAA, Post Approval Changes
- Global MA License Renewals
- Variations Dossier Preparation & HA Responses
- Quality& Proof reading
- Clinical and non clinical summaries and overviews
- Clinical trial documents

Freyr Regulatory Centers of Excellence

CoE / SERVICES	SOFTWARE SOLUTIONS	CONSULTING SERVICES	OPERATIONAL SERVICES	RESOURCE FULFILMENT
DOSSIER 360	√	√	√	√
SUBMISSIONS 360	√	√	√	√
LABEL 360	√	√	√	√
ARTWORK 360	√	√	√	√
IDMP 360	√	√	√	√
CONTENT 360	√	√	√	√
INTELLIGENCE 360	√	√	√	√
STRATEGY 360	√	√	√	√
PV 360	√	√	√	√
COMPLIANCE 360	√	√	√	√
TECHNOLOGY 360	√	√	√	√
CMC 360	√	√	√	√
LEGACY PRODUCT MANAGEMENT	√	√	√	√
CONSUMER 360	√	√	√	√
STAFF AUGMENTATION	√	√	√	√

Freyr Regulatory Software Solutions

Freyr SUBMIT

A specialized Submission Solution - multi-country compliant

A smart eCTD software product for the creation, validation, publishing, viewing and reporting of Regulatory documentation for electronic submissions by pharmaceutical companies to regulatory authorities.

Freyr eTMF

Perfect for small & medium trials to efficiently manage audit-ready eTMF documents for end-to-end compliance

A secure cloud-hosted, pay-as-you-go solution to efficiently manage costly, complex and global clinical trial data across the Lifecycle.

Freyr INSIGHTS

Proactive, comprehensive solution to track and analyse Regulatory compliance changes

An innovative Regulatory Intelligence Enterprise Platform solution offering a complete spectrum of Regulatory intelligence services across comprehensive Product and Regulation categories to provide detailed and customized insights.

Freyr IDENTITY

Accurate, efficient, faster UDI compliance

An end-to-end UDI compliance solution suitable for a company of any size with any number of devices 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 rDMS

Efficiently manage document Lifecycle from inception, collaboration and authoring to submission and archiving of Regulatory documents

An end-to-end electronic Regulatory Document Management solution exclusively designed to enable to seamlessly create, capture, manage, organize, connect, deliver and archive regulatory data.

Freyr LABEL

A smarter, accurate and compliant way to manage Global Packaging and Labeling content

An end-to-end solution that puts companies in total control of all their Labeling compliance needs, right from tracking and managing CCDS deviations, CCDS updates and development to creating and implementing local labels as well as custom reporting.

Freyr IDMP

Efficiently monitor, track, update and create XML files that are compliant with EMA's IDMP requirements

An intuitive, user-friendly, and on-demand webbased solution with state-of-the-art navigation that supports consolidating, clean-up, updating, authoring, approving, publishing, and archival of information in a standardized and structured format.

Awards & Recognitions

1. **Frost and Sullivan:** Freyr bags "2016 India Knowledge Process Services for Pharmaceutical Life Sciences Growth Excellence Award"
2. Freyr Solutions, Finalists of **CPhI Pharma Awards 2016** Excellence in pharma: Regulatory Procedures and Compliance
3. Freyr makes it to the much coveted **Top 10 Fastest Growing Healthcare Tech Solution/Consulting Companies** 2015 List
4. **Silicon India: Freyr stands as one of the "20 Most Promising Pharma & Life Sciences Solution Providers – 2016"**

Have a business query? Call us today and we'll help you with your regulatory needs.

United States
+1 908 483 7958

United Kingdom
+44 2037 012379

India
+91 40 4848 0999

Germany
+49 6181 707 9007

Follow Us

www.linkedin.com/company/freyr-solutions

www.twitter.com/FreyrSolutions

www.facebook.com/FreyrSolutions

www.plus.google.com/+Freyrsolutions-services

sales@freyrsolutions.com

www.freyrsolutions.com