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GLOBAL REGULATORY
SOLUTIONS & SERVICES
AN ISO 9001 & 27001 COMPANY

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CONNECT

REGULATORY INTELLIGENCE

FROM DATA TO FACT-BASED ANALYSIS AND RICH INSIGHTS.
UNLOCKING SUPERIOR REGULATORY AND
NEW MARKET STRATEGIES

Inside

What's Inside

From the Editor's Desk

Welcome To The New Year Edition Of The Newsletter!

Much has happened since the last newsletter, so we hope you will find this as an useful overview on how far we've come and where we are headed. Freyr Connect's latest edition provides the employees and partners with a concise yet comprehensive picture of all the new updates and developments at Freyr.

What's inside this time! Freyr Connect's issue opens with the lead story **"Regulatory Intelligence: From data to fact-based analysis and rich insights. Unlocking superior regulatory and new market strategies"** followed by exclusive regulatory articles. Be sure to check the issue for a 360⁰ overview of Freyr's growth curve over the last quarter.

Lastly, the editorial team would like to take this opportunity to thank everyone who contributed to this edition of Freyr Connect. Please feel free to bring any comments, suggestions or new stories to our attention for future editions. I hope you find this issue an enjoyable, informative read.

Best Regards,
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Management Speaks

A Happy New Year to You All!

We hope you celebrated the start of 2015 in good spirits with family and friends. As we usher in 2015, we are proud of what we collectively achieved in the last year while significantly transforming our organization to better meet the new emerging opportunities.

2014 was quite a year for all of us at Freyr. We have been through many developments to organize, augment and empower our CoEs and functional leads, through change and transition, to create new opportunities and growth.

We set in motion the expansion plans for augmenting sales and marketing functions to ensure wider market and social brand proliferation for increased opportunities.

We created new services and products to expand our portfolio for an increased competitive advantage. Our strategy has paid off and it's energizing to feel the momentum and enthusiasm building.

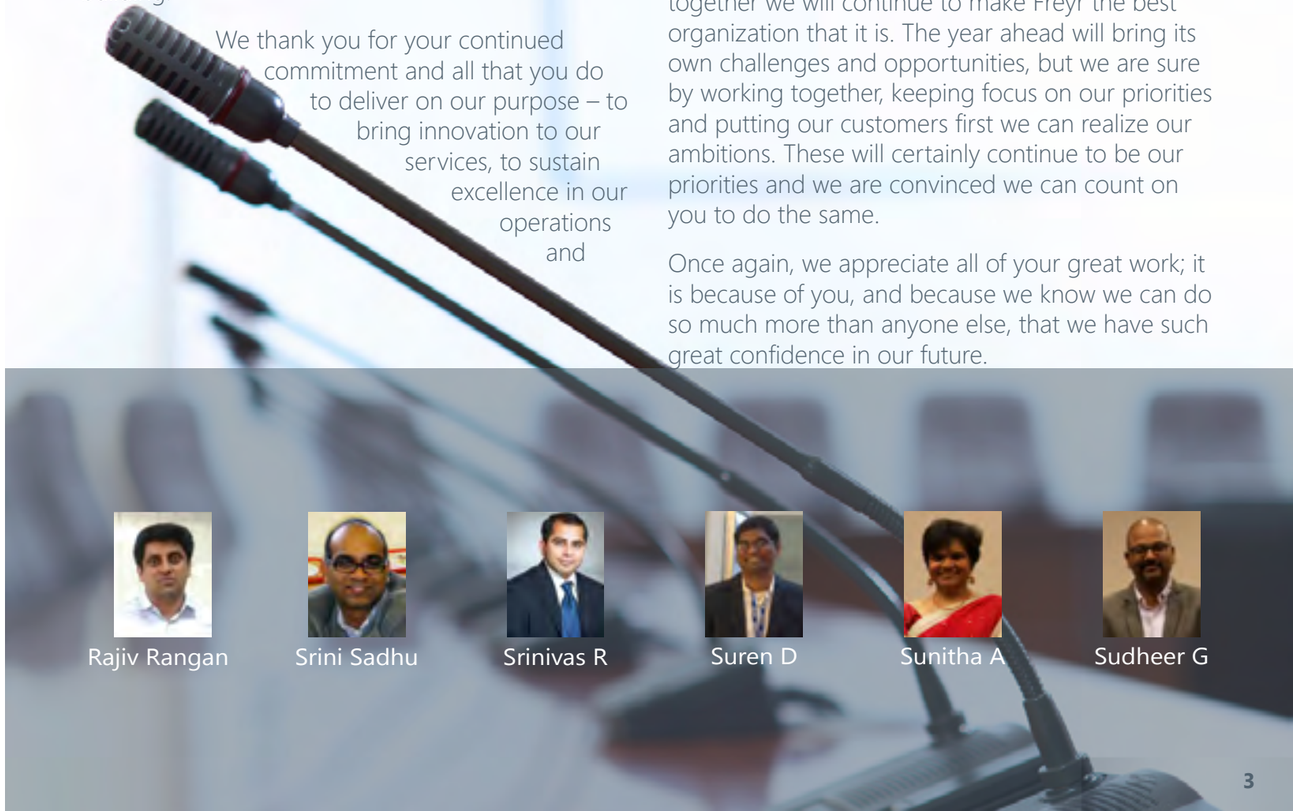
We thank you for your continued commitment and all that you do to deliver on our purpose – to bring innovation to our services, to sustain excellence in our operations and delivery, and to help our customers and clients succeed at every stage of their compliance lifecycle.

Now that we're a few days into the New Year, it's good to look ahead and think about what 2015 may bring us.

We have made huge strides in expanding our work within our customers, implementing best practices in customer reach out programs, operations management and service delivery. We have covered significant ground in achieving our strategic goal of transforming our service offerings into core competencies, and increasing our market share by growing our existing clients and expanding our client rosters. We continue to earn and build on our great reputation as a trusted partner to our customers. And, we want our reputation for excellence to spread to other customers in our domain.

Today we are a stronger, more agile company better organized to serve our customers and clients. We are confident our best years lie ahead of us and that together we will continue to make Freyr the best organization that it is. The year ahead will bring its own challenges and opportunities, but we are sure by working together, keeping focus on our priorities and putting our customers first we can realize our ambitions. These will certainly continue to be our priorities and we are convinced we can count on you to do the same.

Once again, we appreciate all of your great work; it is because of you, and because we know we can do so much more than anyone else, that we have such great confidence in our future.



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LEAD STORY

REGULATORY INTELLIGENCE

FROM DATA TO FACT BASED ANALYSIS AND RICH INSIGHTS. UNLOCKING SUPERIOR REGULATORY AND NEW MARKET STRATEGIES

HISTORY OF REGULATORY INTELLIGENCE (RI)

RI typically is part of a company's global regulatory affairs department and broadens the traditional regulatory affairs function beyond preparing and submitting applications to the FDA and the regulatory agencies of Europe and Asia. The company's leadership is kept informed about current regulations affecting the development, approval and maintenance of products, as well any changes to the regulations and/or regulatory landscape that may impact their efforts.

RI contributes to every pharmaceutical company's bottom line by helping the regulatory affairs teams provide the highest quality submissions to agencies. The company must also understand issues that affect the review of new drug applications in each market in the world apart from regulatory guidance's.

THE REGULATORY ENVIRONMENT

The constant shifts and changes in the regulatory environment requires all the concerned parties/authorities to be abreast of the current information from a variety of sources. Regulatory Affairs professionals can tap industry practices, regulatory agency opinions, competitor information to develop successful regulatory strategies.

REGULATORY INTELLIGENCE (RI)

RI is the act of gathering and analyzing regulatory information for impact or changes in laws, regulations, directives, guidance documents, etc. RI allows a regulatory professional to advise personnel, answer strategic regulatory questions and write or construct a global marketing application in addition, determine requirements for conducting global clinical trials and manufacturing requirements.

RI offers insights on sourcing, filtering, analyzing and applying information to create valuable regulatory intelligence.

Regulatory Intelligence follows a systematic process to streamline the functions within Regulatory Affairs.

HOW DOES REGULATORY INTELLIGENCE WORK FOR YOU?

Before applying for any clinical approvals, the Regulatory Affairs department comes up with a few questions to study the pros and cons of introducing a particular drug/product in different regions and other compliance needs. The research questions are driven by the business needs and linked to decisions and actions. The Regulatory Intelligence process enables flexible research analysis.

It extensively covers the complete product range that includes: *Drugs, Devices, Biologicals, Veterinary Products, Consumer & OTC Products as well as Nutraceuticals*.

The Regulatory information includes: *New Guidelines, Guidelines Amendment, Pharmaceutical Development, Manufacturing, Quality, Clinical & Non Clinical, Stability & Storage, Validation, Packaging & Labeling, Pharmaceutical Excipients, Impurities, Artwork & Promotional Material, Recall Alert, Safety & Pharmacovigilance, Warnings, Submission Formats* and much more.

It is tough for Pharma companies to be cognizant of all existing global regulatory requirements owing to the ever changing worldwide regulations and legislations.

New procedures are always being developed and adopted by regulatory authorities worldwide due to the international harmonization process.

GLOBAL REGULATORY STRATEGY: SIGNIFICANCE

Change in the global landscape can affect the global regulatory strategy as more companies are conducting trials and filing marketing application worldwide.

RI professionals benchmark regulatory developments across different countries, evaluate the adequacy of existing regulatory frameworks in view of latest technological developments or conduct regulatory analysis in the context of due diligence reports.

REGULATORY PRECEDENCE

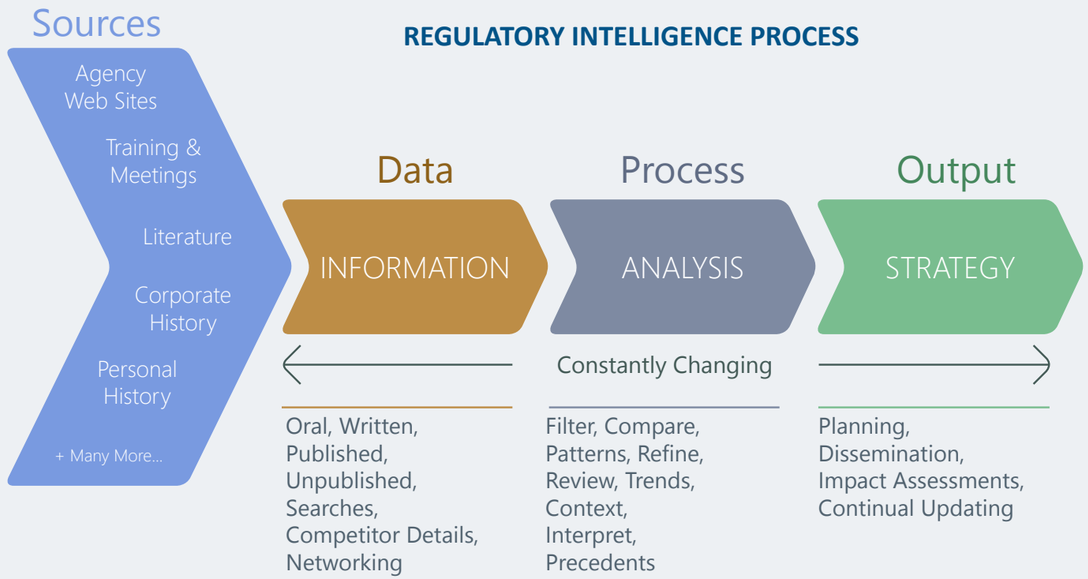
A regulatory strategy can be developed through monitoring and gathering of RI which can result in:

- Reduced time to approval
- Maximization of target markets
- Decreased cost of product development based on current information

SOURCES OF REGULATORY INTELLIGENCE

Regulatory Precedence | Industry Practices | Regulatory Agency Opinions | Agency's Websites | Guidance Documents | E-Mails from Regulatory Websites | Interactions with Agency Reviewers | Warning Letters | Colleagues & Consultants | FOI Requests | Competitor Information | Relevant Journals & Newsletters | Relevant Conferences | Advisory Meetings | Interactions with other Regulatory Professionals

REGULATORY INTELLIGENCE PROCESS



PHARMACEUTICAL COMPANIES AND REGULATORY INTELLIGENCE

New business models including alternative information management platforms are being evaluated by leading pharmaceutical companies to reduce costs, shorten timelines and maintain quality and compliance.

In the current regulatory climate, most of the Pharmaceutical companies are struggling to maintain R&D productivity.

Pharma companies are keen to explore new drug development models which can cut development costs, accelerate timelines and still maintain quality and compliance.

They intend to realize these gains by slowing easing into new business models for data and regulatory management. Innovative information management platforms that can manage the full scope of regulatory and clinical data operations with support across all geographies and regulatory agencies are being explored by pharma companies.

Information management platforms make research data more widely available by standardizing how it is collected formatted and distributed and offer unique perspectives to the investigative process.

Using analytics tools and techniques researchers can provide model outcomes, spot trends and ask the right questions which in turn will help the companies to standardize and optimize processes.

Process reengineering efforts will involve more activity in areas of regulatory, pharmacovigilance and clinical processes. These in turn will be aided by integrated technology and analytics capabilities enabling global regulatory compliance.

The swift turn to modernize their development operations is partly to do away with obsolete models of development in particular, in-house technology solutions that will in turn offset slowing growth rates to achieve bottom line results.

BUSINESS INTELLIGENCE AND PHARMA INDUSTRY

With changing regulations and compliance issues, Pharmaceutical companies simultaneously face the challenges of reducing costs, raising the revenue and operational efficiencies, lower supply chain costs, whilst meeting regulatory and security requirements.

Pharmaceutical companies can strategically make use of business intelligence software to make informed business decisions.

The business intelligence software can analyze, report and monitor vast amounts of data through business intelligence architecture and help companies reduce costs, increase revenue and maximize the value of information.

RI CHALLENGE FOR COMPANIES

Large and mid-tier companies with products in many markets face a definitive challenge in securing authoritative regulatory intelligence from regulatory intelligence groups. Companies presume the regulatory intelligence groups provide an authoritative interpretation of a wide range of national and regional regulations. In addition, the group must also provide an impact assessment of proposed regulatory changes in many more markets.

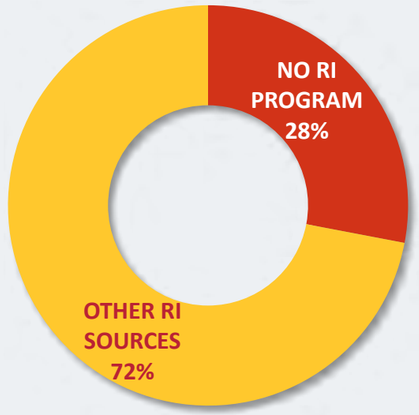
RI GROUPS: PAIN POINTS

In a 2014 survey about centralized RI programs, respondents placed high value but low satisfaction on the products of the RI group.

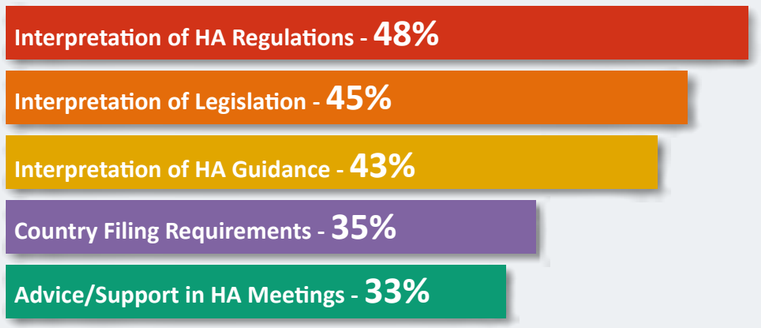
- The central RI program is usually located at the company headquarters and is managed by a relatively small staff
- Work of the central RI group is often relatively broadly coupled with the critical mission tasks
- Rising requirements for information and audits by Health Authorities
- 67% of the companies established a centralized regulatory intelligence office/ program
- A quarter responded “yes” when asked if the centralized RI program is viewed as the authoritative source for *hard and soft intelligence services

REASONS FOR LESSER COMPANIES REPORTING RI GROUP AS THE AUTHORITATIVE SOURCE

- Use other internal experts to produce a complete analysis on regulations or guidance
- Some stakeholders rely on internal networks and external sources to develop an opinion and action plan to meet new regulatory requirements



PRIME NEEDS FOR AN AUTHORITATIVE SOURCE



*Hard and soft intelligence services include core RI services like interpretation of laws, HA regulations and guidance.

COMPANIES ARE PLANNING A CHANGE IN

PROCESS	REGULATORY INFORMATION MANAGEMENT TOOLS	ROLES & RESPONSIBILITIES
Improve internal communication among - central group, regulatory affiliates and functional areas	Improve information access through portals, knowledge management systems and external tools	Organizational changes -To identify and improve delivery to increase stakeholder satisfaction

REGULATORY INTELLIGENCE LONG TERM STRATEGIC BENEFITS

- Monitors regulatory environment and ensures compliance
- Saves time and money through real-time intelligence gathering, analysis and dissemination
- Avoids risk of duplication and redundancies
- Addresses global language barrier with instant access to essential details in English
- Ensures accuracy of critical information obtained from distributors, manufacturers and other industry contacts
- Maintains knowledge data bank by retaining and constantly adding to the regulatory knowledge within the company
- Supports in creating a robust regulatory policy
- Reviews and helps update the old data with current regulatory trends
- Advises workforce of various newly evolving regulatory disciplines
- Provides detailed and customized insights for advance search
- Provides centralized and structured information management system

IN CONCLUSION

All companies perform regulatory intelligence to some extent and more companies are establishing dedicated intelligence groups.

Regulatory intelligence scope does vary in form of active analysis and interpretation, however it does not equate to regulatory information.

Furthermore regulatory intelligence is imperative along with allocation of key tasks to ensure compliance, future awareness and adequate resourcing.

Benefits of having the correct regulatory information will enable to design and implement a good regulatory strategy which can lead to reduced time-to-market both via accelerated development and smoother registration assessment, reduced costs, increased compliance and ultimately optimization of return on investment.

REGULATORY INTELLIGENCE IN EMERGING MARKETS

Emerging markets which have been termed as the promised land, will account for a third of the global pharmaceutical market by 2016.

Emerging markets in Asia Pacific, Latin America and Eastern Europe are increasingly important locations for drug development as sponsors pursue multinational programs to gain access to appropriate patient populations.

Sponsors now have the opportunity to optimize overall development timelines and achieve registration goals.

Companies who are currently suffering from stagnation of mature markets, patent expirations, and increased regulatory hurdles find the emerging markets as fertile ground.

The markets are a hot bed of huge populations, increasing prosperity and improving longevity, another positive aspect.

There are three main clusters the BRICMT economies (those of Brazil, Russia, India, China, Mexico and Turkey), second-tier countries such as those of Southeast Asia; and finally Africa.

Companies must balance their global competences with tailored approaches for regulatory intelligence functions for these emerging markets.

Regulatory intelligence functions must be structured to define market-tailored and effective business strategies for each market segment which will allow companies to avoid losses in terms of revenue and commercial viability.

COSMETIC REGULATORY INTELLIGENCE

INGREDIENT ANALYSIS FOR COSMETIC PRODUCTS

Ensures ingredient or product complies with all international regulatory requirements for purity and quality.

Ingredient analysis helps in assessing the safety limits of individual ingredients used in different cosmetics products like oral, eye, lip, hair, skin care etc., based on rinse off and leave on category in different regions.

It is imperative that cosmetic products must be safe for use and must be within the limits of regulations set by the country specific health authority.

As there is constant monitoring for safety assessment with respect to different applications, new set limits might come up that may increase or decrease limits or may disqualify the product for specific end user eg; like children.

Non adherence to the updated guidelines, may result in non-compliance with the health authorities norms and regulations any may lead to

- Seizure of products
- Levy fines
- Criminal action
- Refusal of entry of an imported cosmetic product
- Product recall

Freyr Cosmetic Regulatory Intelligence Cell

Freyr's expert team differentiates different cosmetic products by end use, end user and application of the product in specific region with correct regulatory limits. Individual products will be reviewed for latest safety limits against

- EU guidelines (Cosing, Annex's)
- Scientific Committee on Consumer Safety (SCCS)
- FDA monographs, FDA 21 CFR title 700
- Cosmetic ingredient review (CIR)
- Personal care product council (PCPC)
- Fragrance guidelines (IFRA 47 Amendment)
- Ingredient list generation with the correct INCI name

Example 1:
In many cosmetic products, several ingredients were on health authority's watch list, like preservatives, or fragrances, or stabilizers. In recent years, they have come under fire as laboratory studies show tumors, cellular changes or disruption of healthy development and reproduction. States are beginning to restrict them, particularly in children's products, which has resulted in elimination of formaldehyde, parabens, triclosan and phthalates from all baby products. In adult products triclosan and phthalates were removed.

Example 2:
Labeling ingredients list- Ingredients should be labeled with correct International Nomenclature of Cosmetic Ingredients (INCI) name and listing ingredients in descending order, means that the ingredient that weighs the most is listed first and the ingredient that weighs the least is listed last.

Freyr has successfully reviewed 3000+ diverse kinds of cosmetic products

FREYR METRICS

Review correct INCI name and ensure correct safety limits based on product type, category and region specific

Product formula review and generate correct INCI list and ensure representation is same on product list

Ensure safety limits of products from different literature search like Cosmetic ingredient review (CIR), PCPC and SCCS

Ensure technical review for each individual raw, reviewing for residual solvents, prop 65 statement, heavy metals statement, Origin, TSE/BSE statement, GMO statement and also correct INCI name

Freyr CoE

FREYR REGULATORY INTELLIGENCE SERVICES

Instant access to an entire range of authoritative regulatory information for informed decision making and to create superior submissions and market strategies

Freyr Global Regulatory Intelligence Highlights

10 Strategic Accounts

3 of the Top 5 and other Top-20, Global Bio-Pharma & Consumer Healthcare and other SMB Companies

90+ Countries

Supported NA, EU, EMEA, APAC & LATAM

374+

Insights

FREYR REGULATORY INTELLIGENCE SERVICES (RIS):

Freyr's Regulatory Intelligence service is uniquely designed and provides comprehensive regulatory intelligence capabilities that support the development of sound, proactive submission strategies.

Freyr applies current intelligence to navigate potential regulatory hurdles in compliance with regional and local requirements to aid in productive review.

Freyr provides material for internal alerts on latest developments and benchmarks to highlight best practices across different countries and regions for clients.

- Research and analysis of regulatory developments and impact on specific stages of drug/device development lifecycle
- Surveillance of regulatory landscape in local and/or cross regional markets on an on-going basis

Freyr regulatory strategists provide the potential impact of current or anticipated regulatory challenges for clients' developmental and approved therapies by surveying the competitive landscape to provide regulatory intelligence services.

Frey's Regulatory Intelligence Solution helps quickly track, analyze and present granular insights and real-time intelligence for effectively meeting compliance initiatives.

Freyr's regulatory experts gather and analyze publicly available regulatory information to enable regulatory professionals in Life Sciences, Consumer Pharma, Bio-Med and Medical Device firms take informed decisions to create superior submissions and market strategies.

FREYR RIS EXPERTISE

1. Access Difficult Markets Globally with Critical Regulatory Intelligence
2. Timely Actionable Intelligence
3. Centralized Intelligence Delivery Across Stakeholders
4. Collaboration with Stakeholders Across Geographies
5. Assign and Track Actions
6. Flexible, Cost-Effective and Efficient

IN-DEPTH ANALYSIS

1. Analysis of Regulatory Pathway & Hurdles
2. Interpretation of laws, regulation and guidance
3. Analysis of regulatory precedent for policy and therapeutic area key intelligence topics (KITS)

FACT-BASED INTELLIGENCE

1. Health Authority Information
2. Regulatory News Sources & Databases
3. Upcoming Regulations Related Discussions/Updates Through Congress Coverage/Trade Associations
4. Laws, Regulations, Guidance
5. Advisory Meetings
6. Approvals
7. Health Authority alerts and websites
8. Ad Hoc Health Authority Queries
9. Regulatory News
10. Regulatory Databases

IN-DEPTH INSIGHTS

1. New Product Development Regulatory Pathway
2. New Market and Geography Strategy
3. Product Classification
4. Product Launch Dynamics
5. Distribution and Pricing Strategy
6. Compound Strategy
7. Due diligence strategy
8. Indication sequencing
9. Establish regulatory precedent / pathway
10. Challenges & critical success factors
11. Assess likelihood of success
12. Health Authority requests
13. TA project challenges

DISTRIBUTION METHODOLOGY

1. Freyr RegInsight Platform
   - Global dashboard
   - Easily share across departments, across geography
   - Assign actions, track progress
   - Discuss, collaborate and share on new updates
2. Email Alerts

FREYR ACCELERATE FRAMEWORK

Custom Regulatory Intelligence Strategy & Implementation Services

REGULATORY STAKEHOLDERS

- SVP/ VP/ Director/ Manager - Global Regulatory Strategy
- Global and Regional Franchise Head
- Functional Heads
  - CMC, Artwork/ Labeling/ Publishing
  - Regulatory Information Management
  - Regulatory Intelligence
  - Therapeutic Area Regulatory Lead
  - Global Medical Affairs

DEPARTMENTS

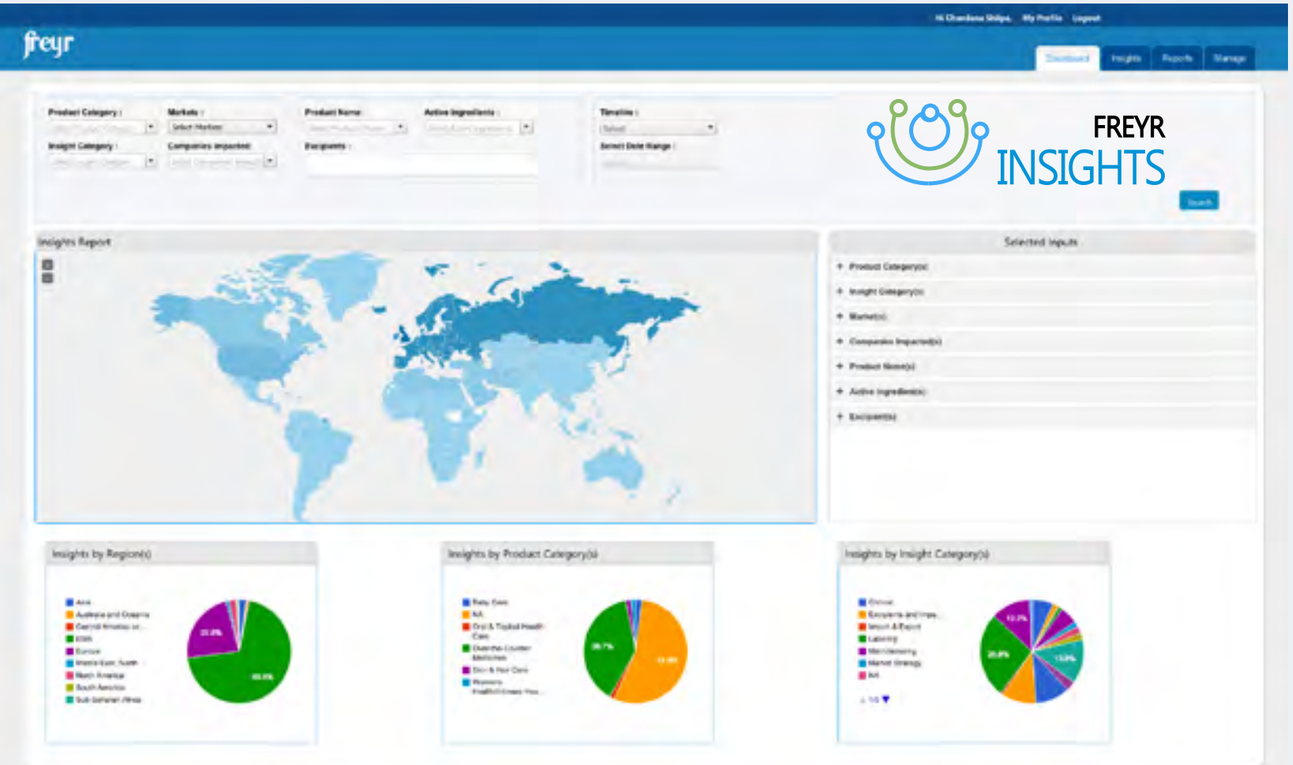
- Regulatory Affairs
- Medical Affairs
- R&D
- Marketing
- Manufacturing
- Export and Import
- Branding & Advertising

FREYR INSIGHTS

FREYR REGULATORY INTELLIGENCE ENTERPRISE SOLUTION

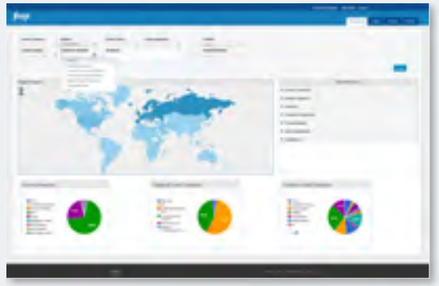
ENTERPRISE SOFTWARE SOLUTION

A regulatory intelligence solution that provides instant access to an entire range of authoritative regulatory information for informed decision making and to create superior submissions and market strategies. Freyr INSIGHTS is built to quickly track, analyze and present granular insights and real-time intelligence.



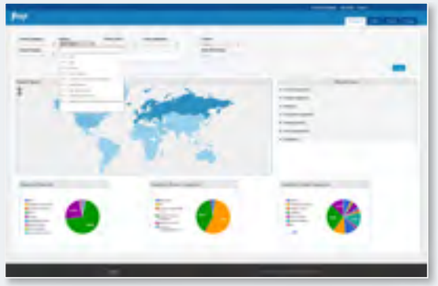
FREYR INSIGHTS FEATURES:

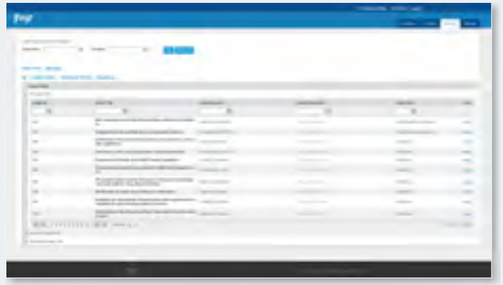
- Provision for a user defined dashboard with holistic overview of the guidelines information
- Robust and dynamic search functionality, enabling the users to look for real time regulatory guidelines and policy change information
- A detailed and customized insights page allowing users to search category based regulatory information
- Ability to export information to all major file formats
- Advanced Admin functions available for managing information and role based users for a targeted audience if required
- Customized alerts and email notification facility



Applicable markets for Insights all over the globe

Impact of Insight on particular type of company





Data view of Insight metrics

COSMETICS REGIONAL REGULATORY AFFAIRS

REGULATION IN THE COSMETIC INDUSTRY

Cosmetic products have an estimated worth of €67bn in Europe, which is regarded as a massive enterprise. The primary requirement during the development of a cosmetic product is to ensure protection for the user's health which is also the basis of the cosmetic legislation. This protection also enables increased consumer confidence in the brand.

COSMETIC LEGISLATION

Cosmetics regulation is the main regulatory framework for finished cosmetic products in the EU market.

The main aim of the regulation is to ensure protection of consumer's health and making consumer's well informed by monitoring the composition and labeling of products and assessment of product safety and mainly focusing on the prohibition of animal testing.

The first law governing the manufacture and marketing of safe cosmetic products was introduced in the European Union (EU) in 1976 in the form of a Directive (76/768/EEC). The Cosmetics Regulation, adopted in 2009, replaces Directive 76/768/EC that was adopted in 1976 and had been substantially revised on numerous occasions.

Since 11 July 2013, the new EU Regulation 1223/2009 (Cosmetics Regulation) is in force.

- It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector
- The regulation simplifies procedures to the extent that the internal market of cosmetic products is now a reality

WHAT'S NEW IN COSMETIC REGULATION?

STRENGTHENED SAFETY REQUIREMENTS FOR COSMETIC PRODUCTS:

Manufacturers must follow specific requirements for preparation of a product safety report ahead of placing a product on the market.

As per Scientific Committee on Consumer Safety (SCCS) guidelines, a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking in account like instructions for use and disposal, labeling and any other indication or information provided by the responsible person.

COSMETICS PRODUCT SAFETY REPORT:

Assessment of safety, which is also deemed as full safety assessment, is to be conducted by a responsible person on the basis of the relevant information.

A cosmetic product safety report (CPSR) needs to be generated for every cosmetic product prior to placing the products in the market.

In accordance to SCCS guidelines, data on Serious Undesirable Effects (SUE) as well as on any undesirable effect become part of the CPSR.

There are two sections in a CPSR, the first section covers "cosmetics safety information" while the second section covers "cosmetics safety assessment".

In addition, No Observed Adverse Effect Level (NOAEL) is the starting point used to calculate the margin of safety (MoS).

It is compulsory to state the reasons, if there is no relevant assessment performed. Furthermore, the microbiological quality report and stability test report must also be submitted before safety assessors embark on the final signing of cosmetics safety reports.

REPORTING OF SERIOUS UNDESIRABLE EFFECTS:

A responsible person will be in charge of notifying Serious Undesirable Effects (SUE) to competent national authorities who will also collect information from users and health professionals.

The information will be readily available to share within other EU Member States.

NEW RULES FOR THE USE OF NANOMATERIALS IN COSMETIC PRODUCTS:

Colorants, preservatives UV-filters and nanomaterial's must be explicitly authorized and other nanomaterial's present in a product which are not restricted by the Cosmetics Regulation will be the object of a full safety assessment at the EU level.

Nanomaterials must be labeled in the ingredients list with the word 'nano' in brackets following the name of the substance, e.g. "titanium dioxide (nano)".

INTRODUCTION OF THE NOTION OF 'RESPONSIBLE PERSON':

As per SCCS guidelines, prior to placing the cosmetic product on the market the responsible person shall submit, the following information to the Commission by electronic means

- Category of cosmetic product and its name
- Name and address of the responsible person
- Country of origin
- Member State in which the cosmetic product is to be placed on the market
- Contact details of a physical person
- The presence of substances in the form of nanomaterial
- The name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR)

COSMETIC PRODUCTS NOTIFICATION PORTAL:

It is a centralized notification procedure opted through out EU for all cosmetic products placed on the EU market. Before placing a product in the market, every manufacturer has to ensure that the product is notified in EU Cosmetic Products Notification Portal (CPNP). It is a free of charge online notification system; CPNP has been created for the implementation of Regulation (EC) No 1223/2009 on cosmetic products. As it is a one-time procedure there is no need for any further notification at the national level in the EU. All information is available electronically to Competent Authorities and Poison Centre's or similar bodies.

PRODUCT INFORMATION FILE:

For every cosmetic product (placed on market) there is a Product Information file created and maintained by the responsible person for a period of ten years (following the date on which the last batch of the cosmetic product was placed on the market).

ARTWORK AND LABELING:

It is mandatory to have listed all ingredients in the cosmetic container labels using identical terms based on the International Nomenclature for Cosmetics Ingredients (INCI) across the whole European Union. Label should include:

- Name and address of the manufacturer, importer or distributor
- Nominal content by weight or volume
- Date of minimum durability or Period After Opening (PAO) for products lasting more than 30 months
- Precautions to be observed in use
- Goods identification reference (e.g. a batch number/ manufacturing code)
- Function of the product (unless it is clear from the presentation)

FREE MOVEMENT:

Member States shall not, refuse, prohibit or restrict cosmetic products availability on the market which comply with the requirements of regulation.

BAN ON ANIMAL TESTING:

As per new regulation and guidelines, it is stated as not to have any testing of finished cosmetic products and cosmetic ingredients on animals in the European Union.

PHARMACEUTICAL SERIALIZATION

AN EVOLVING STRATEGY TO ALLEVIATE THE THREAT OF COUNTERFEIT DRUGS

INTRODUCTION

Counterfeiting, theft, diversion and false returns to manufacturers are few of the problems faced by the pharmaceutical industry across the globe. According to the World Health Organization (WHO), counterfeit drugs make up 1% of the supply in developed countries (including millions of prescriptions in the US alone) and 30-40% in developing countries. By implementing product serialization, counterfeiting by organized crime can be considerably reduced according to pharmaceutical companies and governments of countries across the globe.

Serialization involves a comprehensive system to track and trace the passage of prescription drugs through the complete supply chain. Each product must be identified by a unique serial number along with the origin, shelf life and batch number. This process helps in tracing out the products profile from production, through distribution and finally to dispensation to patients at the drugstore or hospital.

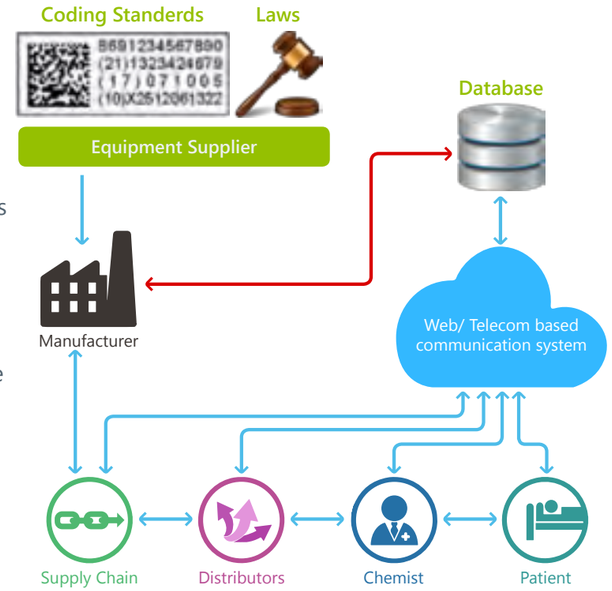
A new standard for drug serialization emerged owing to evolving legal and regulatory requirements. It is learnt that legislations which mandate drug serialization provide no specific methods to be used. It is left up to the manufacturers to choose the appropriate means to track and trace their drugs. The impact of drug serialization on regulatory is tremendous and adds up to the already complex system.

SERIALIZATION

It refers to the allocation and placement of unique markings on a primary package. The markings can be a two-dimensional or RSS bar code, a human-readable letter/number code or unique serialized codes that can be written onto a radio-frequency identification (RFID) tag/label.

Variable data printers or preprinted labels or cartons are employed to position unique codes on each package which are then read by a vision system. Furthermore, the unique codes are uploaded to an event repository database which can be accessed by various parties, including pharmacists, law enforcement officials and even consumers, once the product is shipped and sold.

The individual packages will have unique codes which can be grouped/electronically linked to a shipping case and even to a pallet and other levels of packaging which in turn creates a child/parent/ grandparent relationship.



As a result of the grouping, if the bar code on a pallet is scanned at a warehouse, the brand owner or trading partner will have tracking information regarding all shipping containers and primary containers at that warehouse. In addition, once an ePedigree law comes into action, serialization and aggregation will help to track-and-trace products from the point of packaging to the pharmacy or healthcare facility.

CURRENT SITUATION:

Serialization requirements are in heterogeneous stages of development in the US, Canada, EU and in its member nations as well as in Turkey, India, China, Brazil, Argentina and South Korea.

Despite the variations found in countries laws, each nation's regulations tend to be built around GS1 standards and are quite similar. Although the GS1 format is the most desirable standard, International Organization for Standardization (ISO), Internet Engineering Task Force (IETF) and other competing standards also apply to serialization.

All activities related to drug serialization that are evolving in different countries are backed up by the overarching global initiative conducted on the World Health Organization (WHO) level. The WHO set up the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

Drug Supply Chain Security Act (DSCSA) Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information, released by FDA on 28 November 2014, is meant to address: How information is exchanged between entities within the pharmaceutical supply chain.

DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers was released on 8 December 2014 and explains how wholesalers and third-party logistics providers (3PLs) should report DSCSA information to FDA on an annual basis. Argentina legislation is effective but limited to certain products; however the number of products falling under this legislation is rapidly growing. In January 2014, ANMAT has published a detailed specification of the central Argentina database (trazabilidat) in Spanish.

In December, Brazil published RDC 54/2013, specifying track and trace requirements, accordingly manufacturers must provide serialization and tracking data for three batches of products by 10 December 2015. All pharmaceuticals must be serialized and tracked by 10 December 2016. For a growing market, that's a critical milestone. On 23 January 2014, the first public hearing discussing implementation was held.

Plenty of other countries are preparing for legislation Saudi Arabia by March 2016, Jordan and Ukraine by 2017 including Columbia and Mexico.

TIMELINES FOR IMPLEMENTATION:

Country	Track and Trace Requirements for Pharmaceutical Manufacturer	Target Date (without serialization)	Target Date (without serialization)
USA-FDA (DQSA)	Traceability requirements starting Jan 1, 2015. Year 4-Serialization/ product identifiers Year 10- Complete unit level tracing	2017	2023
Turkey	Future plan to require aggregated serialization data.	2010	2013
India	Primary Level packaging requirement	2014	-
	Secondary Level packaging requirement	2013	-
	Tertiary Level packaging requirement	2011	2015
China	China NDC+ serial number on primary and secondary packages up to the pallet with hierarchy information. Currently, applies for drugs listed in the National Essential Drug List (NEDL). Serialization is progressively introduced and will have to be 100% effective in 2015.	-	2015
South Korea	Incorporation with unique Serial Number and Expiry Date for Special/Professional Drug (including selected drugs)	2015	-
Brazil	3 batches must be done by 2015-12-10. All products must be serialized by 2016-12-10	2016	2016
EU	Serialization only (central database). Countries in the EU have until 2015 to vote their local law	2017	-
Saudi Arabia	Serialization only (central database)	2016	-

POSSIBLE STUMBLING BLOCKS IN IMPLEMENTATION:

Five significant operational problems that may occur by introducing item-level serialization-Pharmaceutical companies need to apply both process and technology changes to meet these challenges. In addition, the companies may need a solution to meet the distributed nature of their operations to facilitate the many disparate actions happening in an operations center.

Bottlenecks	Scalability	Network Performance	Time to Deploy	Ongoing costs
Serialization may create new bottle necks in the physical supply chain (i.e) from performing item level serialization tasks to interact and manage with serialization solutions.	Serialization solutions must be scalable to support distributed operations across a manufacturing facility, distribution center, warehouse, and dispersed geographies. This is a major challenge.	Reduced network and system performance can result when centralized serialization computing solutions are implemented to address a distributed problem.	Long implementation cycles for serialization solutions extend the disruption to the company's operations and delay the benefits of serialization.	Serialization solutions have potential to add yet another ongoing maintenance cost company's already stretched IT departments.

BENEFITS:

The leading companies are demanding solutions that will not only please legislative mandates, but also help them in achieving business benefits beyond compliance. These benefits come from the compact product control that serialization provides. They include:

- Superior product authentication and integrity, which will protect and enhance the company's brands and shareholder value
- Pronounced revenue share by reducing the "gray market" activity that occurs when products are counterfeited and diverted.
- Finer control over and visibility into the supply chains, leading to accurate shipments.
- Fast and efficient reverse logistics or recall processes.
- Serialization also provides huge benefits for clinical trials as they can be conducted, reported and analyzed more efficiently if each of the unit doses being taken in the trial are serialized
- The healthcare industry can benefit from serialization of medical devices as well
- Link between the brand owner and the consumer can be used for creative brand loyalty programs (as marketing tool)
- Companies, in countries with single-payer or other centralized health care systems, reap additional benefits through improved ability to recoup payment from centralized government agencies that reimburse patients drug costs

CONCLUSION:

In order to meet the legislative mandates for serialization, pharmaceutical companies must start planning now. Most of the governments have been extending compliance deadlines, but leading pharmaceutical companies have already started to pivot on implementing a serialization strategy and defining their requirements on trusted partners with production line serialization solutions.

The "wait and see" approach by pharmaceutical companies is not the right way as all pharmaceutical companies will be impacted by serialization regulations.

In the future, every pack of drug will be expected to have a unique identifier before going to the market and the industry must make amends to adjust to the changes.

REGULATORY AFFAIRS **OUTSOURCING**

Outsourcing has become an increasingly common practice in the Pharma and Biotech industry more so in the area of regulatory affairs and Pharmacovigilance. Regulatory outsourcing has now become a norm as most companies are seeking partners to manage operational tasks including report publishing and submission publishing.

Large and small life sciences companies now turn to outsourcing vendors to manage tactical tasks and help adopt best practices. It is learnt that good partnerships offer efficiencies in terms of greater market share and skills and capabilities that enable products to be brought to market more rapidly in diverse markets.

Nonetheless one must consider if the benefits of outsourcing outweigh the costs and one should be discreet in selecting the consultancy or supplier. In 2013, regulatory writing and publishing services segment amounted to 40% of the total regulatory affairs outsourcing market. The regulatory consulting and legal representation services segment is expected to have the fastest growth rate of over 14% from 2014 to 2020.

Since 2013, the biopharmaceutical manufacturing market has shown improvement; traditionally the healthcare sector has been fairly insulated from adverse financial events.

Post-recession period has seen a rise in budgets in areas that help improve performance of manufacturing activities and other areas of productivity and cost-savings.

GLOBAL REGULATORY AFFAIRS OUTSOURCING MARKET & SEGMENTS:

Outsourcing entails in delegation of responsibilities among different manufacturers. The FDA Guidance to Industry – "Quality Systems Approach to Pharmaceutical CGMP Regulations," defines outsourcing as, "the hiring of a second party to perform parts of the overall manufacturing process." These specific legal arrangements pursue a goal: lower manufacturing costs and use of advanced technology to meet a specific manufacturing milestone.

Outsourcing brings products to the market faster with fewer costs required to develop, qualify and then implement all the manufacturing processes than the parent company. A large number of companies are turning to partners to manage operational tasks, including report publishing and submission publishing. Some companies have engaged partners to assist with submission planning and regulatory data management.

In the future almost all aspects of regulatory operations, with the exception of dossier management may be outsourced. Regulatory leaders from several major companies say establishing the regulatory strategy and managing the interaction with the agency will remain in-house.

CHOOSE THE RIGHT OUTSOURCING PARTNER

Companies need a long-term relationship with potential service providers' which is the basis for outsourcing to create a successful partnership

TRACK RECORD

- Does it have the requisite experience and expertise?
- Does it have the necessary global reach?
- Does it have a track record of service commitment?
- Has it been recognised within its own industry?
- Does it track customer satisfaction levels?
- How good are the service level agreements it offers?

RELATIONSHIP MANAGEMENT

- Good relationship management is critical for the business
- Is it prompt in replying from the outset?
- How will the organization's relationship be managed? Is the approach both personal and professional?
- How good and available is the contact(s)?
- How does it propose to report progress?

Outsourcing may involve distance and time zone differences and make interaction more challenging. Companies must take into consideration language barriers and different business cultures including the impact of exchange rate fluctuations particularly in the current global economic circumstances. Regulatory Affairs Market Outsourcing can be categorized into two segments.

A. REGULATORY AFFAIRS OUTSOURCING MARKET, BY SERVICES

- Regulatory Affairs
- Clinical Trial Applications and Product Registrations
- Regulatory Writing and Publishing
- Regulatory Consulting and Legal Representation
- Others (Post Approval Maintenance, Reimbursement Consulting etc.)

B. REGULATORY AFFAIRS OUTSOURCING MARKET, BY GEOGRAPHY

- North America
- Europe
- Asia Pacific
- Rest of the World (RoW)

PERFECTING COMPANY CORE DATA SHEETS

Why a Company Core Data Sheet (CCDS) is required and what is its significance for the marketing authorization holders (MAH).

Creation, maintenance and updating the CCDS costs money to the MAH and requires lot of time and effort. Keeping the CCDS up to date is a continuous process, and as soon as significant new information is noted it should be reviewed for updating the CCDS.

MARKETING AUTHORIZATION HOLDERS: APPROVALS

The MAH has to submit the labels to the local competent authority and get it approved in the countries where they want to do business. After approval, this will become the official label for that country.

The CCDS as per the ICH E2C (R1) is defined as "It is a common practice for MAHs to prepare their own "Company Core Data Sheet" (CCDS) which covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

A practical option for the purpose of periodic reporting is for each MAH to use, as a reference, the safety information contained within its central document (CCDS), which will be referred to as "Company Core Safety Information" (CCSI)."

The local label (SmPC or USPI) is the official label for a product in that country and is approved by its local health authority. This local label can be a prescriber's information, patient information or the label on the carton. Local health authority reviews and approves the label in accordance with its rules, regulations and guidelines.

Hence, the final local label might have difference with the proposed label submitted by the MAH. Hence, the local label might deviate from the company position on a product.

HEALTH AUTHORITIES: LABELING TEMPLATE

Health authorities have their own template for the labels, which is different from others. For example, European Union Summary of Product Characteristics (EU SmPC) template has a section on "driving and using machines" and even if there is no relevant information available for this section the local label should contain this section explaining the same.

However, in the USPI or various other country labels this section is not a part of the template and the information related to driving and using machines would only be included in local label if there is enough evidence to support any impact (actual or potential) on the ability to do work which require alertness like driving and using machines, in that case this information can be added to the appropriate section e.g. the warnings or precautions section.

Hence, it is important for the MAH, especially when doing business in different countries, to have the labeling document which can be used as a reference document globally.

This leads to a question that what should be the template of the CCDS, should it follow any local template e.g. EU SmPC or the USPI or should it use a hybrid template which can cover minimum safety information and leave anything specific to local templates.

GLOBAL HARMONIZED LABELING

It is more important for the companies doing business in multiple countries and regions as inclination to a local label template for the CCDS will pose challenges in having the harmonized labeling globally. The hybrid template can be a better option to cater the needs of all the countries globally.

It should be kept in mind while developing the hybrid template that it should contain all those sections which are related to safe use of the product and allows inclusion of the minimum safety information in the CCDS. However, the local label can still have any country specific information and any information mandated by the local HA.

CCDS: AN IMPORTANT GUIDE FOR THE PRODUCT PROMOTIONAL CONTENT

CCDS is not only used to create the harmonized labeling or for pharmacovigilance but it is also important guide for the product promotional content. It can act as a tool to control the promotional content centrally.

To serve all the purposes discussed above the CCDS for any product need to be updated on the regular basis, and as soon as any new safety information comes to knowledge.

The new information should be added to the CCDS only if it has enough scientific evidences to support the inclusion and should not be driven or influenced by any business interest of the company.

This should be discussed in details in the rationale for the CCDS update and should be authored by the well qualified experts. MAH should also ensure that their promotional material is in line with the labeling.

CCDS also plays an important role in the process of pharmacovigilance, the assessment of expectedness of the spontaneous ADRs in ICSRs for reporting to the HA, is done by using the local label. While, for the assessment of the aggregate reporting (e.g. PSURs) RSI/CCDS is required.

CELEBRATING NEW CLIENT WINS

As an organization, we at Freyr, have always placed the highest value on our business associations and partnerships.

It has been our guiding principle to identify newer opportunities and create exceptional engagement excellence for our clients that transform into long-term relationships.

As always, it is a great pleasure to announce the New Wins of this quarter.

GLOBAL REGULATORY INTELLIGENCE SERVICES FOR $17+ bn TOP-50 CONSUMER PRODUCTS COMPANY

- Provide strategic regulatory intelligence services for a $17+ bn global consumer products company
- Creation of a comprehensive regulatory intelligence report for several product categories (Oral Care, Personal Care, Household Care and From The Dentist) in the client portfolio across target markets including Africa, Middle East, LATAM and Asia
- An updated RegInsight platform, Freyr's Regulatory Intelligence Portal, will deliver the client with regulatory strategies based on current regional guidelines

STRATEGIC REGULATORY SERVICE FOR $600+ mn GLOBAL SOUTH KOREAN PHARMA COMPANY

- Provide regulatory services including end-to-end dossier management, publishing and submission of key active API's (DMF) for a $600+ mn global South Korean pharma client
- Undertake gap analysis and conversion of paper DMF to eCTD format and submission through Freyr's electronic gateway
- Work towards improving regulatory compliance and enhance project delivery while standardizing regulatory operations

CLIENT TESTIMONIALS

We have made great progress in a short duration and are impressed with the 162 positive acknowledgements from EMA for the XEVMPD submission project. I would like to thank the entire team for their support for critical XEVMPD compliance activities.

– Program Manager,
Global Top 5 Pharma and Consumer Health Company

We would like to extend appreciation to the Freyr Copy Development Project Management for their commendable effort. The team has been instrumental in providing timely support and has excellent oversight of all work responsibility.

– Program Manager,
Global Top 5 Pharma and Consumer Health Company

It has been an absolute pleasure working with Freyr over the past few months. Thank you very much for all the hard work- I could not imagine how difficult it would have been without Freyr being so proactive and diligent. I look forward to returning to work in January-an exciting new chapter.

– GRA Operations Professional,
Top 5 Global Pharmaceutical Company

I would like to thank the Freyr team for all the support they have provided. The Ops team is very satisfied with the level and quality of services from all the resources that we have on board. Thanks to their commitment and discipline, we were able to deliver on all key objectives that had been outlined for us in 2014.

– Head of Regulatory Operations,
Top 5 Global Pharmaceutical Company

CLIENT VISIT

Freyr CMC Regulatory Affairs consultants at client site in the UK.

Clients from Top 5 Global Pharmaceutical Company, visiting the global operations center in Hyderabad, India.

CONFERENCE

The Regulatory Affairs in Emerging Markets Conference

Freyr attended a conference "The Regulatory Affairs in Emerging Markets" held in Hamburg, Germany, 21- 23 October, 2014 conducted by Informa.

The event was focused on changing regulatory landscape across emerging markets worldwide including LATAM, Middle East, ASEAN and CIS countries.

There was special interest in CIS countries owing to the complexity in registering the products and co-ordinating with authorities in this market.

Emerging clusters like ASEAN and LATAM countries had been identified as progressive regions that would potentially move towards harmonization and adopt global electronic standards in future.

The UDI Conference 2014

Freyr attended the UDI Conference 2014 conducted by FDA at Baltimore, US - the first conference following the initial set of Class 3 device manufacturers having submitted their DI data to the FDA.

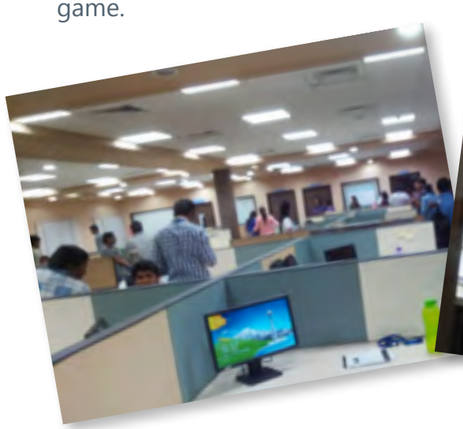
The conference, Freyr got an opportunity to understand how the Top 5 Medical Devices Manufacturers handled the mandate from a technological and process point of view and successfully submitted their Class 3 device data to the GUDID.

The conference also imparted in-person assessment of how medical device companies want to approach the UDI mandate, enabling Freyr to consolidate solutioning insights for Class 2 device manufactures that are expected to comply with the UDI mandate by 2015 and 2016.

GPW EVENTS

TREASURE HUNT:

A mid-day break to play Treasure Hunt! Freyrian's got their thinking cap on and participated in this fun game.



FACE PAINTING COMPETITION:

Creative juices were channeled as Freyrians took part in this colorful task masked in fun.




FRICCO FEST: ANNUAL DAY CELEBRATIONS













FREYR UDI VISION
WEBINAR SERIES

Freyr successfully conducted its **FREYR UDI VISION**, a three part webinar series which took a deep-dive to explain the intricacies and nuances of UDI submission process based on the real-time case scenarios, queries and challenges faced by medical device companies.

The series covered comprehensive understanding and demonstrations by UDI Freyr SMEs on how to achieve UDI compliance in a simplified manner. The speaker panel comprised of Alan Christensen who brings in over 20+ years' experience in the Unique Identifier and RFID space and Prasanna N G who heads Freyr's UDI Practice.

ABOUT THE WEBINAR

1st The webinar was on UDI Readiness, wherein Freyr discussed levels of UDI awareness and readiness, organizational impact, timelines in detail for compliance, master device data management and GUDID submissions.

2nd In the webinar on UDI Labeling, Freyr discussed UDI Compliant labeling, Labeling standards and formats, barcoding standards and formats, issuing agency protocols, labeling requirements for different medical device sectors, general labeling exceptions and RFID.

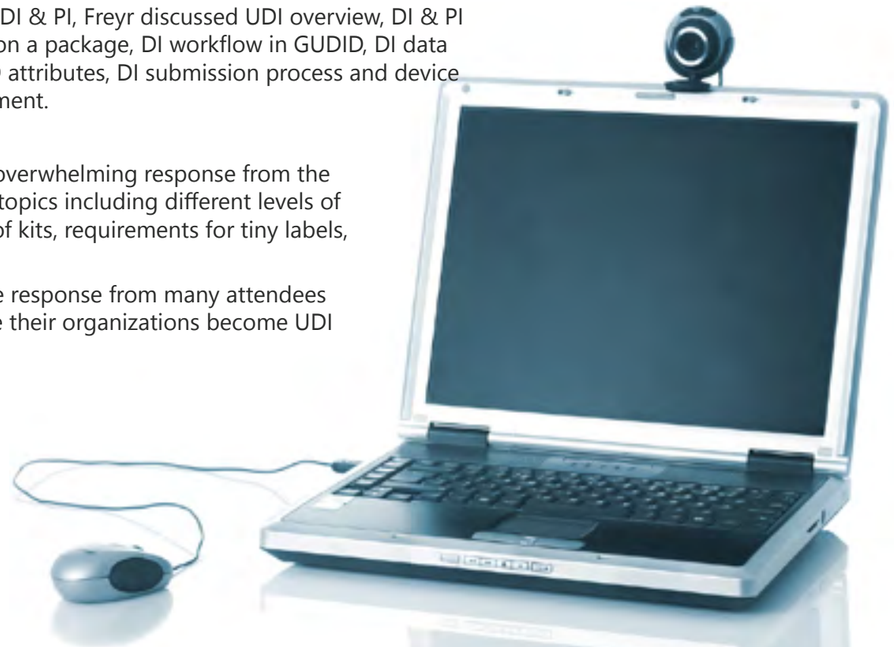
3rd In the session on DI & PI, Freyr discussed UDI overview, DI & PI in detail, DI & PI on a package, DI workflow in GUDID, DI data collection, GUDID attributes, DI submission process and device lifecycle management.

The sessions recieved an overwhelming response from the attendees who discussed topics including different levels of labeling required in case of kits, requirements for tiny labels, direct part marking etc.

Freyr has received positive response from many attendees seeking support to enable their organizations become UDI compliant.

HIGHLIGHTS

- FREYR UDI VISION, a three-part webinar series was successfully conducted between November and December 2014
- The webinar series received an average of 80% attendance; with 60% of the registrants attending all the three sessions



Multi-product Challenges?
Multi-site Global and Local Label Challenges?
Multi-language and Translation Challenges?
Artwork Misbranding Challenges?

Are you completely de-risked against regulatory non-compliance challenges?

Freyr supports global top 10 fortune pharma and consumer healthcare companies to completely de-risk and efficiently manage their Labeling & Artwork Lifecycles and to successfully mitigate all non-compliance and misbranding instances.

Visit **www.freyrsolutions.com/labelling-services/** to know more
or contact us on **sales@freyrsolutions.com**

REGULATORY SOFTWARE SOLUTIONS

Specialized Regulatory and Compliance Solutions and Services

FREYR SUBMIT

A Specialized Submission Solution - Multi-Country Compliant

FREYR eTMF

Perfect for Small & Medium Trials to Efficiently Manage eTMF Documents, Audit-Readiness and Compliance

FREYR Product Register

Seamlessly Sync with Existing Submissions, EVMPD & eTMF Tracking Systems

FREYR INSIGHTS

Proactive, Comprehensive Solution to Track and Analyze Regulatory Compliance Changes

FREYR IDENTITY Simplify UDI

Accurate, Efficient, Faster UDI Compliance

FREYR Drug Info Portal

Authoritative and Validated Information, Audited by Top 10 Fortune Pharmaceutical Companies

FREYR r DMS

Efficiently Manage Document Lifecycle from Inception, Collaboration and Authoring up to Submission and Archiving of Regulatory Documents

FREYR Label

A Smarter, Accurate and Compliant Way to Manage Global Packaging and Labeling Content

FREYR EVMPD

XEVMPD Creation, Submission & Content Management & IDMP Ready

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About Freyr

Headquartered in New Jersey, USA, Freyr is a specialized full-service global Regulatory Solutions and Services Company, offering Consulting, Software & Operations Outsourcing Services of Regulatory Affairs, Operations & Information Management functions to Large & Small-Medium Life Sciences companies in a highly cost-effective model.

Freyr is a trusted partner providing end-to-end multi-geo Regulatory services across Top 20 global brands for 2 of the Global Top 5 Fortune Pharma/ Consumer companies.

Freyr is a rapidly growing global team of 350+ with specialized Centers of Excellence, exclusively focusing on the entire Regulatory value-chain.

Freyr's Global Operations, Delivery and Development Centers are ISO 9001 Certified for Quality Management and ISO 27001 for Information Security Management.

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