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GLOBAL REGULATORY SOLUTIONS & SERVICES
AN ISO 9001 & 27001 COMPANY

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2019

CONNECT

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LEAD STORY

Throwback 2019

A Quick Regulatory Recap

REGULATORY : CONSULTING | SUBMISSIONS | AFFAIRS | SUPPORT | INTELLIGENCE | LABELING | SOFTWARE

What's **INSIDE?**

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FOREWORD

Dear Patrons,

Greetings, and a Happy 2020! Hope you all had a great holiday season!

Stepping into the new year, we take all the pleasure to bring to you the latest Issue of our quarterly newsletter Freyr CONNECT – Volume 7, Issue 4. The last quarter of 2019 has been very exciting for Freyr, not only in terms of business wins, but also for:

- Recording Rapid Growth in Medical Devices and IVD Regulatory Consulting
- Sponsoring AI's Pharma and Device Packaging and Labeling West Coast 2019
- Launching Exclusive Web Portal for Freyr Regulatory Artwork Services
- Presenting Content-Packed Webinar Session on Labeling Best Practices

Breathing into 2020, we feel it's the time of the year to look back, analyze business outcomes, and step ahead with the best possible insights on the industry trends and latest developments of the global Regulatory landscape. Thus, we tried bringing in previous year's Regulatory perspectives and upcoming Regulatory updates with this Issue. In addition, the Issue also focuses on the next big thing of 2020 – EU MDR, along with labeling best practices, and an array of insights on global regulations and thought leadership on compliance best practices.

Wait! That isn't all we have. The fun part begins as we bring you the best glimpses of Freyr's first-ever Family day and our annual bash – Festronix 2019. We hope that you will have a good time visiting our fun-filled internal events section.

We appreciate your interest to read through **Freyr CONNECT – Volume 7, Issue 4**. We are sure, it will be a nice read throughout.

Happy Reading!

Suren Dheenadayalan
CEO

THROWBACK 2019 - A QUICK REGULATORY RECAP

Center of Excellence
Regulatory Affairs

Invention has no limits. It is a continuous process. With many medicinal products and medical devices rolled out in the market, the year 2019 has been a boon for life sciences industry. For good, the industry has seen a significant growth. All thanks to the governance of global health authorities.

The global health authorities were quick enough to alter their governing approaches in reviewing and approving the drug/device inventions. They imposed strict rules to abide by, they continuously released guidance documents to refer to, and they invented new Regulatory pathways for quick product approvals and their market reach. As we bid farewell to 2019, let's take a quick recap of all the notable Regulatory changes that made an impact on the life sciences industry in the last year.

REGULATORY UPDATES 2019 - PHARMACEUTICALS

Center of Excellence
Global Pharmaceutical Regulatory Services

FDA published Final Guidance on the CRP Statements

In 2019, the FDA released a final guidance on the Child-Resistant Packaging (CRP) Statements that will be used for drug labeling. The guidance was released by the agency in order to help the manufacturers and distributors ensure the authenticity of CRP statements and their compliance with the Consumer Product Safety Commission (CPSC) Regulatory standards. It also provided guidelines for text recommendations that should be considered while including CRP statements for drug products. The guidance provided additional recommendations for both prescription and non-prescription drug products.

TGA Proposed Changes to Medicine Labels

In order to align with the global labeling standards, the TGA has proposed changes to the labeling regulations pertaining to medicines. The purpose of bringing these changes was to improve the quality and consistency of information provided through labels. The agency made changes to Active Ingredient Information, Medicine Information, Critical Health Information, Pharmacy Dispensing, and Allergen Information.

FDA Published New Amendments for 'Deemed to be Licensed' Biologics

The FDA published new rules regarding the transition of biological products that are currently approved as drug products and are ''Deemed to be Licensed' as Biologics. The new rules were expected to amend the regulations pertaining to the use of Drug Master Files (DMFs) for biologics. The purpose of the new rule was to ensure that there is adequate supply of the biological products in the market.

REGULATORY UPDATES 2019 - MEDICAL DEVICES

Center of Excellence
Global Medical Device Regulatory Services

TGA's Draft Guidance for Medical Device Cyber Security

To address the threat of cyber security on medical devices, all member health authorities of the International Medical Device Regulators Forum (IMDRF) have released draft guidance documents with Regulatory policies for premarket settings. In relation to the same, the Therapeutic Goods Administration (TGA) of Australia anticipated the need for regulation even in the post-marketing stage of devices and released a draft guidance that span across the Total Product Life Cycle (TPLC).

Through this guidance, the TGA highlighted the cyber security framework developed by the US National Institute of Standards and Technology, which also includes some common examples of vulnerabilities, known standards which can help strengthen the security, and instructions for end-users, clinical trials and healthcare set-ups using the devices.

IVD Clinical Trials in China

The National Medical Products Administration (NMPA), formerly known as China Food and Drug Administration (CFDA), is all set to impose stricter regulations on auditing and reinforcement of clinical trials. To ensure best practices for In-vitro Diagnostic Device (IVD), the agency released "Draft IVD Clinical Trial Guideline for Feedback" on November 22, 2018. The guidelines were expected to come into effect in 2019.

The new guidelines are developed basing on the clinical guidelines published in September 2014. Because of the requirement of fresh samples and significant sample sizes, the cost of clinical trials may go up with the implementation of the new guidelines.

3-Part Strategy of Health Canada's Medical Device Action Plan

The Health Canada (HC) has the most stringent regulations for medical devices. To further increase the safety and effectiveness of the devices, and to optimize the health outcomes for end-users, the Canadian health authority (HA) was in plans to strengthen the then Regulatory framework. As part of the plan, they have a three-part strategy. The aim of the action plan was to take the end users' perspective into consideration while developing policies and regulations in future and thus, to improve communication. Each one of the three parts of the proposed medical device action plan has a sub-set of activities with approximate timelines all through the 2019. In order to successfully complete these activities, the HC has also set milestones to ensure the objectives are achieved.

Spinal Implantable Medical Devices - TGA's Proposal for Reclassification

Australia's Therapeutic Goods Administration (TGA) had published a consultation paper on February 11, 2019, to receive effective feedback from the industry regarding the proposal of reclassifying spinal implantable medical devices to a higher level of classification. The proposal was an effort by the TGA to align its Regulatory requirements with that of the European Union's Medical Device Regulations (EU MDR). The decision was taken after a report was received from the Australian government consisting 58 recommendations from a 2015 Expert Panel Review of Medicines and Medical Device Regulations to reform the Regulatory framework of the TGA with respect to medicines and medical devices.

New Additions to the CDSCO's List of Regulated Medical Devices

On May 15, 2019, the CDSCO had published a notification regarding the classification of new devices. Earlier, the agency added 12 device types in two phases (phase I - 4 types and phase II – 8 types) to the list of regulated medical devices. The notification suggested that all medical devices except IVD devices will be classified based on parameters specified in part I of the first schedule. IVD devices will be classified based on parameters specified in part II of the first schedule. The device classification list has been published in a notification by the Ministry of Health and Family Welfare (MHHFW) in the Gazette of India. The rule will become a mandate with effect from April 1, 2020.

The Role of A UK Responsible Person - In the Case of 'No-deal Brexit'

As the Brexit deadline is fast approaching, the occurrence of a no-deal Brexit is likely. In this context, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK had updated its no-deal Brexit guidance on the regulation of medicines, medical devices, and respective clinical trials. According to the update, medical device manufacturers wishing to place a device in the UK market must have a 'UK Responsible Person' to register their devices with the MHRA, as similar to the European Union (EU) authorized representative.

To put it simply, for manufacturers outside the UK, only a designated UK Responsible Person can legally place a device in the UK market. The 'UK Responsible Person' can be either an individual or a company and should be physically located in the UK. However, the UK Responsible Person of a non-UK manufacturer requires documentary evidence supporting his position.

The Countdown Begins for the EU MDR & IVDR

The EU MDR and IVDR entered into force on May 25, 2017 and are mandated to be effective from May 2020

and May 2022 respectively. Companies must adapt to these regulations failing to which may result in losing their operational license.

While many companies are being due diligent for transition, the United States (US) has raised concerns about the successful implementation of these regulations and sought a delay of three years. The U.S. also opined that with the current product standards and the deadlines imposed by the EU, exporters from the U.S. might not adapt to the new requirements. For most medical device manufacturers, the transition might seem complicated and a time-consuming process as the effective date is approaching. For the U.S., they still have time till 2024.

REGULATORY UPDATES 2019 - COSMETICS

Center of Excellence
Global Cosmetics Regulatory Services

Indonesia Established Regulations for Halal Products

To meet the rising demand of Halal products in the country, the Halal Product Assurance Agency (BPJPH) had established the Indonesian Law no. 33/2014. According to the law, cosmetic and food product manufacturers are required to obtain a halal certificate before distributing the products in the country. The law came into effect from October 2019 and the agency has given a deadline till 2024 to the manufacturers to obtain Halal certificates for their products. Although the guidelines of Halal certification are subject to modifications in the future, they are here to change the face of halal products in the industry.

Ban on Animal Testing for Cosmetic Products

Animal testing has been the talk of the cosmetics industry for quite a long time now. Health authorities across the globe are trying to impose ban on animal testing of cosmetic products. In that perspective, some countries have taken nimble steps towards creating a cruelty-free cosmetics market. For example, the Australian government passed a bill in February 2019 to put a complete ban on animal testing in the country for cosmetic products. The government has given a deadline till July 2020 to the manufacturers to align and strategize their operations as per the new regulations.

FDA Planned to Upgrade the Personal Care Products Safety Act

To enhance the safety of consumers using personal care products, the FDA has planned to upgrade the Personal Care Products Safety Act for the first time in 80 years. As per the revised Act, every five years, the FDA will be required to evaluate the ingredients of the personal care products.

Although the plan of upgrading the Act is still under scrutiny, the FDA is taking every measure to ensure that safe and effective personal care products are made available to the consumers.

EC Upgraded the Cosmetics 'Free From' Claims

In 2017, the European Commission (EC) updated the regulations related to the cosmetic product claims under the EU Regulation (EC No. 655/2013). The updated regulations came into effect from July 1, 2019. As per the latest regulations, 'Annex III – Free From claims' and 'Annex IV – Hypoallergenic Claims' were added to the existing cosmetic claims regulations. The purpose of introducing these annexes was to help the consumers make an informed decision while buying a product.

REGULATORY UPDATES 2019 - FOOD AND FOOD SUPPLEMENTS

Center of Excellence
Global Food and Food Supplements Regulatory Services

FSSAI's New Proposal for Infant Food Regulations

The Food Safety and Standards Authority of India (FSSAI) had issued a draft regulation pertaining to the safety standards of infant nutrition. In India, most of the nutritional products for infants with Inborn Errors of Metabolism (IEM) are imported from foreign countries. With the FSSAI's new proposal for regulations, companies in India are expected to be able to manufacture IEMs locally. The draft proposed by the FSSAI was an updated version of the 2011 released regulations for infant food nutrition and covers the safety standards required for the manufacturing of infant formula for special medical purpose.

12 Major Changes of FDA's New Nutrition Facts Label

On May 27, 2016, the United States Food and Drug Administration (US FDA) published a final rule for nutrition and supplement facts label in the Federal Register. The final rule ensures that the labels reflect new scientific information including the link between diet and chronic diseases like obesity and heart disease. The new rule intended to ensure that the product label is in line with current food habits and practices which are not clearly established in the old label rule. Another significant update of the rule was that the FDA had declared compliance deadlines basing on the annual food sales of the organization.

To sum it up, the year 2019 has been quite eventful in terms of evolving mandates and regulations that were introduced for the betterment of the life sciences industry and in turn for the human health. And as a Regulatory services provider, Freyr was always on its toes to track all the important Regulatory updates, and also made it a point to notify them to the manufacturers through a series of blogs, webinars, and newsletters.

Considering the rapid growth of the industry, and with the ever-evolving regulations, we can firmly say that the year 2020 too will have a lot more to look after, to learn, to align with, and to be complied with. Stay tuned. Stay updated. And Stay compliant.

2020 AND FARTHER -
A REGULATORY SNEAK PEEK

Center of Excellence
Regulatory Strategy

It has been observed for long that innovation drives the life sciences industry, and this would continue perpetually. For the betterment of human health, there have been many innovative drugs/devices released into the market. For good, some of them shaped the humankind well, but alas some had to be taken off the market due to their adverse reactions and manufacturing and Regulatory procedural setbacks.

To reduce the adverse reactions and to ensure each innovative product achieves its ultimate goal of protecting human health, global health authorities, as always, are evolving their regulations and paving Regulatory pathways. In addition, they are continuously laying enormous efforts to educate the industry about upcoming Regulatory scenarios. EMA's Regulatory Science 2025 and Pharmacovigilance 2030 are a few of them. We agree, they seem pretty long term. But they act as stepping stones. Aren't they?

Likewise, many pre-eminent health authorities around the world are updating their regulations. As we just started with 2020, we would like to give you a better perspective on global regulations pertaining to Pharmaceuticals, Medical Devices, Cosmetics, Food and Food Supplements etc. In simple terms it is just a Regulatory heads up for successful compliance in 2020 and farther. Let's take a look at comprehensive list of industry-wise upcoming Regulations.

REGULATORY UPDATES 2020 - PHARMACEUTICALS

Center of Excellence
Global Pharmaceutical
Regulatory Services

Health Canada to Implement eCTD Format for DMF Submissions

As per the latest update by Health Canada, mandatory eCTD format for DMFs will be effective from January 1, 2020. The aim of introducing this mandate is to streamline the submission process for the HC and align with the global Regulatory authorities.

In order to align and comply with the latest advancements of the Health Canada, DMF holders must use eCTD format for all the Regulatory activity types as mentioned below:

- New Type I Master Files - Drug Substance
- New Type II Master Files - Container Closure Systems and Components
- New Type III Master Files - Excipients
- New Type IV Master Files - Drug Products

Conversion of non-eCTD DMFs into eCTD format is not mandatory.

EDQM to Mandate eCTD Format for CEP Applications

As a part of the revised roadmap (2016-2020), the European Directorate for the Quality of Medicines and Healthcare (EDQM) released a notification stating that eCTD format will be mandatory for the submission of Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP) applications.

The eCTD format is said to be effective from January 1, 2020. Post the stated date, EDQM will not accept any NeeS submission for CEP applications including notifications, renewals and revisions.

TGA's Labeling Requirement and the End of Transition Period

The Therapeutic Goods Administration (TGA) introduced new labeling requirements for medicine labels, which came into effect from August 31, 2016. The changes in the labeling requirements were made in order to align with the industry best standards and help the consumers to make an informed choice. The agency has given a transition period of 4 years to the sponsors to align with the new labeling requirements. The transition period will end on August 31, 2020, post which all the medicine labels must meet the requirements of the new labeling rules.

FDA's Extension for DMF Type III eCTD Submission

After pushing the deadline for submission of DMF type III in electronic format twice, the Food and Drugs Administration (FDA) has finally extended the deadline until May 5, 2020. Post the deadline, DMFs submitted in non-eCTD format will not be accepted by the FDA. However, if a DMF is already submitted to the FDA in paper format, it need not be submitted again in electronic format.

TGA's New Product Information (PI) Form

On November 8, 2017, the Therapeutic Goods Administration (TGA) approved a new Product Information (PI) form for medicines. The PI forms were mandated from January 1, 2018, and the sponsors were given a transition period of two years that ends on December 31, 2020. The advancements in the PI form were also a result of TGA's efforts of aligning with global formatting requirements. Key changes in the new PI form include:

- Reordering the content in order to prioritize the critical information
- Updating headings and sub-headings to align with the globally-used standards

TGA's Changes to Ingredient Names

The transition period for aligning with the updated medicine ingredient names will be ending on April 30, 2020. From May 1, 2020, all the medicine sponsors will be required to reflect the updated ingredient names on the medicine labels. Sponsors are required to follow the below-mentioned instructions for medicines before the transition period ends:

- **Existing products** – For medicines that are already in the market, sponsors are required to update their labels and supporting documents to reflect the new ingredient names by April 30, 2020.
- **New Products** – All the new products registered with the TGA are required to meet the requirements of new ingredient names.
- **Registered Medicines** – For registered medicines, sponsors are required to submit a copy of updated label and product information document to the TGA.
- **Listed Medicines** – Sponsors do not need to submit a proof of label change to the TGA.

REGULATORY UPDATES 2020 – MEDICAL DEVICES

Center of Excellence
Global Medical Device
Regulatory Services

EMA's New EU MDR Will Be Effective From May 26, 2020

The next six months are crucial for the Medical Device (MD) industry as EMA's new EU MDR is scheduled to come into full implementation mode on May 26, 2020. The EU MDR is expected to create a robust, more transparent, safe monitoring and secured Regulatory framework for the supply of medical devices. Till May 2020, manufacturers can either comply with the existing MDD Regulatory requirements or align with the new MDR. However, post May 2020, they will have to renew their existing CE certificates, and all the new devices must be aligned with the new MDR. Manufacturers also need to define pathway strategies for Regulatory submissions and need to create a post-market surveillance (PMS) plan to monitor the safety profile of the products.

CDSCO Makes Addition to the List of Regulated Medical Devices

To ensure efficacy and safety of medical devices, the CDSCO drafted and published the Medical Device Rules – 2017. To further aid this, on February 8, 2019, the CDSCO has recognized and added 8 new device types. Previously, the CDSCO had added 4 other

devices to the list and mandated the manufacturers to register them as per the new list before January 1, 2020.

From April 1, 2020, manufacturers and new market entrants willing to sell the newly listed regulated medical devices in the country are required to register with the local health authority CDSCO and foreign manufacturers must obtain an Import License to import and market in the country.

Regulatory Updates 2020 - Cosmetics

Center of Excellence
Global Cosmetics
Regulatory Services

Australia Imposes Ban on Animal Testing

In 2019, the Australian government passed a bill imposing a complete ban on testing of cosmetics on animals. The Industrial Chemical Bill 2017 of the Australian government includes a ban on the animal tests of cosmetic ingredients for collection of relevant data. The ban is also applicable on the cosmetic ingredients used in another product sector. However, it is not applicable to medical testing and ingredients that have been tested in the past. Cosmetic manufacturers are given a deadline until July 2020 to align with the new regulations.

Regulatory Updates 2020 - Food and Food Supplements

Center of Excellence
Global Food and Food Supplements
Regulatory Services

Changes to FDA's Nutrition Facts Label

In 2016, the United States Food and Drug Administration (US FDA) published final rules for Nutrition Facts Label for packaged food. The purpose of the new rule is to ensure that the product labels align with the current food habits and practices, and help the consumers make an informed choice. Food and food supplement manufacturers that are aiming to enter the US market must meet these new revised labeling rules in order to stay compliant.

The major changes in the labeling rules are related to the list of food nutrients that are required to be declared on the label of the food product, along with updating the serving size requirements and a change of design. While many of the food product manufacturers have already started complying with the new rules, rest of the manufacturers with an annual food sales of more than USD 10 million have time till January 1, 2020.

FSSAI Re-categorizes Health Supplements as the FSDU

The Food Safety and Standards Authority of India (FSSAI) has published a guidance document announcing the re-categorization of all the health supplements for sports use as Food for Special Dietary Uses (FSDU). The guidance states that going forward health supplement manufacturers in India will have to comply with the Food Safety and Standards Act, established in the year 2016. It also mentions that the health supplements for sports use cannot contain any unauthorized hormones, steroids or psychotropic ingredients. In addition to this, the health supplements will be evaluated based on the composition of vitamins, minerals, amino acids, probiotics, etc.

To sum it up, the year 2020 promises the life sciences industry a gamut of opportunities, but only when they abide by updated regulations. Mentioned above is just a tip of the iceberg. There are many more upcoming regulations for the year 2020 and may have hidden procedural challenges for compliance. Though it may sound impractical, it is necessary for manufacturers to have a keen eye on each one of the regulations to make their product launch and global market entry strategies compliant. Keep track of the global Regulatory advancements and stay compliant.

Corporate Announcements

Center of Excellence
Global Medical Device
Regulatory Services

Freyr Records Rapid Growth
In Medical Devices and IVD Regulatory Consulting

Obtained
100+
Medical Device Approvals
Globally

Freyr has successfully obtained approvals for 100+ Medical Devices and IVDs within a short span of two years. Freyr partnered with various large to mid-sized Medical devices companies to classify and register their products across the regions irrespective of their class, ranging from Blood collection tubes, IVDs, Laser hair removal, Cardiovascular, Wound dressing, Dermal fillers, Lancets, Catheters, Digital devices, Borderline products etc.

In addition, Freyr has been successful in interacting and conducting pre-submission meetings with major Health Authorities like USFDA (USA), Health Canada (Canada), Thai FDA (Thailand), FDA (Philippines), CDSCO (India), CE (Europe), COFEPRIS (Mexico), CAPA (Kenya), NDA (Uganda), ANMAT (Argentina), MHRA (UK), NPRA (Malaysia), ANVISA (Brazil), NAFDAC (Nigeria), DRAP (Pakistan) etc.

Gear Up for Swift
Medical Device and IVD Compliance

Consult

VALUED PARTNER -
CONTRACTING OUT MARKET ACCESS ACTIVITIES

Center of Excellence
Regulatory Affairs

The world of life sciences is always evolving; so is the need for medicinal product/medical device manufacturers to expand their operations globally. Merely inventing a path-breaking medicine or a device won't fulfil the purpose of life sciences companies. They must ensure that the drug/device reaches the end-user in the quickest and safest possible way. They should create real value for patients in need. But what if the patient segments are distributed far and beyond the origin of manufacturing? In such cases, it is essential to access the markets where the potential patient segment exists. However, market access needs to be carried out with caution to increase the scope of the business and to serve the purpose of life sciences. To gain a competitive advantage in the target market, companies should focus on well-defined approaches that reflect local needs, not only from the product perspective, but also from the Regulatory point of view. The strategy varies from company to company, but with the same underlying goal – successful market access. In the field of life sciences, the market access strategy must align with that of the target market's guidelines and regulations for successful product compliance. There are a few key factors that companies should focus on:

- An intelligence-driven regional market approach
- Appointing local teams inclusive of qualified persons or authorized representatives
- Establishing better contacts with local/regional health authorities
- Analyzing product and organizational readiness.

Though a winning market access strategy must focus on all the points mentioned above, it appears to be of viable benefit only when applied to large manufacturers. Small or midsized companies do not, at times, possess sufficient in-house capabilities to access the markets beyond their reach. Even some larger manufacturers feel that they should invest much of their time and effort in new inventions rather than focusing on market access procedural setbacks. Therefore, they must opt for third-party support, or in simple terms, contract out their market access activities.

> "Partnering enables companies to ensure that the product reaches the market on time by lowering overall business risk"

Outsourcing Benefits

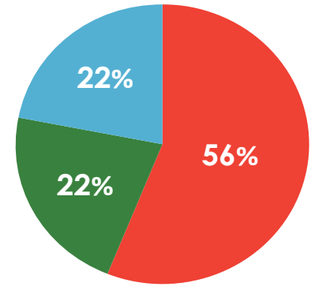
In the past, partnering in the field of life sciences was considered a risky approach, given concerns about clinical data safety, patent transparency, and so on. However, the global life sciences industry is evolving at a rapid pace and becoming more dynamic. The challenges, such as changing regulations and market dynamics, make it difficult for companies to obtain the necessary approvals on time. To ensure that the compliance is taken care of, companies often subcontract their Regulatory activities to regional experts/service providers such as Regulatory affairs specialists, Regulatory intelligence (RI) providers, and life sciences Regulatory experts. The benefits of this approach include:

- **Less time-to-market**: Partnering with regional compliance experts can drastically reduce the go-to-market time for the manufacturers. Regional experts' knowledge of local Regulatory procedures saves time spent on creating, reviewing and submitting the dossiers, leading to increased chances of quick approvals and early entry to market.
- **Reduced costs**: Partnering with compliance experts provides companies with significant cost advantages. Instead of establishing an exclusive local operational hub and recruiting an in-house team which might require specailized training, companies can choose expert consultants who can handle local operations individually at a considerably lower cost.
- **Risk management**: Compliance or Regulatory partners are highly skilled experts and are well versed in the conditions of the target markets. It is easier for them to mitigate the risks associated with the market access strategy and overcome any unwanted challenges. Partnering enables companies to ensure that the product reaches the market on time by lowering overall business risk.

The Current Scenario

Regulatory partnering in life sciences is growing fast; many companies partner with third-party compliance experts to ensure optimum results. The global pharmaceutical Regulatory affairs partnering industry was valued at USD 5.7 billion in 2018 and is expected to grow at a CAGR of 11.9%. The practice of Regulatory partnering has proved beneficial for life sciences companies as it allows them to focus on key areas of operation, thereby improving efficiency.

Regulatory Partnering



Source: *ICVIA*

According to research from IQVIA2, most life sciences companies are in favor of Regulatory partnering. Almost 56% of the pharma companies are partnering with compliance experts for one or the other Regulatory activities. The majority of the manufacturers and new market enthusiasts say that Regulatory partnering streamlines all of their procedural activities and ensures quick market access with lower cost and a managed risk profile. However, caution is needed while choosing the right partnering model.

Partnering and Operating Models

As health authority guidelines and requirements

evolve, the challenges pertaining to market access tend to change. Companies therefore need to choose the correct operational model based on their requirements. Models that companies generally adopt to address the challenges include:

1. **Functional Service Provider (FSP) model**: The FSP model offers companies the freedom to pick and choose the Regulatory functions that they wish to outsource to a third party. The majority of big life sciences companies opt for this model, as it provides the flexibility of resources while reducing cost and maintaining quality.

2. **End-to-End model**: Since small-sized companies might not have specialized resources to autonomously carry out all functions, they choose the end-to-end subcontract model.

3. **Hybrid model**: Mid-sized companies often opt for a hybrid model to manage their Regulatory activities. They use the FSP model to understand the dynamics of the domestic market, and the end-to-end model to ensure successful market entry to international markets.

Regulatory partnering is a beneficial factor for compliant market access. It is time that companies shift from traditional market access strategies. With the plethora of operating models available, Regulatory constraints can easily be overridden, with a special focus on evaluating the right partner. It is important that companies ensure that the prospective partner has the right Regulatory talent, intelligence, flexibility, and fits the bill of delivery models and the high-end technical excellence that suits the submission's needs.

This article was first published by

PHARMAfield

https://pharmafield.co.uk

HEALTH CANADA MANDATES eCTD FORMAT -

FOR TYPE I, II, III, IV MASTER FILE SUBMISSIONS

Freyr PRO SUBMIT

The Health Canada (HC) again postpones the mandatory deadline for Drug Master File (DMF) submissions in electronic Common Technical Document (eCTD) format. Referring to the authority's May 2018 notification, the earlier deadline was January 1, 2019 which later got postponed to September 1, 2019. Now with the recent notification from the authority, the eCTD format for DMF will be effective from January 1, 2020.

With the new mandate, the HC aims to create a common submission intake process, to streamline the existing processes, and to align the Regulatory requirements with other global Regulatory authorities. The agency also stated that the new mandate meant to educate the stakeholders in the preparation and submission of all Regulatory transactions in the eCTD format.

eCTD Mandate and Types of Master Files

To align with the HC's new notification, DMF holders must use eCTD format for all the Regulatory activity types as mentioned below.

- New Type I Master Files - Drug Substance
- New Type II Master Files - Container Closure Systems and Components
- New Type III Master Files - Excipients
- New Type IV Master Files - Drug Products

For the existing non-eCTD DMF applications, the authority recommends converting them to eCTD format, but the conversion is not mandatory, and an exemption will continue on a case-on-case basis.

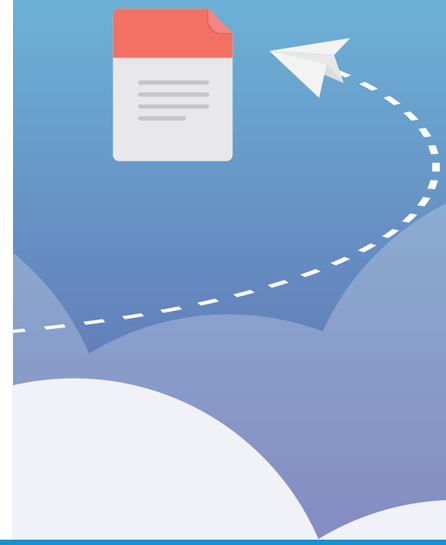
The sponsors/stakeholders also need to note that once they file an eCTD formatted Regulatory transaction for any of the above-mentioned Regulatory activity types, subsequent transactions need to be submitted in eCTD format only. Conversion from paper-to-eCTD format isn't easy as it includes several challenges. Sponsors/stakeholders must track the latest revisions and stay compliant while preparing and submitting DMFs to the Health Canada. Stay informed to be compliant.

Freyr Product Profile

SUMMARY

A smart, cloud-based eCTD software designed to suit all your submission requirements across the globe by creating, validating, publishing, viewing and reporting documents for all regional eCTD formats.

As a proven eCTD software for life sciences industry, Freyr SUBMIT PRO support a diverse range of submission templates and formats required by various Health Authorities such as IND, NDA, ANDA, MAA, NDS, ANDS, DMF, etc. It also aligns with all the major health authorities' regulations including (not limited to) USFDA, EMA, TGA, Health Canada, Swiss Medic, SFDA, etc.



Freyr PRO SUBMIT

FREYR SUBMIT PRO

eCTD Submission Software

FEATURES

- Providing cutting-edge technology
- Supporting/preparing compliant eCTD submissions
- Customized eCTD Submission Support

PROVEN EXPERTISE

- Catered to 125+ trusted clients
- Successfully completed 6500+ eCTD submissions

STRENGTHS

- Inbuilt eCTD Validator
- eCTD Submission Tracking
- Health Authority Query Management
- Integration with Leading rDMS
- Collaborative Submissions, Preparation and Review
- Inbuilt eCTD Viewer
- Inbuilt PDF Manager
- Import Utility
- Module Cloning
- Cross Reference

REFERENCES

"This project, eCTD DMF conversion, was against a very tight schedule and required dedicated resources. Freyr provided the dedicated resources needed to meet our immediate regulatory filing requirements. Freyr was always on schedule/or exceeded the dates outlined in the project plan. All changes were handled within 24 hours and notifications of changes were promptly provided. This project is not yet complete but has been very successful at his point."

Quality Control and Regulatory Manager
US based, Global Innovator Products Manufacturer

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THE COUNTDOWN BEGINS FOR THE EU MDR -

DECIPHER THE KEY FACTORS THAT MUST BE CONSIDERED

Center of Excellence
Global Medical Device Regulatory Services

With just six months for the **EU Medical Devices Regulation (MDR)** to come into full implementation, medical device manufacturers need to start and prepare for the significant changes coming up or they may be at a risk of getting their products removed from the EU market.

As an essential response to technical and scientific developments that are rapidly shaping the medical device industry in the EU region, the EU MDR is expected to create a robust, more transparent, safe monitoring and secured Regulatory framework for the supply of medical devices. With the transitional period for the EU MDR approaching soon i.e., on May 26, 2020, the key factors that device manufacturers must consider include:

- Till May 2020, manufacturers can either comply with the existing MDD Regulatory requirements or align with the new MDR. But post May 2020, they will h ave to renew their existing CE certificates, and all the new devices must be aligned with the new MDR
- Defining necessary pathway strategies for the Regulatory transition
- Creating a post-market surveillance (PMS) plan to monitor the safety profile of the products
- Carrying out a gap analysis between the existing MDD and the new MDR/IVDR so the Regulatory issues can be addressed in time
- Submitting a QMS (quality management system) report for conformity assessment by Notified Bodies along with the other technical documents

With the transitional period coming to an end, manufacturers are obliged to consider the above-mentioned key factors without fail for successful compliance. We say now is the time to prepare yourself and be ready. Gain complete insight on the EU MDR by partnering with the best in the field. Stay informed. Stay compliant.

GLOBAL DRUG LABELING

LANDSCAPE AND THE CHALLENGING SCENARIOS

Freyr LABEL360

The Regulatory landscape has evolved by manifold in the past few years and it continues to grow, refine, and upgrade frequently. By virtue, the drug/pharma companies are bound to introspect and seek compliance in all critical areas because of the continuously changing environment. At the same time, companies find it challenging to track and adhere to the latest industry trends, especially in key areas like safety and efficacy.

How do companies ensure timely implementation of safety updates of drugs in the labels across the world? How do they maintain information transparency all through the product life cycle? How do they become aware of deviations and address them before they compromise on patient safety? These are just a few of the many rhetorical questions, which become peculiar in hindsight.

Considering the time and business process challenges, companies must keep on par with creating, tracking, and managing different aspects of drug labels, on a daily basis. Almost every drug company has reached the breaking point with maintaining regional data in excel workbooks, or trackers, given the exorbitant volumes of data and the complexity in tracking. There are many other pertinent challenges, both linked and interlinked with various daily business operations, strongly necessitating a centrally managed software maximizing the efficiency of a company's existing business processes. Freyr, a leading Regulatory solutions provider, now has a solution for Regulatory labeling – LABEL 360! Intricately designed, this tool meets the end-to-end requirements of labeling and elucidates the complexities involved; from creating, tracking, and distributing label changes to regional labels along with comparison and implementation of label changes to the artwork, printing, and supply chain. Below are a few examples of the major challenges encountered in labeling operations, and how LABEL 360 addresses them.

1. Impact Assessment:

Every organization needs to maintain a track of the key decisions made for a product, during its entire lifecycle. Evaluating the impact of the proposed changes at a global level becomes difficult if there is no record of the decisions made by the product stakeholders (at both global and regional levels). As and when stakeholders propose a global change, assessment towards as a safety or a non-safety change becomes important for calculating the submission timelines.

Global impact assessment revolves around identifying the impacted countries and notifying them of the change. Subsequently, the regional teams must perform local impact assessment and notify the global teams on their decision. The local teams may choose to accept the proposed global change or reject it. In both scenarios, the global teams must be notified, which otherwise may lead to delay in timelines. On the contrary, if the local teams proceed with implementation, they must ensure timely submissions.

What happens when a global change is 'completely rejected' or 'partially' rejected by local country affiliates? How do the local teams convey the reason(s) for rejecting or partially rejecting a change? Where and how do the companies maintain a record of the back and forth communication between the global and local teams? Among the countries which accept the change, how do companies track the implementation of the change in each country?

The entire 'Impact Assessment' cycle solely depends on how effectively the dates are captured at both global and local levels and how promptly the notifications are sent to the teams. If these two parameters are not met, the timelines are sure to vary and put compliance at risk.

LABEL 360 provides a platform to record the decisions at both global and local levels. It is a process integrated 'tracking' tool, which follows the industry's best practices. The system records key milestone dates such as Impact Assessment date, Decision to Implement & Implementation date, Target Submission date, etc.

With LABEL 360, distribution of the proposed changes can be done seamlessly as the tool can integrate with Regulatory Information Management Systems (RIMS). This makes it easier to identify the countries and the registrations impacted by the change. The system also notifies the impacted countries of the change and ensures that they take an action or provide their rationale for complete or partial rejection of the proposed change.

If a change is rejected (complete or partial) by the local affiliates, the system ensures that they provide reason(s) or rationale for the rejection, and route it back to the global team. The system maintains a looping mechanism for such conflicts (back and forth). The loop remains open until a decision is made to implement the change and it is submitted to the HAs. Once the local and global teams are in consensus with one another, the local labels can be updated and tracked within the system.

2. Change Implementation and Deviation Management:

When a product's visibility in the marketspace increases, its variations and submissions to the HAs may also increase. These variations could be related to safety or efficacy. The globally initiated changes once accepted by the local country affiliates must be tracked and monitored closely by the global teams. It is critical for them to know the changes adopted by each country and whether these changes are being submitted to the HAs on time. This helps the global teams understand the trends in the market to further enhance the process.

However, there could be occasions wherein the local and global teams have conflicts in accepting the proposed changes. They could be at odds with one another to accept a change completely or accept it partially. These differences may consequently lead to non-compliance as the submission timelines are not met. It is crucial to track and maintain all such deviations, whether they are agreed to or not, by the global or local teams.

These situations can be handled with ease when we have a robust system like LABEL 360. The tool enables the users to effectively manage the deviations. The agreed deviations can be grouped and implemented together in the system. The system can also accommodate the partial implementation of grouped changes such that, few are implemented immediately and the others, in the subsequent cycle. The system categorizes the deviations as 'Action Immediately' and 'Action Later', which makes it easier for the users to identify and plan the pending deviations. The system does not allow the users to proceed with the new deviations, unless the pending deviations are readdressed.

The deviations which are not agreed to, at global and local levels, are also tracked and recorded in the system. The tool has a looping mechanism, wherein changes rejected/partially accepted at local level are looped back to the global team. The system maintains a record of the reasons provided by the teams, for rejecting a change. Until both the teams mutually agree to proceed with a change, it is maintained in the system as a pending deviation.

3. Bundling and Splitting:

Splitting

There could be occasions when multiple Company Core Data Sheet (CCDS) changes are proposed in one update (Ex: Adverse Drug Reactions (ADRs), Contraindications, Chemistry, Manufacturing, and Controls (CMC), etc.). If it is not feasible to implement all the changes in one cycle, companies may choose to split them into individual changes. Though it is a common practice in the industry to track these details in local trackers (excel sheets), the complexity increases when multiple countries, registrations or dosage forms are involved. It becomes difficult to track the implementation of such changes and their submissions.

Sometimes, changes could be proposed for an ingredient present in multiple products, each having their own labels (E.g. Codeine containing products). In such cases, the request is split at a CCDS level, wherein the dates of implementation and submission need to be tracked closely. This again gets complicated as multiple CCDS are involved and the change should be implemented in each one of them.

LABEL 360 has a well-built tracking system in place, which records the dates linked to split the changes individually. The system also sends reminders and timely notifications to the end users, based on the type of change (safety/non-safety).

The system can also split the requests at a CCDS level and maintain a track of implementation of the changes in all the CCDS documents, within the timelines.

Bundling and Unbundling

A product may have multiple registrations in a country and they could differ either by the dose or the formulations. If a variation is proposed for the different doses of the same product, the associated dossiers need to be updated. There should be an option to group or bundle such requests into one so that the same dates are maintained for all the dossiers when submitted to the HAs.

In LABEL 360, bundling can be done at multiple levels of pack set, registration, and country. The changes can be implemented for the bundled requests together and the dates of their implementation or submission are also maintained as one.

In some cases, the commercial artworks of certain countries could be the same (E.g. Baltic countries). Bundling concept can be well applied for these countries; these bundled requests are considered as 'shared packs', in such cases. For these shared packs, a single artwork request is raised. However, in such cases, it becomes challenging to individually track the further activities in printing and supply chain, at a component level.

In LABEL 360, bundling can also be extended to shared packs, printing, and supply chain. The requests can be bundled at one point and unbundled later, for operational reasons.

The unbundling feature allows the user to remove one or more registrations from a bundle and process them independently.

4. Dependencies:

Some countries may have Regulatory dependencies. The semi/less-regulated countries always depend on other countries for their approval process. They proceed with their approval only when their choice of the lead country gets an approval from the HAs. These are Regulatory dependencies. In the European Union (EU), countries may choose to follow any of the existing procedures for approvals (Mutual Recognition Procedure (MRP), Centralized Procedure (CP), National Process (NP), and Decentralized Procedure (DCP)). These are referred to as procedural dependencies. Also, sometimes a country may arbitrarily choose to follow another lead country, which can be referred to as an Ad-hoc dependency.

The key challenge in having such dependencies is maintaining the SLAs. In some cases, lead countries may fail to update the dependent countries, which causes them to miss the SLAs.

It is highly critical to track the approvals of the lead country in such cases as the dependent countries need to subsequently plan their approvals.

LABEL 360 can take care of all these dependencies (Regulatory, procedural and ad-hoc). The system calculates the SLAs for the dependent countries based on the predefined SLAs of the lead country. Once the lead country receives an approval, the SLAs are re-calculated for the dependent country and they are notified immediately. When such dependent tracking scenarios are taken care of, the SLAs are less likely to be missed.

5. Traceability of Finished Products:

Across the label life cycle of a product, it is pivotal to establish a link between the product registrations, pack sets, commercial artwork components and the supply chain items to an extent that it is possible to trace the product at all locations, right after dispatch from the warehouse and distribution to destination countries, until they reach the shelves in the pharmacy stores.

This level of linking and tracking seems viable until the commercial artwork components are finalized.

The challenge begins when the commercial artworks are printed and sent for packaging. For effective packaging of a product, all its supply chain items including the artworks must be linked to one another.

Through a system-generated unique code, it is possible to maintain this link. However, if companies do not have a system in place to generate these codes, linking the product components at the supply chain level becomes highly difficult. Moreover, it becomes impossible to track these components after they're dispatched from the warehouse.

In LABEL 360, product registrations are linked to pack sets, pack sets to components and the components are in turn linked to finished products. This helps in grouping the supply chain items to form a Stock Keeping Unit (SKU) and trace their distribution from warehouse to different countries until the product reaches the shelf.

6. Content Harmonization:

The entire product life cycle management revolves

around safety and efficacy data. For companies to ensure their labels are up-to-date with changes on safety and efficacy, they need to have a holistic view of all their product molecules. They need to ensure meeting the following conditions:

- Are the labels updated with the recent safety and efficacy developments?
- Are the core labels inline with the
- documents submitted to the HAs?
- Are the artworks updated with the changes to a product's information?
- Are the regional labels in harmony with one another?

The above conditions need to be checked and verified on a timely basis and to do this effectively, there should be a way to compare the labels with one another. This comparison needs to be done by verifying one label against another, to ensure they are in sync.

In LABEL 360, one can perform label to label comparison in different ways; core labels can be compared with regional labels, regional labels can be compared with one another and so on. Labels can be compared at all given times during the product life cycle. This helps in providing better insight about the safety and efficacy data evolving for the product.

Moreover, the system has 'Component Level Authoring' wherein we can perform 'Dynamic Label Comparison' which can be for two or multiple labels at the same time.

7. Multi-purpose Roles and Users:

A system which is used by multiple line functions of a business unit should be flexible enough to accommodate multiple roles; roles which are inter-related with one another and can collaborate to perform their activities.

To finalize one labeling document, multiple process stakeholders are involved. They could belong to the Global teams, (Pharmacovigilance, Medical Affairs, Marketing, and Legal teams), the Regional teams (Regulatory Strategists, Project Managers, Labeling resources, etc.), and the Artwork teams (Commercial artwork, Procurement, Marketing, and Packaging teams). Likewise, we need each process stakeholder to collaborate with the other to perform their day-to-day activities with ease.

LABEL 360 is flexible enough to allow multiple users to access the inter-related features and functionalities. Multiple users can be assigned to a given role and their privileges (features) can be accommodated to ensure effective productivity from each user. The system can allow complete, partial or view-only access to the users, based on their roles in the system. This also helps in maintaining the integrity of data, especially in cases where the access is shared with the third-party vendors (Ex: printing).

8. Linking and Cross-Referencing:

The content of a labeling document is derived from various other documents. These sources include but not limited to, Clinical trial data, Non-clinical Overview, and Clinical Overview. The label content developers must be able to link and cross-reference the new content with its source. If the content reviewers are unable to trace the content to a valid source (documents or links), they may not be able to perform the quality check effectively. Moreover, it's a part of good documentation practices to maintain a track of the references (supporting documents or hyperlinks).

In LABEL 360, referencing can be done by linking the metadata to its source(s). The system enables the users to upload supporting documents, illustrations, journals or provide hyperlinks. The content authors can also cross-reference one section of the label to another, within the system.

The system maintains a 'Literature repository' of all the source data, wherein the authors can choose the references for their metadata, of different labeling documents.

9. Integration, Data Security and Integrity:

Before finalizing a system for labeling, companies must ensure that the system has security controls in place, validated and it can be securely integrated with other systems. It is necessary to ensure data security at all given times, which could otherwise put the entire data integrity at risk.

LABEL 360 has well-defined access controls in place; its database can be accessed only through the application. All its data is encrypted and stored in the database.

The data transfer from the client to the server is done by using secure protocols. Data integrity is managed by the system design which does not allow deletion of any data in the system. It has 'Audit logs' and 'electronic signatures' in place, which are the prerequisites for 21 CFR part 11 validation.

As for integration, LABEL 360 has strong Active Product Ingredients (APIs) in place and it can be integrated with other systems in a way that the system environment and security are protected.

10. Data Migration and Mapping:

Migration of data from one system to another can be highly cumbersome as the data is first moved to a staging environment where it is verified against the source data. Subsequently, it is moved to the live environment, where it is validated. The fundamental quality and integrity of data can be at risk if these critical points are not addressed:

- Data Mapping (The system should accurately map the data from its source to target data points)
- Missing Data
- Incorrect Data

LABEL 360 has strong validation measures in place helping it to identify missing and incorrect data. Missing or incorrect values are easily identified as they are highlighted, providing the user an ease in filling the data.

Would you like to evaluate your existing labeling processes with that of the Freyr LABEL 360 capabilities?

We are game for your evaluation. Let us know when we should schedule a demo for you. sales@freyrsolutions.com

TGA MEDICINE LABEL CHANGES - KEY POINTS

Center of Excellence
Global Pharmaceutical Regulatory Services

Medicine labels act as a first-hand guide for the users and help to use the products qualitatively. Therefore, it is highly important that the information available on the labels is consistent, easy-to-read and error-free, and on par with the global standards.

In order to align with the same, the Therapeutic Goods Administration (TGA) has introduced a few changes in the way the labeling information is presented on the products. The purpose of introducing these changes is to improve the clarity and consistency of information provided to the healthcare professionals.

What Are The New Label Changes?

Though the new information is already taken into consideration and implemented for manufacturers, it is wise to know them in detail for a comprehensive presentation. Below listed are a few of them, that the manufacturers must work on, when defining their medicinal labels.

1. Active Ingredient Information

According to the new rule, Active Ingredients should be:

- Placed more obviously on the front side of the medicine pack
- Should be placed below or next to the name of the medicine on the front of the medicine pack
- Must be easily comparable between the medicines

2. Medicine Information

To ensure that the users and healthcare professionals make an informed decision, the medicine information should be clearer in terms of:

- Critical health information in distinctive labels
- All the mandatory information must be presented in a clearer and more recognizable way against the background color to improve its legibility
- Declarable substances, such as allergens, are required to be mentioned on the label

3. Critical Health Information

Critical health information helps consumers to use the medicine safely by providing important information. The information present in the critical health information table will always be in the same order, although there may be a slight difference in the representation of the information. Critical health information has the following headings and information in the same order:

1. **Active Ingredients:** Name of the active ingredient and its quantity
2. **Indications:** Usage of medicine
3. **Warnings:** Includes warning statements, advisory statements, and additional warning about the usage of the medicine under Direction For Use
4. **Directions For Use:** Includes information about the safe usage of the medicine
5. **Other Information:** Includes information such as storage details, tamper-evident features, sponsor contact details, list of ingredients, etc.

This part may not appear on every medicine

4. Pharmacy Dispensing

According to the new rule, the following changes are made to the medicine dispensers:

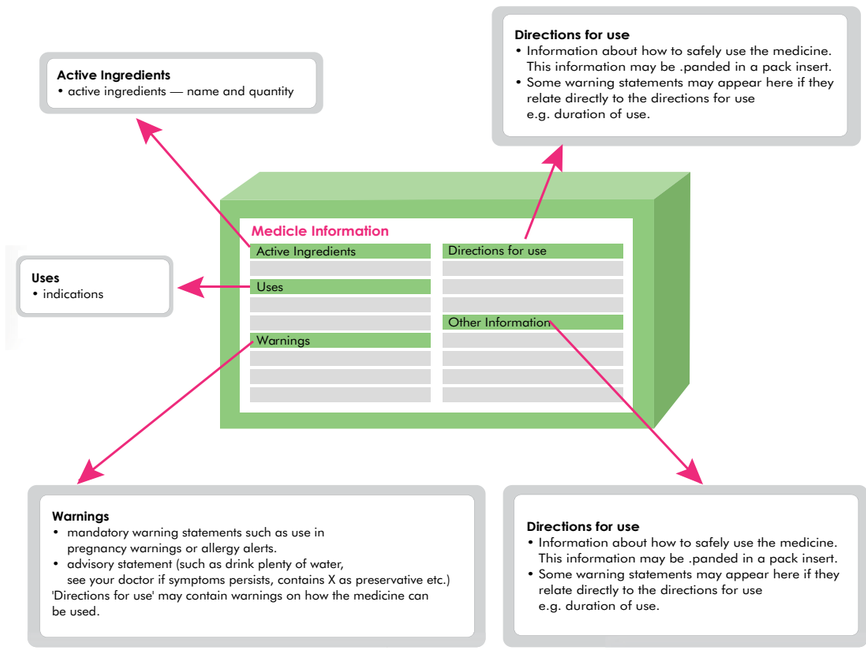
- To improve the identification of the medicines, the cartons of prescription medicines must display its name on the three non-opposing sides
- The labels of prescription medicines must have a dedicated space of 70x30 millimeters unless it is supplied in a primary or a starter pack

5. Allergen Information

Medicines must declare the following information on the labels:

- If present in the medicine, all the substances must be declared on the label
- Additional substances, such as crustacea, fish, eggs, soya, milk, and tree nuts, must be declared on the label
- In the case of new allergens, manufacturers may not include them till the end of the 4 year transition period

Though the TGA has published this information for health professionals, we consider this as a critical requirement for manufacturers, too, to label their products comprehensively. Thus, health professionals can look at the updated information without any confusion and can guide the patients for safe consumption. It is well known that, the TGA has provided the manufacturers a transition period of four years to implement these changes. Post the defined date, the medicine labels must comply with the new labeling requirements. Stay informed. Stay compliant.



Source: *TGA*

WHAT IS COSING?

Freyr What Is..?

CosIng is an official cosmetic ingredient database of the European Union (EU) under the amendment of Decision 2006/257/EC. It features more than 15000 ingredients used in the manufacturing of cosmetic products.

The purpose of introducing the ingredients database was to replace the time-consuming method of gathering information related to ingredients and to promote innovation and dynamism. With the help of CosIng, it is easy for manufacturers to ensure that the changes made in the formulation of any product are compliant with the regulations of the EU. It makes the whole process of manufacturing efficient and cost-effective.

CosIng lists ingredients from the previous inventory as well as the list of banned/restricted ingredients by the EU. The database helps manufacturers to check if there are any restrictions associated to a particular ingredient. The inventory includes:

- Chemical as well as the common name of ingredients as per the Article 33 of Regulation (EC) No 1223/2009; in order to achieve accurate labeling
- The EU regulations related to a specified ingredient
- Links to the opinions on the Consumer Products (SCCP) by Scientific Committee

Further, the inventory is divided into two parts:

Section 1 – It consists of all the cosmetic ingredients; except perfume and aromatic raw material.

Section 2 – It consists cosmetic ingredients related to perfume and aromatic raw material.

The Search In CosIng

A manufacturer can search the database in the following ways:

1. **Simple Search** – With simple search, a anufacturer can search the database for cosmetic ingredients on the basis of Substance names, e.g. International Nomenclature of Cosmetic Ingredients (INCI) names, International Nonproprietary Name (INN), Pharmacopoeia Europaea (Ph. Eur.) name, chemical name, or the status and scope of their Chemical Abstracts Service (CAS) or EC numbers.
2. **Advanced Search** – In advanced search, the manufacturer can extend the criteria for the basic search by including Ph. Eur. Name, restriction and function for ingredients, reference number, regulation reference and/or publication date for substances under the Cosmetics Regulation.

Important Notes

1. If an ingredient exists in the database with an INCI, it does not mean that it is approved for usage in cosmetic products.
2. Ingredients, such as colorants, preservatives and UV filters, are included in the database only if they are approved under Annexes IV, V, respectively VI of the Cosmetic Regulation No 1223/2009.
3. Ingredients for medicinal products can also be found in CosIng.
4. The safety assessment of the product must also support the usage of an ingredient in a cosmetic product.

While the database has proved to be a great advantage to all the manufacturers, the list of its ingredients is not exhaustive. There might be more about the ingredients used in manufacturing which you should know. Any assistance required, reach out to us at sales@freyrsolutions.com.

EU-US MRA ON GMP INSPECTIONS - HEADED FOR FULL IMPLEMENTATION

Center of Excellence
Compliance, Audit and Validation

Do you know? To rely on each other's Good Manufacturing Practice (GMP) inspections pertaining to human medicines, the European Union (EU) and the United States (US) have signed a Mutual Recognition Agreement (MRA) in 1998. However, despite a series of actions and progressive discussions, it was never operational.

But the talks which began in 2014 led to revision of Annex in 2017. As a result, on November 1, 2017, the agreement was brought into force that helped both the territories to recognize each other's inspection expertise and resources.

Now, with the US Food and Drug Administration's (US FDA's) recognition of Slovakia in July 2019, the EU and the US have taken the MRA to a new height and implemented it to a full extent. That means that the US and the EU can now rely on inspection results of both the territories instead of carrying out Good Manufacturing Practice (GMP) inspections individually. Both the territories have agreed that each other's capabilities, capacities, and inspection procedures are equivalent and can rely on them.

This collaboration between the two territories is a testimony to the importance of the EU's strategic partnership with the US and implies the following:

- With the MRA turning fully operational, the authorities in both the EU and the US will now be able to rely on each other's inspection results and can make the best use of their inspection capacities
- The MRA yields greater efficiencies for the Regulatory systems in both territories, avoiding duplications in the inspections
- It facilitates both territories to free up resources
- As a biggest relief, with the MRA implemented, a batch-testing waiver will also come into force, which will be beneficial for products manufactured in the US and entering into EU market. In such cases, those products are not required to be batch tested as they have already gone through proper quality controls in the US

With the MRA headed for a positive implementation, both the territories, for sure can now look forward for easy market entry within the quickest possible time. But to do so, manufacturers should assure that their GMPs are on par with that of each side's health authorities. Are your GMPs audited periodically and have they been assessed and properly validated? Evaluate now with a proven Regulatory expert.

UK'S NEW COSMETIC REGULATIONS IN THE LIGHT OF BREXIT

Center of Excellence
Global Cosmetics Regulatory Services

Though scheduled to take place from March 29, 2019, the Brexit has now postponed to October 31, 2019. The decision is assumed to give more time to the United Kingdom (UK) and the European Union (EU) to agree upon the terms of the UK leaving the EU.

Until now, the EU regulations directly affected the cosmetic products that are distributed in the UK. However, with the Brexit in scenario, they are no longer expected to be applicable in the UK region as the UK is expected to be treated as a third country. In simple words, the UK will not have to comply with the regulations applicable to the EU member states. Therefore, to align with the Brexit changes, for Cosmetic products, some new laws have been laid before the UK parliament.

The UK Cosmetic Regulations Draft

The Cosmetic, Toiletry and Perfumery Association (CTPA) has proposed the UK Cosmetic Products Statutory Instrument to the UK parliament to ensure that post the Brexit only safe cosmetic products are distributed in the UK. The new draft will be in line with that of the EU's including the list of banned and restricted ingredients.

To enter the UK cosmetics market, companies will be required to appoint a UK-based Responsible Person (RP), who is expected to notify the product to the competent authority. To make sure the notification process is streamlined, the CTPA seems to be in the process of building the required product notification portal for the UK similar to that of the Cosmetic Product Notification Portal (CPNP) of the EU.

Once Brexit takes place, all the cosmetic products notified to the EU through CPNP are expected to be notified to the UK notification system within ninety (90) days. Following are the prerequisites for notifying a product in the UK.

- The name and category of the cosmetic product
- The name and address of the responsible person
- The content and ingredients of the product

In addition to this, the label of a cosmetic product must also bear the name and address of the Responsible Person. Post Brexit, cosmetic products labeled with an EU-27 address and compliant with the EU labeling regulation will be considered compliant for 2 years in the UK. In case of imports also, the UK will have to comply with the import regulations of the EU.

According to the industry experts, if the UK leaves the EU with a no-deal, the entire supply chain of cosmetic products will be affected heavily. However, as the regulations overlap in many regions of the EU and the UK, the industry is yet to identify the exact impact of Brexit to ensure compliance in both the regions.

As the cosmetic regulations of both the regions are still unclear, it is advised for the companies planning to enter both the cosmetic markets (EU and UK) to consult Regulatory experts with strong local presence for compliant market entry. Be informed. Be compliant.

DRUG REGULATIONS AND PHARMA COMPANIES' PLAN OF COMPLIANCE

Center of Excellence
Regulatory Affairs

The Pharmaceutical industry has been growing in parallel to human evolution. Either inventing path-breaking medicines for some of the incurable diseases or eradicating the viral threats from their roots; the industry has put in enormous efforts for the safety of humankind.

In the last two decades, the industry has seen a new shift only to improve the efficiency and effectiveness of the medicinal production. In a way to be flexible and qualitative while benefitting the patients, the industry has been mainly focussing on bringing out the new classes of drugs and new-age technologies such as Gene Therapy, Stem Cells, Nanomedicine, New Drug delivery systems, etc. Standing with the industry's growth, the global health authorities, too, endorsing the patients' safety, have been coming up with new drug approval systems, compliance best practices, and procedures. In this scenario of 360^0 evolution, how should companies design their plan of compliance? What should be their main focus is what we are going to cover in the following sections.

It is widely known that it takes an average of 14 years and 350 million dollars for a pharmaceutical company to get a new drug from a laboratory to the market. As each phase of these 14 years is completely regulated, companies should carefully plan the entire drug life cycle, right from the patent application, marketing approval, post-market sustenance and amendments to the patent expiration. In addition, they must consider phase-wise drug regulations to withstand global competition.

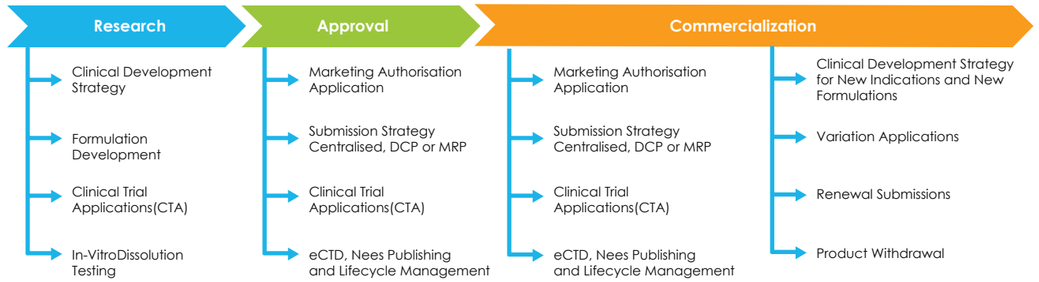
Phase-wise Regulatory Outlook

Health authorities control every stage of the drug development procedure including post-approval and the marketing stages as well. For the benefit of their assessment, evaluation, validation, and review procedures they mandate manufacturers to follow certain guidelines and best practices right from research to approval to commercialization to post-market amendments as depicted below.

Let's discuss about these phase-wise regulations and procedures in detail.

Preclinical Testing:

New drug development starts with the pre-clinical stage where pharmaceutical companies examine thousands of compounds to find a therapeutic value targeting a specific disease. The preclinical studies have to be conducted by following the Good Laboratory Practices (GLP) as suggested by respective health authorities. The principles of GLP govern the planning, performance, monitoring, recording, reporting, and archiving of preclinical studies. In this phase, the drug undergoes trials (in vitro and in vivo) on laboratory animals to evaluate metabolism (pharmacodynamics [PD] and pharmacokinetics [PK]), safety, toxicity, dosage, and efficacy. Companies are obliged to show enough evidence to the respective Health Authority in the form of an Investigational New Drug (IND) application for the drug's chemistry, manufacturing, and controls (CMC) to assure the identity, strength, quality, and purity of the drug.



The above picture depicts various Regulatory activities involved in the drug development process

Out of various compounds subjected to testing, if any of the drug compounds show promising results, only then can a company file an Investigational New Drug (IND) application. If safety concerns arise in the IND review, the health authorities can place the application on partial or full clinical holds. Often, such a case might be a disaster for companies striving to move forward to conduct their clinical trials.

Clinical Trials:

The objective of clinical trials is to evaluate the safety and efficacy of medicinal product/s in humans. Clinical trials involve four phases and each phase must comply with regional requirements as well as Good Clinical Practices (GCP) as per the respective health authorities' guidelines. The purpose of Good Clinical Practice (GCP) is to ensure that all clinical trials adhere to ethical and scientific standards to protect the rights, safety, and well-being of trial participants as well as the reliability and credibility of trial results. GCP is also concerned with the data integrity.

Clinical trials held in the first three phases are conducted to collect safety and efficacy information to support the licensing application and phase IV is conducted post-marketing i.e., once the product reaches the market. The phase-wise details are explained in the following sections.

Phase I - Phase I clinical trials aim to find the best dose of a new drug with fewer side effects. These trials include initial single-dose studies, dose-escalation, and short-term repeated-dose studies. The goal of Phase I clinical trials is to determine what the drug's most frequent side effects are and, often, how it is metabolized and excreted. If the drug is found to be safe enough, it is appropriate for further testing.

Phase II - Phase II clinical trials are considered as exploratory trials (as in this phase further assessment of drug safety is evaluated). Clinical pharmacology studies are also included in this category. Phase II trials begin only if Phase I trials don't reveal unacceptable toxicity.

The drug, if found to show positive results is then considered for Phase III testing. At the end of phase II clinical trials, the manufacturer will have to discuss and update the health authorities regarding the development process, and the protocols for phase III clinical trials, which is the most extensive and expensive process of drug development.

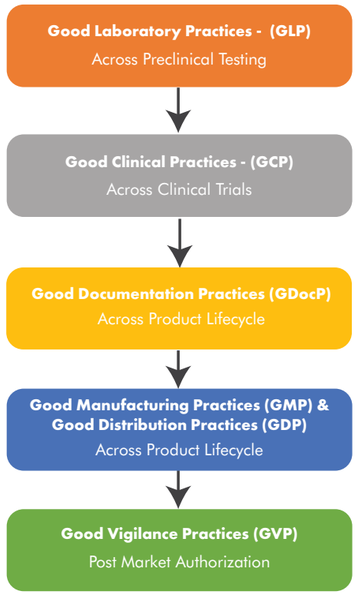
Phase III - Phase III clinical trials or confirmatory trials are conducted to obtain additional information about the drug's effectiveness and safety to assess the benefit versus risk of the drug. If approved by the health authority, the trail data can then be utilized for drug labeling process.

During the clinical trial stage, improper study design, cost computability, timeline, and lack of knowledge of pharmacovigilance may affect the company's plan of compliance. Apart from these, companies must also review and check the accuracy of all submission materials in comparison with guidance documents from the Regulatory agency and safety topics from the International Conference on Harmonization (ICH).

Across the clinical trial life cycle, different types of data are generated, which has to be accurately reported to address specific research questions. Companies use this data to submit detailed Clinical Study Reports (CSRs), which forms the basis for marketing applications. Inaccurate or incomplete data may impact the product approvals. Therefore, maintaining data integrity is a mandatory requirement throughout the drug development process. Manufacturers are also obliged to follow Good Documentation Practice (GDocP), which applies to the creation, maintenance, and retention of documents.

Approvals:

GxPs To Be Followed – Across the Product Lifecycle



Once the phase III clinical trials are completed, and if the data demonstrate the safety and effectiveness of the drug, the manufacturer will have to compile the trial data to file a New Drug Application (NDA) or a Biologics License Application (BLA) depending on the type of the product. NDA or BLA usually comprises all the data, related to nonclinical and clinical testing and manufacturing, which must be in accordance with the Regulatory requirements.

In addition, while filing the NDA or BLA, manufacturer should consider the preferred regional format for submission either paper or electronic. Only once the Health authority approves the NDA or BLA, the manufacturer can commercialize the drug in their jurisdiction. If there are any deficiencies (major/minor) found in the data submitted, and the data provided with respect to safety, efficacy, CMC and labeling information is found to be inadequate, the health authority may reject the application and would ask for necessary clarifications.

Marketing and Commercialization:

Once the drug is approved, manufacturers need to submit marketing authorization applications in every country as per their targeted market-entry list by following Good Manufacturing Practices (GMP). Compliance with GMP is necessary in obtaining a marketing authorization. This is because the health authorities validate the quality of drug products by carefully monitoring drug manufacturers' compliance with GMP regulations. The GMP regulations govern manufacturing facilities, methods, processing, controls, and packaging of a drug product to ensure the identity, strength, purity, and quality of a product is appropriate to its intended use.

Apart from aligning to the GMP, companies must also follow the Good Distribution Practices (GDP) to ensure that there is no alteration to the drug's innate formulation and to its package elements during the distribution.

In case if the drug is already approved in one country and the targeted country considers accepting the available marketing authorization, the process can be a little easy for manufacturers. If it is not the case, the level of scrutiny would be higher. Then manufacturers may face challenges in terms of compiling qualitative region-specific clinical documentation, providing supplemental data during review stages if any deficiencies are figured out, and bridging evidence gaps, if any. En-route they may also have to consider targeted country's assessment methods for marketing authorization applications.

NDA or BLA usually comprises all the data, related to nonclinical and clinical testing and manufacturing, which must be in accordance with the Regulatory requirements.

Pharmacovigilance (PV) and Quality Monitoring:

Once the drug is approved and released into the market, manufacturers will have to conduct post-marketing surveillance to evaluate the performance of the drug or to report any unwanted and dangerous reactions. This is also known as Pharmacovigilance (PV).

Like other stages, PV too has its significance in controlling the drug's market position. Though the manufacturer's core responsibility lies in developing and releasing a safe drug into the market, they also need to track the drug's performance and its effect on end users once it is released. If any adverse reactions take place, they should shoulder the responsibility of confronting it. Health authorities globally especially of the U.S. and Europe take adverse reactions seriously and mandate the industry to follow Good Vigilance Practices (GVP) to track the drugs' performance once they are out in the market. The purpose of Good Vigilance Practices (GVP) is to ensure that continuous safety monitoring activities take place and all appropriate actions are taken to reduce the associated risks.

Hence, a manufacturer is expected to have a well-established PV system in place to monitor drugs' safety cautiously and submit periodical reports about the benefit-risk profile of the drugs. In case of any discrepancy found in the post-marketing surveillance, there is a chance that health authorities may ask the manufacturer to withdraw the drug from the market. To avoid non-compliance and associated penalties, manufacturer must ensure that their PV systems are aligned to evolving regulations.

Though the phase-wise Regulatory outlook seems almost similar for many countries, there exist certain diversifications in obtaining approvals. Even if the procedures are different, the aim is mutual i.e. to protect the end user's safety. To protect the same, the need of the hour is to harmonize the regulations, drug development, and approval procedures across the globe. Health Authorities should look upon a common global platform to govern and regulate the industry and bring in more centralized and commonly acceptable procedures.

In this way, many innovative products can see the light of the day globally as soon as they are invented, and many unmet patient needs are addressed within the timelines. While Health Authorities should start working on centralized regulations, companies, with a unified view across development, approval, marketing and quality-monitoring stages, should build a robust plan of compliance i.e. to keep abreast of global standards and regulations and apply best compliance practices right from the first step (preclinical) to patent expiration. ■

Freyr Advertisement

VIGILANCE IS ALL THAT MATTERS

To Avoid Adversities

Not all the drugs demonstrate the intended efficacy once they are out in the market. Though they have been tested and tried on focused groups during clinical trials, there are chances [sometimes] that they react beyond a Marketing Authorization Holder's (MAH's) expectations. For good, we wish they are of positive impact. But what if they result otherwise? In such cases, the core responsibility of the MAH lies in reporting, evaluating, and mitigating the risks immediately.

Freyr believes Pharmacovigilance (PV) is all that matters to reduce/avoid adversities by offering:

PV Consultation	PV Database, System Setup, And Strategy	Aggregate Report /Periodic Safety Report	Preparation and Review Of ICSR, PASS, GIP, ISS, ISE, and DBE Tables
Signal Detection	Literature Monitoring	Safety Monitoring	PV Audit Support

DEPLOY EFFECTIVE PV SYSTEMS

CONSULT

+1 908 483 7958 sales@freyrsolutions.com www.freyrsolutions.com

WHAT IS DAILYMED?

Freyr What Is..?

DailyMed is a source of information about drugs which are marketed in the United States (US). It officially provides Food and Drug Administration's (FDA) label information (package inserts) to the general public. The website provides comprehensive, standard, updated, and downloadable resources about the content and labeling of medication package inserts.

DailyMed is provided by the National Library of Medicines (NLM) as a public service. The information available on DailyMed is either currently used by the FDA or is recently submitted to the USFDA. The information includes warnings undergoing FDA review, editorial changes etc. The information on the website is presented in a revised format which is easier to read and understand for public. The drug labeling information available on Dailymed may vary from the product currently distributed in the market. Drugs which are marked as "unapproved" are under review with the FDA for their status of safety and efficacy. NLM continuously monitors the information submitted to the FDA to update the information on DailyMed for public access.

Exploring DailyMed

The DailyMed is publicly available for use. A user can search through the database by using drug name, National Drug Code (NDC), manufacturer name, drug class or SET ID. Users can also opt for "Advanced Search" option which refines the search results based on the criteria set by the user.

Databases like DailyMed are necessary for the general public and life sciences companies as they provide crucial information related to the Health Authorities in a much simpler format. Would you For more information related to DailyMed or similar healthcare databases, reach out to Freyr at sales@freyrsolutions.com.

Type of information available on DailyMed

TYPE OF INFORMATION	DESCRIPTION
NAME	Drug name
CLASS	Pharmacologic class of the drug
INGREDIENT	Active ingredients contained in the drug
INACTIVE INGREDIENT	Inactive ingredients contained in the drug
ACTIVE MOIETY	The molecule/ion responsible for the action of the drug
ACTIVE MOIETY UNII CODE	UNII codes of the active moiety of the drug
ACTIVE INGREDIENT UNII CODE	UNII codes of the active ingredients of the drug
INACTIVE INGREDIENT UNII CODE	UNII codes of the inactive ingredients of the drug
LABEL TYPE	Usage of the drug (for Human or Animal etc.)
INDICATIONS	Indications & Usage section of a drug label
CONTRAINDICATIONS	Contraindications section of a drug label
ADVERSE REACTIONS	Adverse Reactions section of a drug label
WARNINGS	Warnings & Precautions section of a drug label
BOXED WARNING	Boxed Warning section of a drug label

Reference: *DailyMed*

Center of Excellence
Global Cosmetics Regulatory Services

CLAIM IT COMPLIANTLY!

Unsure of Your Product Category?

Ensure Conformity to the FD&C Act,
For Informed Claim and Successful Compliance.

For Procedural Assistance...

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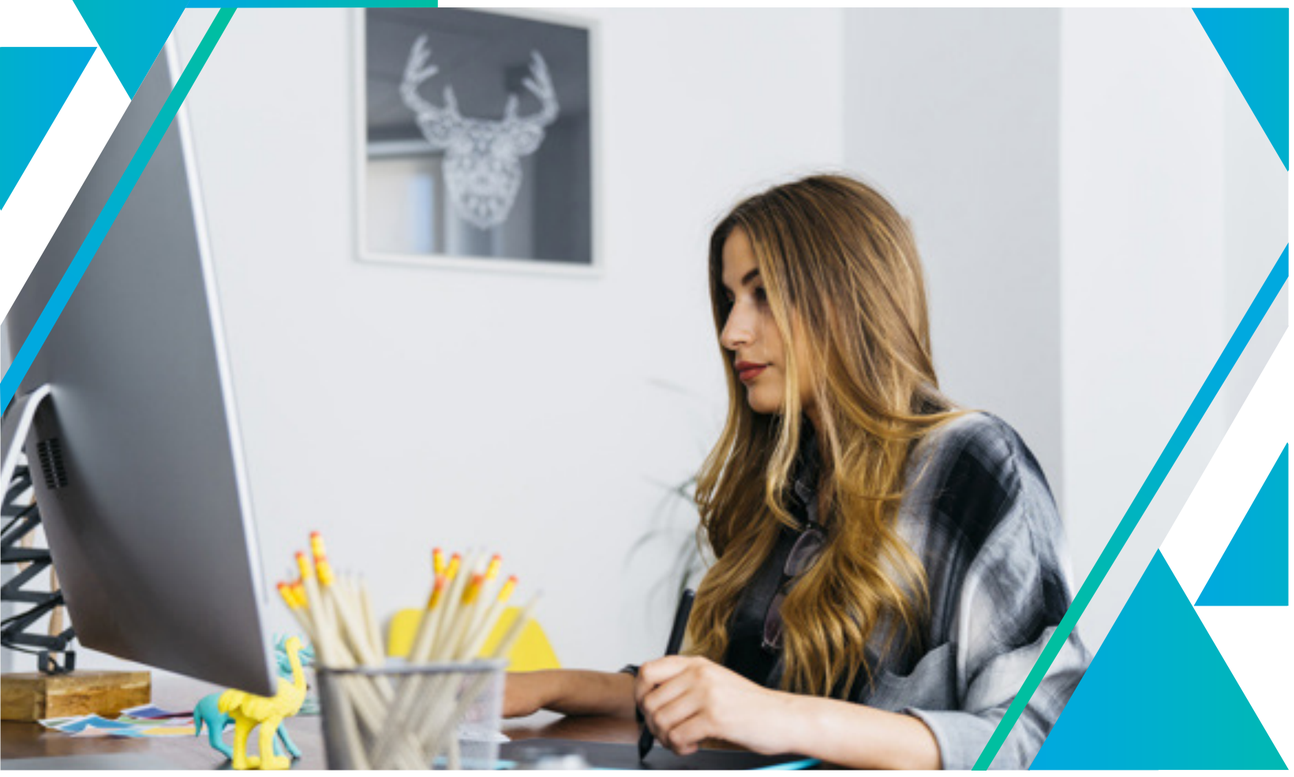
Case Study

FREYR REGULATORY ARTWORK SERVICES



CENTRALIZING THE ARTWORK PROCESS AND MIGRATION OF 11,000 LEGACY ARTWORKS

Clients
Top global pharma company

Geography
Global

Solution
Consulting for artwork process centralization

Function
Regulatory operations

BENEFIT HIGHLIGHTS

- Harmonized 30 workflows to 5
- 11,000 legacy artworks' migration
- Onsite training of approximately 6 weeks
- Quick (turnaround time) TAT

Business Imperatives

- The client was in view to streamline and centralize packaging and artwork design processes, which over many years, had evolved into a complex, disparate global collection of operations which made the task almost impossible to achieve
- The client had plans to reduce their Artwork recall rate due to packaging design, whilst at the same time be able to understand and reduce the complexity of its pack range and associated components

Challenges

- Decentralized operations
- No defined process documentation and as a result leading to high risk non-compliance findings
- Lack of process adherence and deviations from documented SOPs (Standard Operating Procedures) that require immediate corrective and preventive action
- Routing of work through inefficient and archaic channels
- Lack of transparency
- Longer workflow cycles (over 60 to 75 days or more for each request)
- Delayed timelines
- Noncompliance due to manual documentation
- Long audit preparation periods

Freyr Solutions and Services

- Detailed analysis and report presentation
- Phase-based methodology implementation
- Return on investment detailed analysis and month on month summary during transition
- To- be process (high level) during different phases of transition
- To-be resource and technology model during phases of transition
- Service Level Agreements (SLA) during different phases of transition
- Draft statement of work for implementation phase
- Looked at more than 30+ workflows
- Strategy development plan in just 8 weeks
- Proposed universal pack management system with a complete product lifecycle management

Client Benefits

- Harmonized 30 workflows to 5
- 11,000 legacy artworks' migration
- Onsite training of approximately 6 weeks
- Quick TAT

Case Study

Center of Excellence
Regulatory Medical Writing

Timely Preparation and Evaluation of 250 PDEs

Clients
Pharmaceuticals manufacturing giant

Countries Supported
India, EU, Bangladesh, Korea

Solution
Consulting for artwork process centralization

Therapeutic Area/Indication
Multiple

Products
Generics

Function
Toxicology evaluation

Technological Environment
Toxicology data base, (Q)SAR tools, MS Office

BENEFIT HIGHLIGHTS

- A well prepared Permitted Daily Exposure (PDE) and supporting documents as per European Medicines Agency (EMA)
- Acceptance in the EU markets
- Minimal input or efforts from client end
- Regulatory queries handled by Freyr
- Archival provided as per request

Business Imperatives

- The client approached Freyr for 250 PDE evaluation for established medicinal products

Challenges

- No document provided by client
- Toxicological information was difficult to gather
- Scenarios of exposure is entirely different, which require assumptions

Freyr Solutions and Services

- Streamlining the process
- Defined Standard Operating Procedure (SOP), work instructions and process flow
- Supported toxicology data with Quantitative Structure–activity Relationship ((Q)SAR) and read across data
- Evaluated PDE values with justifications
- High quality and first time right document delivery – 5 levels of internal quality check done

Client Benefits

- Cost advantage
- Streamlined process with submission ready document
- On time delivery of documents
- First time right delivery

CLIENT TESTIMONIALS

"Thank you very much Freyr for all your help in creating the strategies. There have been a lot of documents and discussions based on very little information from us. I am happy to see that you have provided all the deliverables as agreed within a tight deadline."

VP Established Portfolio, Global Development
A Multinational Danish Pharmaceutical Company

"Thank you Freyr for rapidly responding to our extremely pressing issue regarding SPL submissions. Though the requirement was on a short turnaround time failing which the application to FDA was to be cancelled, you guys have worked it out without compromising. We are extremely happy to see your rapid response in sharing the package to FDA. The entire Freyr team is to be congratulated on being able to provide an important service in a very short period of time. Again, thank you for the unbelievably rapid response to our pressing request."

VP Established Portfolio, Global Development
A Multinational Danish Pharmaceutical Company

"It was a very good first engagement with Freyr Solutions. Given their remarkable efforts in all the aspects right from solutioning to operational expertise to compliant transition, we are for sure, looking forward to working with them on future programs as well."

Sr. Director, Combination Products
A Clinical-stage Biopharmaceutical Company

"I am very pleased with Freyr's performance. Even during high work pressure situation, the Freyr team did not hesitate to go an extra mile to complete the given submission on time. The team ensured smooth communication to complete the given tasks correctly as per the expectations of the company. Freyr also provided guidance for publishing activities to our in-house experts and helped solving our queries related to eSubmissions. The support of Freyr team is highly appreciated and I look forward to continue working with them in future, as well."

Manager Regulatory Operations
A Japan Based R&D Driven Specialty Pharma Company

"I would like to commend the Freyr team on their outstanding job to get 25 submissions out the door, on time. This shows that the team has put in extra efforts to tackle the additional task that was given to them on an ad hoc basis. I would like to appreciate the Freyr team for their great coordination and ability to handle large volumes of work effortlessly."

Associate Director, Global Regulatory Affairs Operations
A Japan Based Leading Pharmaceutical Company

"We needed a robust Regulatory publishing and submissions platform to streamline our submissions to various health authorities. We are very happy to come across Freyr SUBMIT PRO that perfectly fits our requirement of pre-defined and region-specific submission templates. Above all, Freyr's submission tool has successfully been integrated with our existing DMS. Thank you Freyr for making our submissions more compliant and on time.

We would certainly recommend Freyr SUBMIT PRO as a highly competent and reliable submission management tool."

Regulatory Affairs Director,
A Leading US-based Pharmaceutical Company

"We have been very happy to use Freyr SUBMIT PRO for compliant submissions. We could make our submissions even more streamlined with its in-built validator and cloning features especially submitting the already submitted dossier in one country to another. And the best of the tool is, it's a single-stop platform to look into the all Health Authority related issues. SUBMIT PRO's HA correspondence ability is simply the need of the day for any applicant."

Publishing and Submissions Project Coordinator,
A Multinational Pharmaceutical Company

"That's amazing! Freyr LABEL 360 is true to its branding. The tool enabled us not only to track the global label changes in real time, but also to implement them across the impacted geographies simultaneously. We are overwhelmed to have this tool easily integrated with our existing systems.

Thank you Freyr for this one-stop labeling solution."

Vice-president, Regulatory Operations,
A Fortune Top 20 Pharmaceutical Company

FREYR FESTRONIX 2019

SPORTS SHOWS SAGAS










KERALA

The Scenic State of Culture, Wildlife, Food, and Spices

"To Travel is To Live", one of my favorite quotes by Hans Christian Andersen, is a true motivation for all my travel stories. And this is why, I believe in living the places that I visit. I had heard a lot about Kerala from many people and wanted to visit the place eagerly. Therefore, I quickly planned the itinerary and soon I was aboard on a plane to explore the beauty of Kerala.

Kerala, known as "God's own country", "Spice state", "Tea state" and many more such names, is the most serenely beautiful state in India and has a special place in the heart of every Indian. Apart from being famous for its Houseboats, Ayurved Massages, Authentic Spices, and Palm-lined Beaches, Kerala is also home to a huge group of wildlife animals and is a paradise for seafood lovers. Being travel enthusiasts, my husband and I regularly travel to different places and explore different regions. As it was my first visit to Kerala, I was all excited. I was even more fascinated to look for the traditions the locals have been following from generation to generation, the beautiful geographical landscapes, the wildlife, and the tea estates (being a tea lover).

We chose to fly in the month of September. The ideal time to visit Kerala is in the months of August and September, as the rain makes the terrain look greener and the temperature is cooler than normal. Although Kerala doesn't have extreme temperatures and you can roam around comfortably in the streets or alongside the beaches. Our itinerary included **3 places – Munnar, Thekkady, and Alleppey,** as it was a short 4 days trip.

Munnar

We started our journey from RGIA – Hyderabad airport and landed in Kochi airport around 9am. We had booked an online Taxi that would stay with us for the entire trip and would also help us with sightseeing and traveling from one destination to another. As soon as we landed, we straight away drove to **Munnar** for 2 days stay. Road journeys are always exciting and this one was no less. Kochi to Munnar takes around 4 hours by road and en route you will find lush greenery and waterfalls all through until you reach Munnar.

On the way, we saw **Cheeyappara waterfalls** that cascades down in seven steps. Later, we visited a Spice garden and had a short Elephant ride by the riverside. There is some magic in the mud of Kerala that you can see all kinds of spices being grown in this region. Now you know where you get all the spices from! While roaming around in the spice garden, it started drizzling, turning the weather in our favor. Driving through the hills with little showers was a blessing in disguise. As Munnar is a hilly terrain, temperatures were pretty low, and we could see the sun playing around in the green bed of tea plantations. The aromatic wind forces you to forget everything and relax in those tea estates forever, thus, adding to your ethereal experience. However, nothing lasts forever and so we had to move ahead to visit the next spot.

Our next destination was one of its kind **Tea museums** situated in the hills of Munnar, officially known as **Tata Tea Museum or Kannan Devan Hills Plantation (KDHP) Tea Museum.** Being one of the oldest tea estates, it dates back to the 1880s but was officially started on April 1, 2005. The museum highlights the entire journey of tea production. This includes tea plantations, various machinery used, and methods followed for producing tea. Tea lovers can enjoy the three-step process of making tea – Crush, tear, and curl. Visitors can also buy original and pure tea powders from the store available at the museum. Later we just walked through the tea plantation lanes and soon got lost in the greenery. That marked the end of our day 1 with lots of Tea inside me. We started for day 2 by visiting the local waterfalls, viewpoint, and Mattupetty dam. Munnar is so beautiful that you can't capture it in a few pics. We also bought homemade dark chocolates and a box of white chocolates. They were super yummy and just melted in the mouth. (I preserved them for a long after coming home).

Thekkady

Our next destination was **Thekkady**. We started from Munnar in the morning and on the way, witnessed several small waterfalls and viewpoints. All the viewpoints were picturesque, and our phone memory would have been exhausted if we hadn't stopped clicking pictures. We reached Thekkady in the afternoon and after check-in, we went for Jungle safari at **Periyar National Park.** The national park is famous for Elephants, Bisons and migratory birds. Although it is declared as a Tiger Reserve, there aren't many tigers that can be sighted. The off-road ride to Periyar National Park was amazing with loads of jumps and bumps. As, it started raining and we could only see a few Bisons and Elephants, but too far. We had to leave the park with disappointment, as we couldn't see the wildlife as expected due to rains. In the evening, we went to see the **Kathakali Dance** Show and **Kalaripayattu Martial Arts** show. Kathakali is a difficult dance form as the artists take around 3-4 hours to get ready and complete their make-up. A beautiful form of classical dancing, Kathakali is more of a story-based dance form expressed majorly with hand movements and facial expressions. On the other side, we saw Kalaripayattu show, which is the oldest form of martial arts. Young boys performed several martial art poses and showed some extraordinary stunts with fire.

Alleppey

The next morning, we drove to **Alleppey (Allaphuza) – the backwaters.** The major attraction at Alleppey is the **Houseboats.** We hired a houseboat to stay overnight and get the experience. But to my dismay, the backwaters have become crowded and you may hear all kinds of human noises around. However, we decided to ignore them and enjoy our houseboat ride through the backwaters. Every houseboat is unique and looks beautiful in its own way. Food lovers can enjoy yummy seafood dishes in their houseboats. The backwaters is also a place for locals to reside. We could see several houses with small boats parked in front of them. If you feel hungry moving around in the backwaters, you can go grab a coffee, some chips, and cold drinks from the restaurants available on the sides of the backwaters. The best part about the houseboats are the sunsets. What a surreal experience! Setting Sun, calm waters, coconut trees, and some 100s of houseboats around, Alleppey was worth visiting.

On our way back, it took us 3 hrs. from Alleppey to Kochi. As our flight was in the evening, we thought of exploring Kochi as well. We strolled by the beach and came across Chinese fishing nets through the coast that sell fresh fish. We even explored the interior of old Kochi by looking around the colonial houses and lanes, organic cafes, art galleries, churches and the Kochi Fort. When it comes to heritage and architecture, Kochi is influenced by multiple cultures as it is a home to several immigrants of British, Portuguese, Dutch, and Arabic descent. We also visited an Indo-Portuguese museum and churches like Santa-Cruz Basilica. For shopping, tourists usually prefer the lanes near Fort Kochi, as there are plenty of shops that sell organic and Ayurved products. You can also fill your bags with loads of tea, antiques, and organic products.

As the sky turned orange because of the sunset, a beautiful trip ended. I'm planning a second one soon, as I'm yet to see so many places in Kerala where you can have fun, eat, and relax. Have you visited Kerala yet? If not, add it to your bucket list now!

PRATAP GOUDA

For The Best of Technological Transformation

Hi Pratap, firstly, a big thanks to you and the entire IT team. You guys have made us rock solid whenever an immediate attention and action was required for client visits, late-night calls, presentations, etc. How do you describe your journey in Freyr?

When I first stepped-in, Freyr was a 170-employees team, with a different IT scenario. That day I realized it would be a big challenge to transform the then IT infrastructure to what it is today. The challenge was not at all with installing/reinstalling software or relooking at the technological procedures. It was about changing the people's mindset. To make them adapt to new technology without downtime and reacting to infrastructure hassles. I'm happy that in all these years we were able to bring positive technology-wise changes that are driving the business successfully. The credit goes to the entire Freyr Executive Management for their support in the process of transition phase, which otherwise usually takes a longer time in other organizations.

Today, it has been 5 years and I feel that I have had a great journey. With a small team of 6 members, assisting or supporting 650+ in-house Regulatory experts is like a dream come true.

Freyr as an organization is going places. With new markets and many regional teams, how challenging is it to centralize all the processes? Are there any additional technological measures that Freyr is working on to streamline the operations across the all the operational centers?

Yes. We are growing explicitly, and now we have 450+ clients with 13+ global operational centers. All through, we had to align with growing organizational requirements such as setting up advanced IT systems, giving customized control/access, and backing up the data within no time. We came up with several plans to make the user feel that his/her information is in a centralized folder and can be accessed from anywhere. However, centralizing the processes was the biggest challenge. To increase the productivity all across our operational centers, we are continuously aiming at streamlining communication between our offices in different countries and implementing the best possible practices that can suit any given scenario.

Today, we can take a backup of the entire organizational data in just 24 hours, per week. Besides all this, we had gone through successful IT audits, and received positive responses on the IT infrastructure and technology procedural workflows.

People don't just choose a job; they also choose a boss. Do you agree with this? If yes, as a boss how would you like to credit your team?

Not as a boss, but as a colleague, I would give entire credit to my team. They made the impossible as POSSIBLE. Though I was involved in planning and strategizing the transitional workflows, they have worked on it on the ground. They knew that I am a tough guy to work with, but they stood by me and have been putting their faith in my open-door policy. I believe that if I am strong, the entire team will be strong.

Many of us are not aware of your workmanship during the location shift from LANCO Hills to Phoenix. How did you make it look so smooth? Anything specific you remember?

Apart from supporting massive client visits, technical support for various client presentations, one of the biggest achievements for Freyr IT team was moving the 250+ work stations during Freyr's location shift from LANCO Hills to Phoenix. We had just two days starting Friday evening to Sunday evening to ensure the smooth transition of entire IT infrastructure, which was indeed needed to be right up and running for the Monday morning's client visit. Those 48 hours were critical, and we did enjoy the challenge to make it a smooth transition. To our hard work, everything was ready, and the client visit was successfully done with a positive feedback. I will cherish that incident all my life and I can surely say we couldn't have achieved this without the existing team with a zero downtime.

If you are provided with enough budgets, what is the first thing you would like to modify at Freyr? What's the next big thing at Freyr in terms of technology and infrastructure that is suitable for **next-level business transformation?**

If I am provided with budgets, I would like to bring in the latest technology available in the market. But, as we are in a Regulatory landscape, we just can't implement or adopt every new technology, even though it is a best bet for process. We have certain limitations in view of data security. If that is not the case, I would want to build Freyr as a technologically empowered organization suiting to the current day's technical aspects.

We fondly believe that behind an always-work-focused Pratap Gouda, there is an easy-going friend. When can you introduce him to us?

I'm trying my level best for 5 years. (Laughs). I have always been asked, "what will I achieve for my family, this year?" And my obvious answer was, "I would like to spend good quality time with my family and go on a holiday this year. But that year has never come." (Laughs) I'm a jolly person and I crack jokes when I'm with my family or close friends.

Beyond that, I firmly believe that this is the real time to work hard and to make a note in my life diary that, "Okay! That time, I was busy working."

If not IT what would Pratap choose as his career? What is he passionate about?

ARMY! My entire family is in the armed forces and I'm the only civilian. You can figure out from my persona - the way I talk, carry myself, etc. I always believe that if you wish to do something, then do it for your country but not for your own, and never lead a selfish life.

Tech, used wisely, can give us the best and safe working environment. What's your note on the procedural best practices to be the safest in this vulnerable IT space?

To be frank, nobody is safe now! In today's world there is no best practice. Big search engine giants and software companies have their best practices written, but aren't they prone to data breach? Isn't their data being hacked?

There is nothing called best practice. As long as things are working fine, they are quoted as the best practice. Any technology has both plus and minus and you have to balance both and ensure utilizing the technology wisely.

Rapid Fire

Your Motivation – My Previous Boss

Your Inspiration – My Father

Best Holiday – The Time When I Was Hospitalized…

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