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freyr
GLOBAL REGULATORY SOLUTIONS & SERVICES
AN ISO 9001 & 27001 COMPANY

CONNECT

● LEARN ● INSPIRE ● INNOVATE

100+ CLIENTS

FREYR SURPASSES THE 100-CLIENTS MILESTONE

SUPPORTING CUSTOMERS ACROSS 50+ COUNTRIES

REGISTRATIONS & SUBMISSIONS TO 40+ HEALTH AUTHORITIES

6 of the Forbes Global Top 10, Pharma Companies

3 of the Forbes Global Top 7, Consumer Healthcare Companies

5 of the Forbes Top 6, Biotech Companies

6 of the Top 15 and **20+** Generic Companies

10+ of the Global Top Medical Device Companies

50+ Small Medium Life Sciences Co's,Medical Device Co's, CROs, Consulting Firms and Agencies / Standards Authorities

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

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FOREWORD

Hello Everyone,

Welcome to another episode of Freyr Connect!!!

Now, the excitement is two folded at Freyr. One, for the way we are galloping to win the clients across the globe and the other, for the way we are conquering the globe with our exclusive global delivery centres. We are pleased to announce that Freyr has surpassed the 100+ clients milestone just in a handful of years since the inception serving clients across 50+ countries to meet Regulatory requirements of 40+ global health authorities. Icing on the cake is that we are emerging to be bigger and better with rapid global expansions, too. In an endeavour to reach out to our growing clientele in the MENA region, we have now set up our 5th regional delivery centre in Dubai, UAE, after the US, UK, Germany and India. Dive deep into our excitement.

So, what's there inside this time? Here's a quick sneak peek.

The global Regulatory regime is evolving and so the organizations' Regulatory needs. As the needs are unconventional in nature, what organizations firmly require is a specialized set of strategic Regulatory services. Having said that, we start this edition with a cover story that focusses on how Freyr enabled many of its clients to surf through the unique Regulatory landscape, "Evolving Global Regulatory Regime and The Role of Emerging Strategic Regulatory Services".

Following that, this edition signifies the mandatory eCTD submissions and the best practices to be followed for the FDA second-phase submissions for Commercial INDs and Master Files. Pairing with our previous edition's Orphan Drug Designation – an EU perspective, this time we've published an US perspective, which you may find informative along with other stories on Regulatory Artwork, Packaging, significance of Regulatory Intelligence and the types of clinical study designs.

The fun element is an integral part of Freyr. You can find it through a few glimpses of Freyr recreational club activities organized throughout. At last, don't miss out the interesting Freyr 360° towards the end of this edition.

Thanking everybody who contributed to this chapter of Freyr CONNECT, we hope this edition will enlighten your day.

Happy reading!

Freyr Team

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Freyr is excited to announce that the organization has surpassed the 100+ clients milestone. Achieving it in just a handful of years since the inception, Freyr as an organization feels grateful to avail every single contribution all through the journey and acknowledges every stakeholder for being part of the success.

Since the beginning, Freyr has catered specialized Regulatory services for many life sciences organizations that include top 10 Forbes global Pharma, Biotech, Consumer Healthcare, Generics, Medical Devices, and fast-growing companies. With a recent Hong Kong-based client win, Freyr has surpassed the 100+ client's milestone and is marching past to continue the growth curve. Across 50+ countries, Freyr has served many renowned clients for their unique Regulatory requirements for 40+ health authorities including FDA, EMA, SFDA, TGA, HC, MCC, WHO etc.

"It's great to have won 100+ clients within a short period. Achieving the feat in this competitive Regulatory landscape acknowledges Freyr's strategic Regulatory approach and value-added operational and consulting services," said Rajiv Rangan, Co-CEO, Freyr. "We have been growing, thanks to our clients invaluable trust on us and our employees' commitment towards the organizational goals. Going forward, we strongly believe that our employees continue to extend the best possible support to our clients in quick TAT enabling the latter win-over their unique Regulatory complexities and challenges."

Strategy 360
Global Regulatory Strategy and Business Consulting

EVOLVING GLOBAL REGULATORY REGIME

AND THE EMERGING ROLE OF STRATEGIC REGULATORY SERVICES

With the rise of globalization, pharmaceutical companies across the globe are eyeing on expanding their business by launching innovative products across different geographies. Be it the ambiguous state of regional Regulatory regime, or the necessity to keep abreast with ever-evolving health authority standards or the region's complex/challenging legislative procedures or the peculiar state of their innovation, companies are puzzled about the pathways to approach the global markets/regions. That might put them in the risk of delayed or deviated compliance activities leading to increased cost pressures. The best way companies can handle the situation is through opting for an expert Regulatory partner who is not only capable of addressing the time-critical requirements in a compliant way, but also has a local presence across the globe. In simple terms, the need of the hour is to address the complexities in a strategic way.

Tapping into the growth opportunities, the incentives to opt for strategic services may seem huge, but selecting the right channel/partner may pose a great challenge for companies. While maintaining in-house expertise could be a costly affair, getting a global partner support for unconventional requirements might demand them to check on partner capabilities and track record. A perfect blend of Regulatory Intelligence, solutions and ability to map them with the requirement for the first-time-right-approach plays a crucial role here. The partner should be equipped with that. Their solutions or services should not only stand apt to the need but should also be sustainable in terms of building a competency in the market in the longer run.

Being equipped with such kind of competent framework, holding a pool of specialized Regulatory experts across the globe, Freyr has helped many of its clients to get recognized in saturated and highly competitive markets and, also assisted them for firm establishment in an economy that is just taking off. Banking highly on the belief that there is no "one-size-fits-all" approach, Freyr offered well-defined need-based strategic services that played a critical role in deriving customized solutions to clients' table. Cited below are few examples on how Freyr catered specialized strategic Regulatory services to its clients' unique and unconventional needs.

THE LOCAL/ REGIONAL PRESENCE

Across all upcoming markets, access is a highly significant challenge. It has been observed that having and maintaining local subsidiaries in those countries, or a local sales force might be a prerequisite to growing business. Also, building good relationships with both local governments and local players are among the key factors for success. Freyr has a well-established local presence across a formidable number of countries across the globe. And as a strategically designed team, we can understand the requirement, identify the gaps and together collate and provide the right solution in the quickest turn-around-time.

Case 1: For a last-minute requirement, Freyr assisted a client in solving a **Regulatory operational complexity:** to renew product registrations in another region. Challenges involved local lobbying and how to help them retain their market presence because once the product licence expires, they can't export their product to the region. Even in the case of a Hong Kong-based company that wanted to establish its product in Mexico, the prime requisite was the local

presence. This is exactly where FreyrX team-Freyr's 'Xtended Global Presence with Local Expertise' came into the picture. It is mostly about establishing a local geographical presence to enable our clients avail the best of what we offer with quick turn-around-time.

Case 2: As part of another milestone in extending our local expertise, Freyr has helped a Hongkong based company to market their products (10 in number of cosmetics, herbals, food supplements etc.) in Mexico. In this case, our strong presence across the globe helped us to crack the deal as we could easily talk to necessary authorities and navigate the client through the respective region's regulatory regime.

MARKET-TAILORED BUSINESS STRATEGIES

With the rapid business expansion, defining market-tailored business strategies gained utmost significance. Right from decoding the requirements for defining comprehensive strategies to implementing them availing the best possible approach, companies should consider having abundant knowledge and a grip over the Regulatory regime. Many organizations have struggled to do this adequately in the past which resulted in consequent losses in terms of revenues and brand presence.

Case 1: The Regulatory Intelligence arm of the pharmaceuticals industry also plays a key role in establishing one's presence in the market. When an India-based company approached Freyr to help it with Good Manufacturing Practices (GMP) certification, Freyr looked at the whole picture. Either due to lack of competency or time, there are companies that fail to undergo auditing capabilities and adhere to the US or Europe GMP criteria. At such times, they opt for the WHO GMP certification instead. Right from listing down countries where WHO GMP is valid and helping the client launch its products in those countries first, to providing information about the additional work that is required for the next set of countries, Freyr did it all.

Case 2: For an existing customer, Freyr is glad to take up the project of deriving the ex-factory pricing. It was all about giving a number which we need to provide as a regulatory part while proposing the price as part of the pricing strategy. Instead of standard primary and secondary research and giving them a vague pricing number, Freyr suggested the client the best approach, i.e. to consult distributor to find out the floor pricing and take the margin which can help deciding the final price proposal. Everything said and done, client reverted with the same requirement for 28 more countries.

Case 3: For a globally evolving therapy concept, an India-based company obtained approvals in India and they are in plans to take their Pharma and Cosmetic product to APAC region. Freyr with a globally distributed expert network is working towards developing needed regulatory strategies getting to touch with respective health authorities to help the products registered across.

DEVICE/ PRODUCT CLASSIFICATION ACROSS THE MARKETS

The healthcare market is diverse, so are the services required. As a regulatory solution-provider company, one must be prepared to deal with unconventional products and ambiguous requirements, traverse through the constantly evolving regulatory landscape and provide a feasible solution in the end.

Case 1: To cite an example of the complexity, Freyr was recently approached by a medical device client based in China wrestling with the classification of their product for Europe market. The challenge was that the product has many active ingredients and it was very complex to decode the necessary proceedings. With a right catch of local expertise, Freyr was successful in obtaining detailed information for the client required for classification and now in the process of evaluating a document as the last step.

Case 2: In the other case, a food supplements company based out of Mumbai was finding ways to classify the required claims that they can do to take their natural extent product to JAPAC region. The irony was that the organization is concerned not only with regulatory approvals, but they need the claim classification to market their product in that specific region. Leveraging the Regulatory expertise, Freyr has presented a clear-cut analysis on the current claim status and suggested with what kind of formats they can improve or create a niche for themselves.

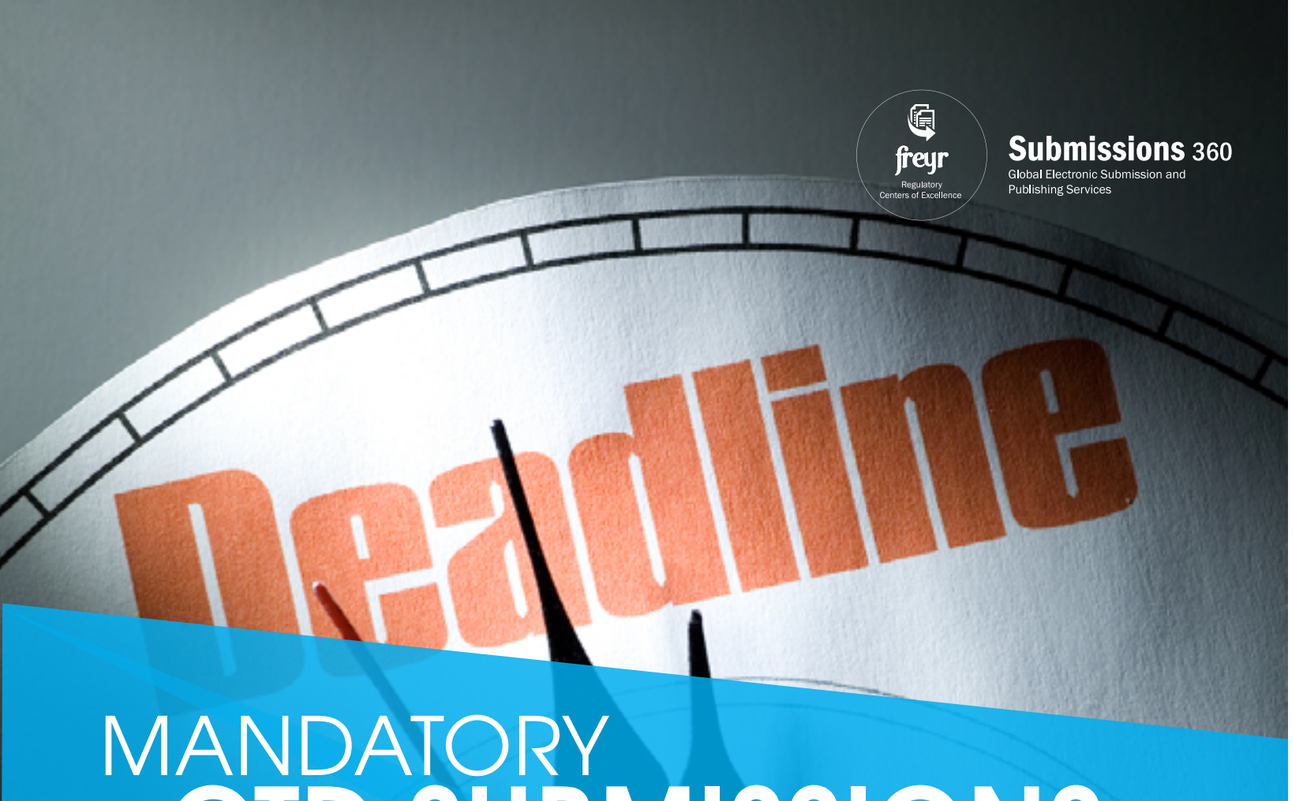
Case 3: On another case, the client was involved in developing a technology for which they were not sure of any (device) classification, which is currently being referred to. Freyr in consultation with our experts, assisted the client to contact the FDA and prepare 513(g) to figure out this unconventional requirement.

Case 4: On similar lines, there was a client, acquired by a search-engine giant, who developed an algorithm to be used for diagnostics purpose and was puzzled whether to integrate it to a medical device and promote or classify it as a separate HA defined product and put in the server. As said earlier, our expert consultant team are working together with the client to speak to the health authority and looking forward to giving a feasible solution.

Conclusion

All leading study reports reveal how the global life sciences industry is expected to grow at a formidable rate. But these expectations will be met only if the industry moves toward more specific market strategies. A comprehensive understanding of the highly significant but very diverse markets is therefore essential. One of the biggest drawback with past approaches is treating and keeping every given market in the same bucket. But the need of the hour is to create new, individualized approaches that exploit opportunities while avoiding pitfalls. To deliver optimum results, a regional Regulatory expert is all you need by your side.

Right from building on competency levels, increasing the consultant bandwidth, integrating the network, enhancing solutions and mapping the entire process and turning it into a well-defined structure, Freyr is firm to decode any given ambiguous challenge and is capable of catering a suitable solution to help you step into the unknown waters or perhaps never touched arenas of life sciences market terrain. All through, Freyr has been constantly playing a key role in working within regulatory parameters, balancing our clients' global competencies with tailored approaches for local markets, and providing the "right solution".



freyr
Regulatory Centers of Excellence

Submissions 360
Global Electronic Submission and Publishing Services

MANDATORY eCTD SUBMISSIONS. DECODE 'EM IN-DETAIL

For several years now, regulatory experts and the FDA alike have reiterated the many virtues of eCTD submissions. Right from being a faster and more efficient standardized process, enabling concurrent reviews and easy cross-referencing, the format of eCTD seems efficient and time-saving. But with the final guidance published in the Federal Register in May 2015 by FDA began the countdown to the mandatory implementation date when electronic submissions are required by the agency. This article talks about the regulatory requirements, challenges, and solutions to convert an Investigational New Drug Application (IND) to eCTD format.

Regulatory Requirements for eCTD submissions

» **Legislative enforcement:** Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), requires that submissions under section 505(b), (i), or (j) of the FD&C Act and submissions under section 351(a) or (k) of the Public Health Service Act (PHS Act) be submitted in electronic format specified by the FDA (or Agency) beginning no earlier than 24 months after the Agency (FDA) issued a final guidance specifying an electronic submission format.

» **FDA mandate for eCTD implementation:** In continuation to this legislative enforcement, on May 2015, FDA issued final guidance for submitting regulatory submissions in eCTD format and defined timelines for implementation of electronic submission (eCTD) requirements. This guidance mandates that any submission

(i.e. initial submissions or subsequent amendments/ supplements/reports to already submitted dossier) that is submitted to the agency after the date of requirement mentioned for the submission types identified in this guidance must be submitted in the electronic format described in this guidance document.

(Guidance Reference: "Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications."- May 2015)

Implementation timeline for electronic submission requirement

Submission Phase	Submission Type	Date requirement begins (Mandatory date for eCTD implementation)
Phase 1	NDA, ANDA, BLA	5th May 2017
Phase 2	Master Files, and Commercial INDs	5th May 2018

What happens after the deadlines for eCTD submissions?

» No paper and/or non-eCTD submissions are accepted after these deadlines for the submission types described in above mentioned FDA guidance.

» Submissions that do not adhere to the requirements stated in the eCTD Guidance will not be filed or received.

Phase 2 of mandatory eCTD Submissions

While the Pharmaceutical industry is busy in conversion of their applications to meet the first phase of eCTD mandate, all commercial IND holders and DMF holders must start searching for ideal ways to switch-over to eCTD format to comply with the second phase of eCTD mandate that starts from 5th May 2018. Let us decode the types in detail.

Commercial INDs: An IND for which the sponsor is usually either a corporate entity or one of the institutes of the National Institutes of Health (NIH). In addition, CDER may designate other INDs as commercial if the sponsor intends the product to be commercialized later.

Note: Food & Drug Administration (FDA) has exempted all submissions regarding non-commercial INDs from the requirements under section 745A(a). Although these submissions will be exempted, FDA will readily accept these submissions electronically.

Master Files (MFs): A Master File is a confidential, detailed document submitted by a pharmaceutical manufacturer to the US FDA. Based on the type of Master File, it will contain detailed information about facilities, processes, or ingredients used in the manufacturing, processing, packaging, and storing a concerned drug. Examples of Master Files are Drug Master Files (DMFs type I, II, III, IV & V), Biological Product Files (BPFs), Device Master Files etc. According to the FDA, a Master File is neither approved nor disapproved, but its information is used to review an IND, NDA, BLA, ANDA, or any other Application that refers the Master File.

Phase 2 Implementation and approach

» Most of the IND sponsors are not very clear about eCTD requirements and do not have regulatory set-up or in-house technology (submission tools) to convert their paper submissions into an eCTD format

» Most of the paper submissions of INDs were submitted in non-CTD format; most of the IND sponsors are new to CTD format and are not familiar with the organization of the IND technical information into CTD format

» Unlike a marketing authorization application, changes in the investigational phase are dynamic and these changes are required to be notified to the agency in the form of IND amendments/ Annual reports. In some cases, INDs may have

more than 100 amendments. Therefore, it is a tough challenge for an IND sponsor to switch-over to eCTD format for an IND with multiple amendments, especially when the subsequent submission requires a reference from previous submissions that were in paper format.

Therefore, IND sponsors require intensive support for conversion of their submissions to eCTD format. This can be successfully achieved when the IND sponsor has a suitable collaborative partner for eCTD conversion.

IND Submissions - Possible Paper to eCTD Switchover Approaches

Switchover from paper to eCTD for IND submissions can be done in the following two ways.

Approach 1 - Direct change over to eCTD format

» Since FDA does not insist to resubmit all the information of an IND that was previously submitted in paper format, sponsors can plan for direct change over to eCTD format for the subsequent submissions/amendments that are planned after 5th May 2018 for an already submitted IND.

» In this case, the applicant may require to re-submit the previously submitted (paper submission) data that might have referred in the new submission (amendment) in eCTD format to facilitate instant access for FDA reviewer.

» However, this approach may not be an ideal way for INDs with multiple amendments as the re-submission of reference data every time from previous submissions will be a difficult job for sponsors.

Approach 2 - Preparation of Baseline IND submission

» Even though FDA does not insist to resubmit all the information (in eCTD) that was previously submitted in paper format, a baseline submission is an ideal way to switchover from paper submissions to eCTD. This is because changes to investigational drug require referring the data from previous submissions every time a new amendment is submitted. Regulatory review without a baseline submission will be a daunting task for FDA reviewers as they would need to request for old paper submissions from the archives to refer to the information from previous submissions.

» In this approach, an applicant can create a data tracker in the first step. This data tracker will help in identifying the current (live information) from already submitted paper submissions (initial submissions & amendments). In the next step, the applicant can prepare a baseline IND by compiling the current information from previous submissions into Baseline IND with the help of the data tracker.

Major activities involved in IND conversion to eCTD format

» Communication to concerned Regulatory Project Manager at FDA about switchover plan to eCTD format, and intent to submit a Baseline IND sequence (if planned).

» ESG (Electronic Submission Gateway) accounts creation – This process includes creation of test accounts and production accounts, and dummy submissions to FDA to confirm that the intended electronic submissions meet all applicable standards.

» IND templates creation and compilation of submission package.

» Submissions in eCTD format (subsequent amendments or a Baseline IND).

» IND life cycle management in eCTD format.

Conclusion

Now that the eCTD conversion deadline approaches, it's time all pharmaceutical, biologic and generic manufacturers across the globe aiming at the US market convert the required applications in the eCTD format way ahead of time and prevent any last-minute hurdles. However, legacy eCTD conversion tools might hinder organizations' compliance efforts. Take advantage of a publishing and submissions and an eCTD conversion expert.

ORPHAN DRUG DESIGNATION

DECODE THE US PERSPECTIVE

In the article "Orphan Drug Designation- Decode the EU Perspective" published in our last newsletter, we discussed various criteria to qualify for Orphan Drug Designation when it comes to the European Union. In this article, we'll explore further and shed some light on how the methodology differs for the US market.

Even when the US and the EU agreed to apply a common application process for orphan drugs back in 2007, both the agencies maintain separate approval processes. The two Regulatory agencies have varied opinions when it comes to interpretation of acceptable risks and benefits, disease burden, affected populations, and associated economic costs. They also tend to have difference of opinion in terms of GMP inspections. For example, the FDA conducts its own audits and does not accept GMP certifications from other Regulatory agencies. Addressing these differences and further expanding the similarities can improve the alignment in the Regulatory requirements in the US and the EU, and result in greater cooperation in the orphan drug development and approval process.

Introduction to Orphan Drug Act – United States

People suffering from rare diseases must be equally entitled to receive quality treatment like other patients who are affected with well-established diseases. Approximately 25 million people across the globe are affected by more than 7,000 diseases which are categorized as rare diseases. There are hardly any approved drugs available for the treatment of these rare diseases. Surprisingly, in a span of 11 years (1972 to 1983), only 10 new drugs were approved for rare diseases. To provide quality treatment for patients suffering from rare diseases, the United States signed the Orphan Drug Act (ODA) on January 4, 1983, establishing a public policy with an intention that the Federal government will assist in the development of products for diagnosis, prevention, or treatment of the rare disease or condition. The key incentives/ benefits, as per the ODA to the sponsors who intend to develop orphan drugs are presented in Figure 1.

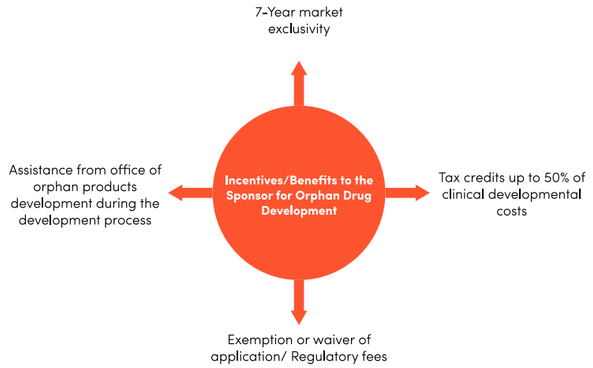
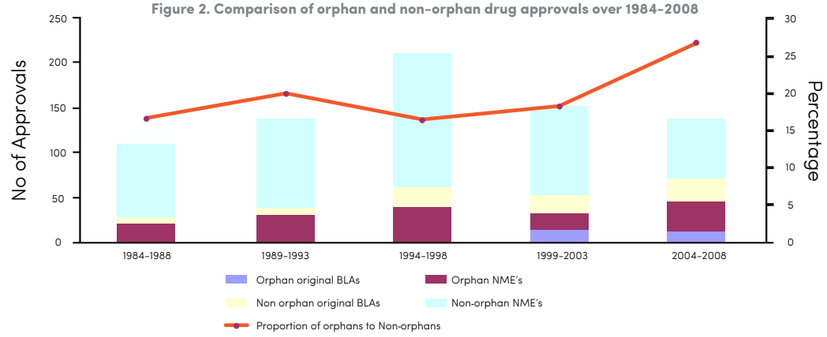


Figure 1. Incentives/ Benefits for Orphan Drug Development

The introduction of ODA has boosted the Orphan Drug Designation (ODD) grants as well as approvals for the treatment of rare diseases. Figure 2 depicts the orphan drug approvals over a period of 24 years from the year 1984 to 2008. Of the 3,500 ODDs issued by Office of Orphan Drug Development (OOPD) since 1983, 500 have resulted in marketing approval. Most of these have orphan exclusivity. During the Fiscal Year (FY) 2015, OOPD received a record 440 new applications for ODD. These included potential treatments for several kinds of rare cancers, sickle cell disease, and Ebola. OOPD designated a record 355 orphan drugs in FY 2015. Food and Drug Administration (FDA) approved 40 orphan designated drugs for marketing in FY 2015. The ODA grants ODD status to a drug or biological product to treat a rare disease or condition when sponsor requests. For a drug to qualify for ODD, the drug and the disease (or condition) must meet certain criteria specified in the ODA as well as FDA's implementing regulations as per 21 Code of Federal Regulations (CFR) Part 316

Figure 2. Comparison of orphan and non-orphan drug approvals over 1984-2008



Challenges for the Sponsors seeking Orphan Drug Designation and Grants

Being aware of the right process for Orphan Drug Application is crucial for the sponsors. The following are some of the challenges faced by the sponsors in the process of ODD application:

- The criteria for a drug and a disease to qualify for ODD and a rare disease, respectively
- A thorough knowledge of the application process
- The review process of Food and Drug Administration of Office of Orphan Drug Development (OOPD)

The subsequent sections of this article provide clear and concise information on the requirements and the essential steps for the ODD application to the OOPD:

- Criteria
- Tips for applying
- Review process and
- Benefits of Orphan Drug Application/Status

Prevalence Criteria to Qualify for a Rare Disease1, 2

The ODD is applicable to drugs that are used to treat conditions which meet any one of the two criteria mentioned below:

» The condition affects <200,000 people in the US, or

» The condition affects >200,000 people in the US, but the sponsor must successfully demonstrate that there is no reasonable expectation that the costs of development will be recovered solely from profits resulting from the sales of the developed drug

Criteria for Drugs to Qualify for ODD Application[4]

A sponsor may request ODD for:

» A previously unapproved drug, or a new use for an already marketed drug

» A sponsor can apply for ODD for a new drug to treat a rare disease for which an ODD drug is already designated for the same condition. However, the sponsor should provide a justification as to how the second drug is clinically superior to the already approved drug

» More than one sponsor can receive ODD of the same drug for the same rare disease or condition but each sponsor seeking ODD must file a complete application to the OOPD

A sponsor seeking ODD for a drug must submit a request for designation to OOPD with the information required in 21 CFR 316.20 and 316.21. The granting of an orphan designation request does not alter the standard Regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well controlled studies.

Content and Format of a Request for ODD Application[4]

A sponsor must submit 2 copies of a completed, dated, and signed request for designation that contains the following:

1. A statement that the sponsor requests ODD for a rare disease or condition, which shall be identified with specificity.

2. Sponsor's contact details, sponsor's primary contact person including title, address, telephone number, and email address; the generic and trade name, if any, of the drug, or, if neither is available, the chemical name or a meaningful descriptive name of the drug; and the name and address of the source of the drug if it is not manufactured by the sponsor.

3. Description of the rare disease or condition for which the drug is being or will be developed, the proposed use of the drug, and the rationale for the therapy.

4. Detailed description of the drug ranging from active moiety, physical and chemical properties, preclinical and clinical studies in detail proving the safety and efficacy of the drug in the treatment of the rare disease for which ODD is being claimed.

5. If a sponsor intends to seek ODD for a drug which is similar to a drug which is already designated as ODD, a proper explanation should be given as to why the proposed new drug may be clinically superior compared to the already existing ODD drug.

6. If a sponsor requests for ODD for a drug for only a subset of persons with a particular disease which otherwise affects more than 200,000 people (Orphan subset), the sponsor must demonstrate that the drug is not appropriate for other people and it has use only for the population for which it is being claimed.

7. Summary of Regulatory status, marketing application status, under investigation, IND and diseases for which the drug is being marketed in the United States and in foreign countries.

8. Documentation, with appended authoritative references to demonstrate that both the drug and the disease meet the criteria to qualify for ODD and rare disease, respectively. Also, there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the US.

Tips for Submitting an Orphan Drug Designation Application

1. The required information to be included in the application can be found under 21 CFR 316.20(b), shown as (8) items
   – Number the items in application 1 through 8 and respond to the 8 items as described. Creative numbering is not helpful

2. All the 8 items will be reviewed
   – The application will be reviewed most critically in two areas: scientific rationale and population prevalence. Prevalence and incidence are two different entities and it is recommended to be cautious while presenting; as they cannot be substituted for one another.
   – The application must contain a copy of every reference used in the application. References can be included from published sources, authentic websites, etc. A hard copy of each reference must be provided to the health authority to ease the review process.

3. Information provided by the sponsor relating to Item 7 (A summary of the Regulatory status and marketing history of the drug in the United States and in foreign countries) is often incomplete. It is advisable to provide Investigational New Drug (IND) or New Drug Application (NDA)/Biological Application (BLA) numbers, if available.
   – Sometimes sponsors may submit an NDA/BLA after they have requested orphan designation. In case the OOPD has not decided on the ODD application by the time the NDA/BLA is submitted, the sponsor can amend the application for ODD by providing a copy of the NDA/BLA (or supplement) acknowledgment letter received from the FDA Reviewing Division.
   – In case a product is approved abroad, list the countries where it is approved along with additional details of market exclusivity. It is helpful for the reviewers if copies of the package insert(s) are also provided.

4. Application should be formatted appropriately. The reviewer of the application should be able to examine your application with ease.

5. Submit the original and one photocopy of the application in separate binders or report covers to the OOPD. If there is a cover letter with the original, there needs to be a copy of the cover letter with the photocopy as well. It helps to label the front of each report cover with the name of the sponsor, drug/biological, indication, and date of application.

6. Submit the application (one original and one photocopy) for orphan designation to:

   Name of the person
   Director, Office of Orphan Products Development
   10903 New Hampshire Avenue
   WO 32-5295
   Silver Spring, MD 20993

Review Process

Application is received by OOPD

A designation application number is assigned and logged into OOPD database

An acknowledgement letter is sent to the sponsor

Assigned OOPD reviewer completes the review of the application by preparing a review

The review is forwarded to the OOPD Team Leader for a 2nd level review and concurrence

The review is forwarded for a 3rd level review by the OOPD Office Director

Post Office of Orphan Products Development(OOPD) Director's concurrence, a designation letter, a letter requesting additional information, or a denial letter is prepared for the Director's signature and the letter is issued to the sponsor

Conclusion

The introduction of ODA in the US has been successful in enabling patients with rare diseases to receive quality treatment. Since the approval of ODA in the US, 448 orphan products have received approvals. In addition to the incentives, additional Regulatory pathways which help to expedite the development and approval of drugs for conditions of unmet medical need have been of great help for the sponsors. In addition, the active involvement of patient organizations in the drug development process itself is changing the way orphan drugs are being developed.

Appropriate approach towards the Orphan Drug Designation (ODD) application is essential for sponsors who intend to provide treatment for patients suffering from rare diseases. Knowing the rules and regulations of the FDA and proactively submitting the ODD application with the applicable requirements, is highly advantageous for the sponsors in receiving faster approvals and grants for Orphan Drugs.

References

1. Hall AK, Carlson MR. The current status of orphan drug development in Europe and the US. Intractable & Rare Diseases Research. 2014; 3(1):1–7.
2. Thomas MT. The Orphan Drug Act and the development of products for rare diseases. Office of Orphan Products Development Food and Drug Administration.
3. Office of Orphan product development. US FDA. Available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM488554.pdf. Accessed on 03 Feb 2017.
4. US FDA. How to apply for Orphan Drug Designation. 2015.
5. US FDA. Tips for submitting an application for Orphan Designation. 2015.
6. US FDA. Designating an orphan product: drug and biological products. 2015.

FREYR CONTINUES ITS RAPID GLOBAL EXPANSION

Establishes an exclusive regional hub in Dubai, UAE

> *We see it not only as another regional establishment, but also as a regional hub in terms of offering highly localized Regulatory support and services to our clients across Middle East and Africa as well as global companies looking to have their products registered / managed in the region.*

As an integral part of its global expansion strategy, Freyr establishes, Freyr DWC LLC in Dubai, its 5th Regional office / delivery hub after US, UK, Germany and India. Proposed to serve its significantly growing client base in the region, the new set up, Freyr DWC, LLC, covers both the Middle East and African markets to cater localized regulatory strategies and services along with technology-driven solutions

With proven expertise in enabling the successful registrations and approvals in the region, Freyr through its Dubai's regional hub will embark its focus on emerging business opportunities in the region. Located at one of the prestigious Investment Parks in Dubai (Dubai Logistics City at Dubai South) Freyr DWC, LLC is focused to meet the dynamic Regulatory challenges with high-quality Regional regulatory services at low delivery costs.

"We see the Dubai office set up not only as another regional establishment, but also as a strategic hub in terms of offering highly localized Regulatory support and services to our clients across Middle East, Africa as well as global companies looking to have their products registered / managed in the region. Addressing the needs of growing client base in the region, we hope our new set up will address the needs of companies seeking a reliable, regional, regulatory partner. With a successful track record of regional registrations and approvals, the Freyr office in Dubai stand a great testament to our growing international presence and enduring customer relationships."

THE IMPORTANCE OF RIGHT-FIRST-TIME (RFT) IN DEFINING MEDICAL WRITING SPHERES

Quality defects have significant costs associated with them – some of the most obvious ones being money, time, resources, and lost reputation. At the same time, programs to eliminate quality defects can be both expensive and time-consuming. In such scenarios, adopting the notion "Zero defect" can be a viable option for organizations. "Zero defect" is a defined and a thorougly thought process which reinforces the fact that defects are not acceptable, and that everyone should "do things right at the first time".

The very fact revolves around the philosophy of 'right-first-time (RFT)' and how one can increase profits both by eliminating the cost of failure and by enhancing customer satisfaction. It does so by demanding that you:

» Recognize the high cost of quality issues

» Continuously think of the areas where flaws may be introduced

» Work proactively to address the flaws in your systems and processes, which allow defects to occur

From high level strategic planning and decision making to detailed execution of work elements, quality is mainly concerned with continuous improvement across the lifecycle. Thus, RFT also deals with continuous improvement. It stems from the belief that mistakes can be avoided and defects can be prevented. The root cause of such mistakes can be identified and eliminated, and repetition can be prevented by changing the process. There are two major mechanisms of prevention:

» Preventing mistakes (defects) from occurring (mistake-proofing)

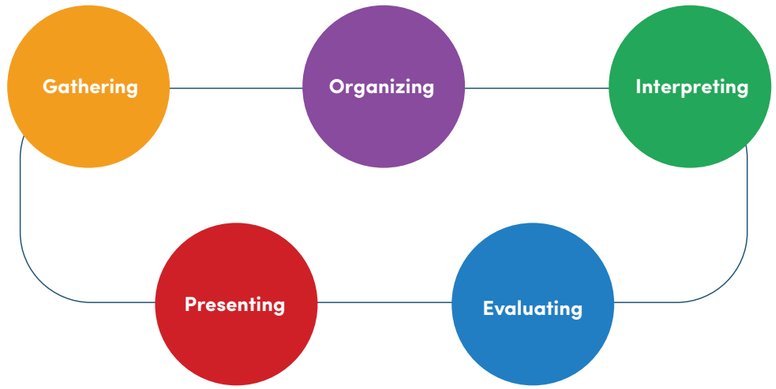
» Where mistakes can't be absolutely prevented, detecting them early to prevent them being passed down

Continuous improvement must deal not only with improving results, but more importantly with enhancing capabilities to produce better results in all aspects of work: people, processes, technology and machine capabilities.

With that said, adapting the right-first-time starts with defining a good set of requirements, which is critical for project success and is hardly a technical issue. It primarily involves human interaction and coordination, along with an organized approach. Most of the projects succeed when they stay focused on the outcome, so that whatever is developed aims to satisfy the need and deliver only what is required.

Applying the same in scientific documentation involves navigating through a set of Medical Writing Spheres: gathering, organising, interpreting, presenting, and evaluating.

Five Medical Writing Spheres



Gathering

» Determine purpose of the document

» Identify target audience

– Assess needs

– Identify knowledge gaps

» Select appropriate output type (for example, publications, regulatory documents, patient education)

» Check gathered information about

– Content (quality, relevance and level of evidence)

– Context (credibility of sources and suitability of purpose)

» Apply effective process to gather information

– Conduct literature search

– Elicit information from collaborators and stakeholders (for example, researchers, statisticians, clinicians)

– Identify other relevant sources (websites, databases, data outputs, clinical guidelines)

– Identify relevant writing guidelines, instructions, and ethical standards (regulatory requirements, journal instruction for authors)

– Identify relevant document models and templates

Organizing

» Design project work plan

– Determine deliverables

– Develop timelines

– Recognize roles, responsibilities, and processes

» Develop an outline

» Apply templates and guidelines to documents

» Determine organization of documents

» Identify and prioritize key elements of content

» Structure the content to communicate accurate message

» Determine structure of tables and figures to best communicate the data

» Determine which references to cite in the document

» Track progress and status of projects (internally and externally)

» Determine process for tracking changes and version control

Interpreting

» Comprehend relevant medical and scientific content

– Understand terminology

– Understand concepts (i.e., molecular level, population level)

– Understand study design (e.g. clinical trial, case-control, longitudinal study)

– Understand statistical concepts (e.g. P value, confidence interval, power)

» Interpret clinical and numeric data

» Derive key messages

» Determine inferences, implications, or clinical relevance

» Synthesize and integrate information

» Revise or repurpose existing content

Presenting

» Present the message logically and coherently (i.e., tell the story)

» Retain the intended meaning of source documents or original document

» Communicate content in an appropriate manner

» Communicate statistical content in an appropriate manner

» Develop clear and concise prose

» Structure the abstract (e.g. for presentation or publication) or executive summary

» Tailor prose to the audience

» Build persuasive and science-based arguments

» Apply proper mechanics

» Apply rules of grammar, spelling, and punctuation

» Apply proper word usage (general and medical), correct nomenclature, and non-discriminatory language

» Construct effective sentences

» Construct effective paragraphs (e.g. topic sentences, transitions, repetition of key terms)

» Apply techniques for cohesion between paragraphs and sections

» Apply principles of visual presentation of data

» Write document to adhere to standardized formats, guidelines, instructions, and ethical standards

» Be consistent

Evaluating

» Perform fact or data check

» Identify inconsistencies in data or other content presented

» Conduct critical review of draft

– Assess quality of writing (e.g. clarity, readability, logic, organization, consistency and flow of information)

– Provide constructive criticism

› Think through the options for solutions

› Craft appropriate queries

– Evaluate representation and description of data

– Recognize ethical considerations with respect to self and others (e.g. copyright issues, conflict of interest, disclosure, authorship, plagiarism, duplicate publications)

» Evaluate for completeness, fair balance, and absence of bias

» Determine appropriate levels of editing (e.g. quality check, proofreading)

Conclusion

The question that often comes up is whether Right-First-Time (RFT) is ever attainable or not. RFT is NOT about being perfect. It is about changing your perspective and a measure against which any system, process, action, or outcome can be analyzed. It is one of the best ways to resolve the discord between what we expect for ourselves and what we can accept for others. Adapting or integrating RFT into organizational medical writing processes could lead to streamlined processes and meticulous documentation for end-to-end compliance.

TYPES OF CLINICAL STUDY DESIGNS

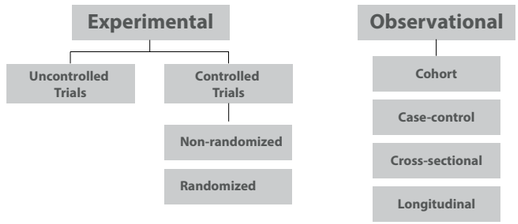
Clinical study design is the formulation of trials and experiments, it also deals with observational studies in medical, clinical and other types of research (e.g., epidemiological) involving human beings.

The goal of a clinical study is to assess the safety, efficacy, and the mechanism of an action of an investigational medicinal product or procedure, or new drug or device that is under development, and which has not yet been approved by a health authority (e.g. FDA, TGA, EMA).

Clinical study design can be used to investigate a drug, device or a procedure that has already been approved or which is still in need of further investigation, typically with respect to long-term effects or cost-effectiveness.

Types of Clinical Study Designs

Analytical Study



Study designs can be categorized into Experimental Study and Observational Study

Experimental Study

It is the study in which a treatment, procedure or a program is intentionally introduced and a result or outcome is observed. True experiments have four elements i.e. manipulation, control, random assignment and random selection. Manipulation and control are the most important elements. 'Manipulation' means that something is purposefully changed by the researcher in the environment, wherein 'Control' is used to prevent outside factors from influencing the study outcome. Moreover, experiments involve highly controlled and systematic procedures to minimise errors and bias.

1. Uncontrolled Trials:

It is a study without a control group which is in contrary to a controlled clinical trial.

A study in which all the participants are given a treatment and simply followed for a period of time to observe if they improve, with no comparison against another group (control group) that is either taking another treatment or no treatment at all.

2. Controlled Trials:

Controlled trials are clinical trials which involve at least one control treatment and specified outcome measures for evaluating the studied intervention, and a bias-free method for assigning patients to the test treatment.

The treatment can be drugs, devices, or procedures studied for diagnostic, therapeutic, or prophylactic effectiveness. Control measures include placebos, active medicines, no-treatment dosage forms and regimens, historical comparisons, etc. When randomization, such as the use of a random numbers table and mathematical techniques, is employed to allow patients to test or control treatments, the trials are characterized as Randomized Controlled Trials (RCTs).

a. **Non-randomized Clinical Trial:** A study where participants have been assigned to the treatment, procedure, or intervention alternatives by a method that is not random. The investigator defines and manages the alternatives.

   Non-Randomized Trial is used under the following conditions:

» When the act of random allocation may reduce the effectiveness of the intervention

» When it would be unethical to do random allocation

» When it is impractical to do random allocation (e.g. cost or convenience factors)

» When there are legal or political obstacles to random allocation

b. **Randomized Clinical Trial (RCTs):** RCTs are quantitative, comparative, controlled experiments in which investigators study two or more interventions in a series of individuals, who receive them in random order. It is one of the simplest and most powerful tools in clinical research.

   RCT is a study in which people are assigned at random (by chance alone) to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice, a placebo, or no intervention at all. The one who takes part in a randomized clinic trial (RCT) is called a participant or subject. RCTs seek to measure and compare the outcomes after the participants receive the interventions.

Observational Study

It is a study, which draws inferences from a sample to a population where the independent variable is not under the control of the researcher because of ethical concerns or logical constraints.

The uses of observational study are as follows:

» It provides information on "real-world" use and practice

» It detects signals about the benefits and risks of the use of practices in the general population

» It helps formulate hypotheses to be tested in subsequent experiments

» It provides part of the community-level data needed to design more informative pragmatic clinical trials

a. **Cohort Study:** A particular form of longitudinal study where a group of patients is closely monitored over a span of time. A study in which a defined group of people (the cohort) is followed over time, to examine associations between different interventions received and subsequent outcomes.

   A 'prospective' cohort study recruit participants before any intervention and follows them into the future.

   A 'retrospective' cohort study identifies subjects from past records describing the interventions received and follows them from the time of those records.

b. **Case-Control Study:** A study originally developed in epidemiology, in which two existing groups differing in outcome are identified and compared based on some supposed causal attribute.

   A study that compares people with a specific outcome of interest ('cases') with people from the same source population but without that outcome ('controls'), to examine the association between the outcome and prior exposure (e.g. having an intervention). This design is particularly useful when the outcome is rare.

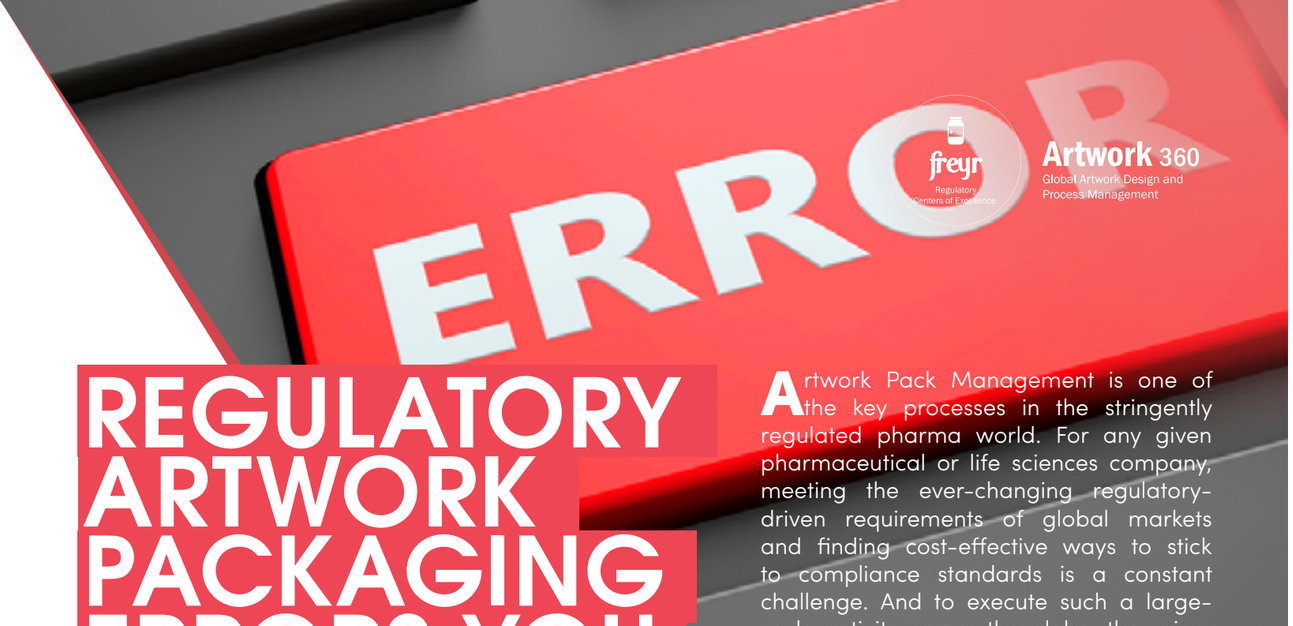
c. **Cross Sectional Study:** It involves data collection from a population, or a representative subset, at one specific point in time.

   A study that collects information on interventions (past or present) and current health outcomes, i.e. restricted to health states, for a group of people at a particular point in time, to examine associations between the outcomes and exposure to interventions.

d. **Longitudinal Study:** It is a correlational research study that involves repeated observations of the same variables over long periods of time.

Conclusion

Clinical study design is the formulation of trials and experiments involving human beings. Through these study designs, the safety, efficacy and the mechanism of action of an investigational medicinal product or procedure or new drug or device that is in development, but potentially not yet approved by a health authority can be determined. Various factors should be taken into consideration while selecting a study design as different types of studies are subject to different types of bias.



REGULATORY ARTWORK PACKAGING ERRORS YOU MUST AVOID

Artwork Pack Management is one of the key processes in the stringently regulated pharma world. For any given pharmaceutical or life sciences company, meeting the ever-changing regulatory-driven requirements of global markets and finding cost-effective ways to stick to compliance standards is a constant challenge. And to execute such a large-scale activity across the globe, the prime requirement is the right mixture of business processes, design, information technology, and facilities.

The primary objective of any organization is to experience zero product recalls, faster turn-around time, increased transparency and an integrated model that supports multiple languages across the globe. But when it comes to developing and managing Artwork and Packaging for huge product portfolios involving many personnel across the globe and pertaining to different organizations, errors are bound to happen. To streamline the artwork processes, organizations must avoid certain errors anticipated.

Packaging Artwork Errors, You Must Avoid

» Gross Error: This involves a significant information being overlooked while designing and packaging. For instance, if an organization fails to change a piece of artwork in accordance with the latest regulatory requirement, it will lead to incompliance and it should be avoided.

» Contextual Error: When any given information is provided in an ambiguous or unclear way, it creates undue confusion in turn.

» Content Error: Any possible significant omission or incorrect usage of content.

» Technical Error: As the name suggests, any error or omission in the technical aspects of the artwork. For instance, an incorrect barcode.

To avoid any grave and far-reaching implications of such errors affecting overall costs of an organization, a robust Artwork Management System (AMS) needs to be in place. The pharma and life sciences organizations could try reaching out to specialized companies that combine their well-adept regulatory and creative process expertise and diligently provide innovative, scalable and cost-effective regulatory artwork pack management solutions and services to support industries across the globe.

STEP-BY-STEP PROCESS OVERVIEW OF REGULATORY ARTWORKS

With years of time spent on innovating new drugs, life sciences organizations, sometimes, take a backseat to allocate sufficient time for artwork design processes that result in inaccurate and incompliant marketing of products followed by product recalls affecting the overall costs. With defined Regulatory artwork processes, organizations can sustain critical situations like these especially in time-bound outcomes.

What exactly are defined artwork processes?

Defined artwork processes are standardized procedures for managing artwork creation as per pre-defined source files, dielines, brand guidelines, and print supplier requirements from a central web-based enterprise platform - Artwork Design and Pack Management system. Right from gathering the required content to delivery and distribution of a given product, the system defines the steps involved to release error-free artworks consistently with minimal effort. Such as:

01 Content Collation

All related project information is usually scattered at multiple locations. The primary requirement is to gather all the source files, specification files, key lines and briefs for reference.

02 Artwork Creation

To begin with, the core design team primarily requires expertise in Illustrator, Indesign, Quark Express, and few other specialized designing software. Secondly, the team must have a basic understanding of the market, site and print supplier requirements.

03 Version Control

The version control keeps track of all created drafts and versions of an artwork file. It also regulates all approvals and authorizations of new artworks, along with systematic control to identify the latest artwork for amendments.

04 Artwork Approvals

The robust web-based Artwork Management System does not involve the hassle of paperwork. All functional approvals during the artwork process are carried out through electronic signatures on electronically stored originals.

05 Digital Asset Management

In the regulated industry, authorities and quality standards define high demands on how records such as files and information are stored and maintained in electronic archives. The archiving system must comply with requirements for audit trail, electronic signatures, version control.

06 Delivery and Distribution

Once the artwork and print-proof approvals are done, the order is released for production, delivery, and distribution.

What appears as simple packaging types namely, labels, cartons, leaflets etc. require concerted effort of different parties and sponsors which take months for beautification and to be presentable with print-ready artwork. Not only reducing the compliance risk, but also making the artwork creation process cost-effective poses significant challenges for the manufacturers and marketers. A regulatory solutions and services provider with defined artwork design and pack management system could prove useful during large-scale productions for biopharmaceutical companies.

Freyr IDMP

WHY WAIT UNTIL THE FINAL CALL?

Embrace the IDMP Data Standards, Right Away.

- Define data models / structures that are capable to be aligned with final IDMP rule
- Harmonize enterprise-wide master data to progress towards IDMP compliance
- Be future-ready by integrating efficient, effective, and agile system

GET READY.
FREYR IDMP.

REACH US AT

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STRUCTURED PRODUCT LABELING

WHAT ARE ITS COMPONENTS?

Managing product information is quite a task. In the stringent world of life sciences, to do so, manufacturers must follow certain standards and procedures which are aligned to FDA's regulations. Not only do they have to follow the set procedures but they are also required to maintain accuracy and integrity of information to be prescribed for end-to-end compliance.

With so many stakeholders namely, patients, physicians and pharmacists relying on the prescribed information, there might be a chance for significant discrepancies. There arises a need for developing uniform labeling content. Consistently revising the content and formats of the prescribing information, the US FDA adopted a set standard called Structured Product Labeling (SPL) to assist in greater patient safety and increased usability of product information.

What exactly is Structured Product Labeling (SPL)?

Structured Product Labeling (SPL) is a Health Level Seven International standard (a standards development organization accredited by the (ANSI) American National Standards Institute) which defines the content of human prescription drug labeling in an Extensible Markup Language (XML) format.

The new format enables health care professionals to quickly search and access specific prescribing information and reduces medication errors in turn. It also supports initiatives to improve patient care through electronic prescribing and improves the drug labeling review process enabling FDA to provide immediate access to the most recent drug information.

SPL documents primarily consist of two main components:

» First, the content of labeling that include all texts, tables and figures for a product

» Second, the additional machine readable information constituting the drug listing data elements such as product ingredients, generic names, dosage forms, routes of administration, appearance, and packaging quantity and type

Challenges & Solution

Product labeling in life sciences is a highly regulated and complex process. Not only should it be extremely specific in its content, but it should also comply with country-specific labelling regulations. Structured Product Labels (SPLs) may be a small component of eCTD submissions, but it can be quite a task for an organization's regulatory team if the technical specifications and time requirements are not well grasped and followed. Without working knowledge of how extensible markup language (XML) works, it is highly probable that an organization would encounter several technical issues and spend considerably more time and energy. Consult an industry expert, familiar with the intricacies of XML to avoid an SPL rejection, and ensure error-free and timely implementation of FDA submissions.

THE IMPORTANCE OF REGULATORY INTELLIGENCE

Wading through uncharted waters is always risky and mount numerous pressures on organizations. It not only affects an organization's financial status quo but also imposes threat to its brand image. If it is the same in the life sciences sector, the situation may lead to incompliance and untimely drug approvals, thus posing a threat to patient safety. Having said that, the need of the hour is to gain insight on the ever-evolving market updates. Whether it is the recent announcement of cutting down a major part of the FDA's regulations or warnings on data integrity violations, manufacturers must know the industry insights to pave a strong strategic Regulatory pathway. Today's regulatory professionals must understand not only the regulatory guidance for each geographical market in the world but also the hot-button issues that affect the review of new drug applications in these regions. With the globalization of life sciences industry making the regulatory landscape more complex than ever before, there is a growing need of intelligent Regulatory information services. Here we explain why...

What is Regulatory Intelligence?

Regulatory intelligence (RI) is a relatively new arm of global regulatory affairs (RA). Usually part of a biopharmaceutical company's RA department, it broadens the traditional regulatory affairs function beyond preparing and submitting applications to the FDA and other regulatory agencies across the globe. The primary scope of RI involves keeping the company's leadership up-to-date about current regulations affecting the development, approval, and maintenance of drugs/devices/cosmetics to updating them of any changes to the regulations that may impact their efforts.

Besides this, RI focuses on regulatory pathways associated with drug development and approval process, often using historic decisions of regulatory agencies to gauge potential future decisions. It also contributes to every biopharmaceutical company's bottom line by helping the RA teams provide the best quality submissions to agencies.

The Importance of Regulatory Intelligence

Continuously changing regulations and increased liability: Change is constant and one needs to keep pace with it. In 2015 alone, 243 new guidance documents were issued, in comparison to only 117 back in 2012. In today's pharma world, even a seemingly small shift in the business or regulatory environment can have huge ripple effects.

» Data-driven decisions: A study conducted by the MIT Centre for Digital Business revealed that data-driven organizations reported 4% higher productivity rates and 6% higher profits than others in the industry. Knowledge of these numbers significantly affect the overall bottom line of a company and hence is hard to ignore.

» Hard benefits: The most obvious Return on Investment (ROI) calculation is the cost savings created by eliminating manual processes. For example, an integrated RI system can help eliminate the requirement for a manually updated spreadsheet-based regulatory process, which is also liable to errors. An RI system accurately organizes all relevant documents into one research, thereby improving the visibility and accountability for all data-driven regulatory decisions.

» The 'soft' benefits: A decently set-up RI tool can extensively track competitor activity without requiring significant man-hours to do so. Not only will this lead to more productive research time, but would also let staff easily handle workloads and deadlines.

» Time-saving: Keeping up to speed with the ever-changing global regulatory environment is vital to professionals involved in the clinical development, launch, and post-marketing surveillance of drugs. With many different sources of information, finding and analysing what you need for submissions and beyond is a time-consuming task. To make the right decisions for your organization, quick access to accurate information can make all the difference.

» Information analyses: Only knowing where to find the applicable regulation is not a regulatory consultant's only service. They are hired to interpret those requirements, which is what regulatory intelligence is. It can be gained through experience working with regulatory agencies and companies developing novel products. Regulatory consultants, who spend a lot of time talking with regulatory agencies, understand current agency thinking. They also likely have gained useful knowledge from past projects contributing to reduced risk for the current client project.

Conclusion

In conclusion, change is permanent. Sailing along with it or being ignorant makes all the difference. Regulatory change is viewed as a key component of organizations' strategic planning process. To support your company with a single, comprehensive source for global regulatory information in order to make faster, more informed decisions, you need an industry expert with a dedicated Regulatory Intelligence discipline.

Regulatory **Dossier** 360
Global Regulatory Dossier Services

A QUICK GUIDE TO THE FDA CLASSIFICATION OF MEDICAL DEVICES

Before you launch any product in the market, it's important to have a fair understanding of the product classification. Not only will this invaluable knowledge help you assess what all you need to prepare at your end before the product is valid to be sold in any given market, it will also help you establish what is required during product development & design controls, and most importantly, it will enable you to determine the cost to launch this product in the market and estimate the amount of time it would take to launch it. The same theory applies for a Medical Device product. In this article, we'll discuss as to how the US FDA's Center for Devices and Radiological Health (CDRH) classifies this product under different categories. But first, let's determine if your product meets the definition of a device.

What is a Medical Device product?

A Medical Device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for:

» Diagnosis, prevention, monitoring, treatment or alleviation of disease,

» Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

» Investigation, replacement or modification of the anatomy or of a physiological process,

» Control of conception

In short:

"a product which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"

Medical devices are central to medical practice, although they are often lesser known to the public and policymakers than other products including pharmaceuticals. According to Global Medical Device Nomenclature (GMDN), there are over 14,000 different product types such as adhesive bandages, drug delivery devices, diagnostics, implanted cardiac, cardiovascular, and neurological devices, stair-walking wheelchairs, robotic surgical systems and magnetic resonance imaging devices. Medical devices and diagnostics allow people to live longer, healthier and more productive lives.

Pre-Amendment Devices Vs Post-Amendment Devices

The term "Pre-Amendments devices" refers to devices legally marketed in the United States by a firm before May 28, 1976 and which have not been significantly changed or modified since then; and for which a regulation requiring a premarket approval (PMA) application has not been published by the FDA.

"Post-Amendment devices" are medical devices marketed after 28th May, 1976. Because medical technology has changed greatly since 1976, almost all 510(k) submissions claim substantial equivalence to a "Post-Amendment" device that has been recently cleared under the 510(k) process.

	Pre-Amendment Devices	Post-Amendment devices
Classification	Received a recommendation from a device Classification Panel Published the Panel's recommendation for comment, along with a PR classifying the device; and Published a Federal Register (FR) classifying the device	Post-amendment devices are automatically classified into Class III Those devices remain in Class III and require premarket approval, unless and until -the device is reclassified into Class I or II -FDA issues a Substantial Equivalence (SE) determination
Reclassification by FDA	In a proceeding that parallels the initial classification proceeding Based upon "new information" developed because of re-evaluation of data before FDA originally classified or not presented, available, or developed at that time	Maybe initiated by either FDA or Industry FDA may, for good cause shown, refer the petition to a device classification panel The Panel shall make a recommendation to FDA respecting the petition

FDA Classification of Medical Devices

FDA classifies medical devices based on the risks associated with the device.

Class I: General control

Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as Class I device. They are:

» Subject to the General controls & least regulatory control

» Are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury

Most are exempted from the premarket notification and/or GMP regulation

General controls include:

1. Prohibition against adulterated or misbranded devices
2. Premarket notification (if reserved)
3. Banned devices
4. GMPs
5. Registration of manufacturing facilities
6. Listing of device types
7. Record keeping
8. Repair, replacement, refund

Class II: General controls with special controls

Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and

effectiveness. For example, powered wheelchairs are classified as Class II devices. This class of devices are subject to special controls, special labeling requirements, mandatory performance standards and post-market surveillance. Few are also exempted from the premarket notification.

Special Controls include:

1. Performance standards (discretionary, voluntary national or international standards, or ones recognized by rulemaking)
2. Post-market surveillance (required or discretionary)
3. Patient registries
4. Development and dissemination of guidelines/ guidances
5. Design controls
6. Recommendations and other appropriate actions
7. Tracking requirements

Class III: General controls and premarket approval

Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. For example, heart valves replacements are classified as Class III devices.

A Class III device needs:

» Premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I device

» Usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury

Ambiguity related to Medical devices and Drug in India

In India, the most common misconception about medical devices is that they are the same as pharmaceuticals. For example, only six percent of survey respondents believe that devices are different from drugs, a misconception that stems from the fact that both are used to treat diseases. However, as the table below highlights, the two are very different.

	Medical Devices	Drugs
Diversity	Extremely diverse group of products involving several components	Single-molecule drugs
Scientific disciplines involved	Active components are generally based on mechanical, electrical, and materials engineering	Based on pharmacology and chemistry, and increasingly encompass biotechnology and genetic engineering
Product development	Typically have a short product life cycle (18 to 24 months) and investment recovery period. Even in early stages, market competition is intense	Typically have a long commercial life-cycle (10-20+ years), during which they do not undergo significant changes
Patent structures	Due to the wide variety of structures and technologies embodied, many different patents cover a single medical device. Thus, patents are not the basis for competition and do not confer market exclusivity	There are typically very few patents for individual pharmaceutical products. Patents form the basis of competition

Link/ References:

1. https://www.fda.gov/AboutFDA/Transparency/Basics/ucm193731.htm
2. https://ec.europa.eu/growth/sectors/medical-devices_en

CASE STUDY

Time-critical GMP Audit Services and Report Preparation

Compliance360
Global QA, GCP, IT Validation Services and Audit Support Services

CLIENT

Swiss-based, Fast growing Generic Pharmaceutical Organization & CMO

GEOGRAPHY / LOCATION(S)

Geneva

FUNCTION(S)

Audit and Compliance

SERVICE(S) / SOLUTION(S)

cGMP

THERAPEUTIC AREA(S) / INDICATION(S)

Anti-tubercular

PRODUCT(S)

APIs

BENEFIT HIGHLIGHTS

- Quick turnaround in audit completion and report preparation in 10 working days to avoid potential Non-Conformance (NC) from Regulatory Authorities
- Planning, execution and report preparation in quick turnaround timeframes, completed in 2 weeks
- High quality Audit with recommendations as per the latest Agency standards
- Avoiding a potential Non-Conformance from Regulatory authority (regarding auditing API suppliers)

Business Imperatives

Client wanted Freyr to audit their API Suppliers

- Manufacturing Facilities
- Processes

Challenges

- Quick turn-around-time since the Pharma company was about to undergo a Regulatory audit
- There are two API providers
- cGMP regulations and guidelines plus Swiss-specific regulations
- Audit to be completed in one day

Freyr Solutions & Services

- Freyr proposed a team of auditors (2) with GMP expertise for Facility audit
- Pre-audit checklists were customized and sent to API suppliers to understand facility and organization structure and determine the scope of the audit
- The audit of Quality Management System (QMS) documentation and Facility were separated out to prevent any delay
- Draft of audit report was generated within 1 week and discussed with the Company
- Complete audit report was submitted in 10 working days

CASE STUDY

Global Regulatory Assessment

Consumer 360
Specialized Regulatory Services For Consumer Healthcare

CLIENT

Global Top 5 Consumer Products Company

GEOGRAPHY / LOCATION(S)

Piscataway, New Jersey

FUNCTION(S)

Regulatory Affairs – Consumer and Pharma

SERVICE(S) / SOLUTION(S)

Regulatory Consulting, Regulatory Lifecycle Management

THERAPEUTIC AREA(S) / INDICATION(S)

Oral Care, Personal Care, Skin Care

PRODUCT(S)

OTC/Consumer

BENEFIT HIGHLIGHTS

- Global Regulatory workload assessment for entire portfolio
- Optimal volume and resource model development based on data
- Provision of future state centralized resource model
- Significant benefits of centralization for Regulatory operational activities
- Comprehensive roadmap for implementing a centralized process for global Regulatory operations
- Advanced strategy derived to collate operational resources into a centralized location
- Locally-placed Regulatory leads to focus more on Regulatory Strategy and Product expansion while having limited oversight on operational activities

Business Imperatives

The company is known popularly for its oral care and personal care products. Freyr is associated with the client's Regulatory Affairs and Operations Strategy with regard to:

- New Product and Lifecycle Management
- Labelling and Artwork
- Export Activities
- Formulation Review
- Regulatory Assessments

Challenges

- Lack of a global centralized document repository
- Dossier requirements varied across regions
- Global brands were classified differently across markets
- Review process for artwork and formulations were not consistent across regions due to technology not being fully implemented
- Resource activities varied based on level of Regulation at local markets

Freyr Solutions & Services

- Reached out to 22 Cluster Leads across 5 global divisions and obtained data for regulatory activities and volumes in 130+ markets
- Classified the data into 6 broadly defined functional categories
- Performed a resource versus estimated effort assessment at the cluster, division and global level
- Presented new resource model to manage activities using a centralized process
- Provided phased centralization blueprint based on four product market categories

WALKING TALL

WITH SUDHEER SAGAR GOPARAJU

VP - Operations

Some people are born with the kernel of leadership, while some evolve into being leaders through the events that transform their lives. Some insist on learning lessons by making mistakes, while others seek knowledge from a mentor. To some extent, the ability for great leadership is instinctive. However, learning how to be a more effective leader is within everyone's reach whether you direct a whole company or lead various teams or just a single employee. There are certain characteristics that great leaders share in common. Here is an excerpt of our conversation with Sudheer Sagar Goparaju, Vice President, Global Operations, to keep you inspired to walk tall, all the way.

Being in the industry for quite some time, where do you think the Regulatory world of Lifesciences has reached so far, and where is it heading?

With many specialist service providers in the market, the Regulatory scenario of various life sciences entities – Pharma / Biotech / Medical Devices / Cosmetics has been good so far. However, there are few exceptions. Overall, the industry is in news with positive results for streamlining required Regulatory procedures, enabling organizations to be audit-ready within shortest turn-around-time and saving costs to organizations and manufacturers. If the recent reports are of any consideration, the global growth rate for Pharma as an industry is expected at 6.3% CAGR through 2022. The Pharma market will worth $1.22 trillion by 2022. That emphasizes the increased need for specialized Regulatory services either to track the updated health authority requirements or to enable clients align with them with effective strategies and pathways. There is a huge potential even now amid uncertainties over the Brexit, and the aftermath of US presidential elections and other Regulatory challenges across the globe. To tap the market potential in a cost-effective way, organizations across the globe are now looking for glocalized services.

How is Freyr prepared to sustain the industry shift?

To sustain the industry-shift, one needs to walk that extra mile to ensure clients sail through smooth market approvals and product releases globally. With an intention to serve the need of the hour, Freyr has established a specialized global network called FreyrX that consists of a pool of Regulatory experts with a deep understanding of regional/local Regulatory requirements enabling Life Sciences companies expand to newer markets, in an accelerated model.

What does FreyrX stand for?

The "X" stands for Extension. To be more precise, it is Freyr's 'Xtended Global Presence with Local Expertise.' FreyrX exists to make the brand Freyr even stronger in catering regional Regulatory services through a worldwide network of Regulatory experts. It is mostly about establishing a local geographical presence to enable our clients avail the best of what we offer in quick turn-around-time.

What's the most rewarding part of leading FreyrX?

Working together towards a common vision in itself has always been the most rewarding part. More than the formidable network of consultants we could pull off till date through FreyrX, it's the act of bringing several teams together and syncing with them to push the limits at Freyr is a great achievement, I feel. Had read somewhere how no one can whistle a symphony alone.

From Sales & Operations to the youngest department of Freyr. How did it all come through?

My career at Freyr began with supporting the Sales & Operations team which was mostly about numbers and managing the workforce. I have got the opportunity to witness the transition phase that the organization was going through, back then. A lot many ideas were thrown around and diverse elements were incorporated. There ignited the concept of FreyrX. Interestingly, FreyrX as a team was primarily established to serve the requirements of a major global client that has glocal presence. Taken-off well to serve several renowned global clients in succession, FreyrX eventually expanded to be an invaluable asset to Freyr and with that our presence has reached close to 120 countries and counting.

In your opinion, what makes a successful leader stand out in the crowd of mediocrity?

In my opinion, the trick to a good leadership is to make time for the hard work that continual learning requires. There must be a willingness to learn and improve. And if one doesn't make this a priority, the organization is at risk of becoming complacent.

Leading a team can be stressful at times. What keeps you going with a smile on your face all day? What's your instant stressbuster?

Ironically, it's the very team that keeps me going. I believe each person in the team brings a different strength to the table. Whenever I'm stuck in the middle of a problem, I have an open discussion with the team. They come up with varied ideas and strategies to tackle any given crisis and we're always at the forefront to solve it together. That itself is a stressbuster. The credit goes to the team.

What does leadership mean to you in 3 words?

Patience, Motivation, and Learning

What is life for you, apart from work?

Family, Photography, Music & Art.

freyr

Redefining The Regulatory Compliance Landscape

In a digitally evolving Life Sciences Regulatory world, at times, it is necessary to act hard on the legacy systems/software. Either their outdated features or their incapability to upgrade, pose a significant risk not only to operational efficiency but also to compliance. In such scenarios, the need of the hour is to implement robust technological solutions, which are scalable, easily-configurable, cloud-hosted, purpose-built, and fully compliant with Health Authority standards. For each of your unique Regulatory requirements, here are some of the equivalent software solutions that you might wish to integrate.

Regulatory Challenges	Regulatory Solutions
Tracking down the current regulations, industry guidance, policies, legislations to sustain the constant advancement of Health Authority regulations	Freyr INSIGHT — Instantly accessible on-demand intelligence solution that tracks the authoritative global/local regulatory information for informed compliance
Managing gamut of clinical/preclinical research data, documentation as per region-specific formats, electronic conversions & submissions	Freyr SUBMIT — A robust and secure submission publishing software that plans and manages the entirety of audit-ready eCTD regulatory submissions
Tracking and managing various aspects of drug labeling lifecycle: review & approval work-flow, regional/national label alignment etc	Freyr LABEL — A cloud hosted centralized label lifecycle management solution that ensures effective CCDS management and structured and compliant labeling
Lack of a single source of truth on data elements, formats and terminologies for the unique identification of information on medicines.	Freyr IDMP — An integrated software that ensures seamless data transition for IDMP compliance and provides IDMP readiness support data management
Capturing, configuring and managing all the critical 62 fields of Device Identifier (DI) attributes and 6 fields of Production Identifier (PI) attributes	Freyr IDENTITY — An end-to-end UDI Compliance solution to assess, plan and manage all critical changes for smooth GUDID submissions
Traditional document management systems typically being retrofit for archiving and exchanging the regulatory documents	Freyr rDMS — An integrated electronic rDMS built ground up to efficiently handle enterprise-wide content for seamless document sharing
Stacks of essential electronic/paper-based clinical trial documents to be sourced, tracked and managed affecting audit & inspection-readiness	Freyr eTMF — A cloud-hosted eTMF software that efficiently creates and manages complex and global clinical trial data across the lifecycle

Mysore... To Ooty

Drive through an eclectic mix of city life and countryside

Don't we all crave for a whiff of fresh air in the routine humdrum of our everyday life? Imagine wide open spaces and highways, azure skies above, car windows pulled down and blaring stereo, the gushing wind ruffling your hair as you sing your hearts out making fond memories along the way. A well-planned road trip with your loved ones and a good playlist could be your ultimate stressbuster to shed old skin, and live a little.

While India has something to offer for everyone, an impressively beautiful trip that you should all take at least once in a lifetime is the scenic road trip from Mysore to Ooty. An eclectic mix of both city life and countryside, this trip would transform you from a tourist to a storyteller. If you're beginning your journey from Bengaluru early morning, you can't possibly miss the popular

breakfast joint "Brahmin Coffee Bar" just 20 minutes away from the city. A filling share of piping hot idlis dipped in spicy chutney and hot brewing cups of coffee wiping your sleep away, it's time to hit the alluring NH-17 that would take you to the royal Mysore city.

Must-Do's When in Mysore

Ranganathaswamy Temple: About 15 odd kms from the main city, the temple is an important Vaishnavite shrine of South India. The principal deity is Sri Ranganatha, a manifestation of Lord Vishnu, in a sleeping posture, with Adi Shesha- the serpent with seven heads and Goddess Lakhshmi sitting daintily by his feet. The breath-taking architecture of this temple will numb your senses. Once you pay obeisance, don't forget to spend some time admiring the outer sanctum of the temple, beautifully painted with mythological stories.


Ranganathaswamy Temple


Mysore Palace

Mysore Palace

The sprawling Mysore Palace is located right at the heart of the city. This majestic three-storied structure has several attractions within its famed walls; the doll pavilion showcasing dolls made of gold, silver, ivory and almost 900 years old being one of them. The royal marriage hall is another awe-inspiring structure.

Chamundi Hills

The centuries-old Chamundi Devi temple, an incarnation of Durga or Parvati, is situated right atop the hill. One can view the whole city from up there, the most scenic of all being the race course. Another prime attraction on your way back is the mammoth idol of Nandi, measuring 16 feet in height and carved out of a single black stone. It is said that there are only five such Nandi idols across the world. Two of them in Tamil Nadu, one in Andhra Pradesh, one in Bengaluru within city limits and the other right here in Mysore.


Chamundi Hills


Brindavan Gardens

Brindavan Gardens

You must see to believe the brilliance of this much-acclaimed terrace gardens modelled on the lines of the Mughal-style Shalimar Gardens in Kashmir. Right from the terraced views, lush green lawns, well-kept flower beds, cascading water channels and coloured fountains, come over early evening, take a leisurely stroll and later sit back and watch the dancing fountains and the garden alight in numerous hues.

Mysore Zoo

Mysore Zoo

If you're a nature enthusiast, this place is where you should head without second thought. This century old zoo spread across a sprawling 250 acres of land is a delight to be in. For one, it is home to a rich breed of flora and fauna that is not easily seen at other zoos across the country. But most importantly, how the animals are kept in well-spaced enclosures would instantly warm your heart. So, plan your visit on any day of the week besides a Tuesday and you're in for a lot of fun and pleasant memories.

Shopping

From the famous Mysore silks and sculptures, to incense sticks, rosewood handicrafts and the mouth-watering delicacy Mysore pak, the city is a shopper's delight and there's plenty to keep you happily engaged. You could hop around the Devaraja marketplace, rub shoulders with the locals, buy jasmine strings, fresh betel leaves and freshly ground coffee powder and soak in the smells and colours of the ancient city. You could also walk along the Devaraja Urs Road and Sayyaji Rao Road for silks and handicrafts.

Once you wrap up the Mysore edition nibbling on the irresistible Mysore pak, it's time to head to the Queen of hills- Ooty. But first, a word of caution. Tighten your seat belts because the journey ahead is quite a roller coaster ride with nearly 40 hair pin bends. You'll drive through the lush Bandipur forests on the way and if you're lucky, you'll also spot a deer herd, or an elephant family merrily crossing the roads, or purple-faced langurs gaping at you. Where the Bandipur National Park ends, you simply enter Tamil Nadu and land into the Mudumalai Tiger Reserve. In another 73 kms, you'll reach your destination Ooty.


Devaraja Market Place

Rightly called the Queen of hill-stations, Ooty lies snuggled in the blue Nilgiri mountains. Even when some may argue that the hill town has lost its old

charm and quietude after development ploughed through its terrain, it doesn't take long before you discover the right places to soak in the pleasures of life in the hills.

Must-Do's When in Ooty

Botanical Garden: Generously spread across 55 acres of land, the famous Botanical Gardens of Ooty is home to a staggering 650 distinct species of plants and trees. Few rare species which you would only find here are the cork tree, the paper bark tree, the monkey puzzle tree and an old fossilized tree, estimated to be 20 million years old.

Doddabetta peak

Doddabetta peak

If you wish to feel at the top of world, in a literal sense of the word, head for the scenic Doddabetta peak, about 10 kms away from the city. The Telescope House at the top offers panoramic views of the whole town, and once done filling your lungs with fresh mountain air, and enjoying a spectacular sunset view, go sip some local tea at the adjacent tea factory.

Tea Factory

This place is your live encyclopaedia to the refreshing world of tea! If you're an ardent tea lover, this is your place to be. Right from when the tea leaf is brought into the factory to the last stage of it being crushed and juices extracted, you'll get to experience the entire process in front of your eyes. Also, the tea museum and gift shop are not to be missed. Be it cutesy handcrafted saucers and tea cups engraved with snippets on the history of tea or neatly packaged superior quality nilgiri tea leaves, there's a souvenir for every soul.


Tea Factory


Ooty Lake

Ooty lake

Skirted by tall eucalyptus trees and its waters fed by streams that meander through the hills, strolling around it or a quiet ferry ride is the kind of experience you should indulge in. If you're a Bollywood buff, you would identify how the famous "Dil Deewana" song from the film "Maine Pyar Kiya" was picturized out here along with few scenes of the film "Ajab Prem Ki Ghazab Kahaani".


Rose Garden

Rose Garden

Arguably the largest rose garden in the country, it's perched high at an altitude of 2200 metres, on the lush slopes of Elk Hill. It has close to a staggering 20, 000 varieties of roses assembled from various sources around the world. If you have never seen a green or a black rose, this is your place to be. Also, don't forget to get clicked with the beautiful angel statue amidst the colourful roses.

Nilgiri Toy Train Ride

The Nilgiri Mountain Railway was declared a World Heritage site back in 2005 and the picturesque 46-kms stretch from Ooty to Metupalaiyam via Coonoor traversing through 250 bridges and 16 tunnels, rocky terrains and ravines, tea plantations and forested hills, is unmissable. Grab a window seat in one of those quaint blue and cream wooden carriages, croon the Shahrukh Khan-starrer Chhaiya Chhaiya song picturized on this legendary toy train, get down at the stations, click pictures and hop back and weave a thousand memories.


Nilgiri Toy Train

Cocoapods

Shopping

Ooty being most famous for its tea plantations, don't forget to pick from a variety of what it offers. Epicures can shop for fresh spices while the rest can sink in their sweet tooth in handmade chocolates and marshmallows, truffles and fudges. 'Cocoapods' is the best place to shop for these sweet savouries. Locally produced cheese and aromatic oils are few other prime attractions.

All in all, this vacation had all the perfect ingredients that a delightful road trip called for and in turn charged us all to get back to our lives in the city. What are you waiting for? Get your car inspected by a trusted mechanic to make sure every wire is in place, take ample rest before you embark on your journey so that you're energized to make the most of all the time you have in hand, don't forget to stock up on your first aid and emergency kit, charge your power bank so that your phone and camera do not die midway, pack your bags, fuel your ride and hit the road!

CLIENT VISITS

It was a great honor to welcome a multi-million pharmaceutical company at Freyr to oversee the ongoing projects for Labeling and discuss the future perspectives for medical writing services.

Client delegation met the Freyr core group to discuss business aspects aligning with ANDA dossier preparation & publishing. The client also explored other capabilities on artwork and labeling during the visit.

SEIZE THE MOMENTS

The age-old adage that "a happy workforce is a productive one" is a business philosophy that rings true even today. To cultivate a sense of camaraderie and team spirit among our employees, Freyr Clubs – a group of fun enthusiasts - organized varied fun-filled activities throughout the last quarter. Here are a few glimpses of the fun-packed events for you to relive the moments again.

ENJOY THE SNAPSHOTS.

ECOLOGICAL

GARAGE CLUB

LOL CLUB VOICE VS. NOISE

POT POURRI

SANKRANTI

WOMEN'S DAY

Rewards & Recognitions

Freyr conducted the Rewards & Recognitions for Quarter 4 to acknowledge employee efforts towards meticulous implementation of projects and successful accomplishments. The rewards were handed over to employees who went an extra mile in different categories like Target Oriented Performance, Critical Incident Performance, Deadline Meeting Performance, Innovative Performance, and Client Appreciated Performance.


















DON'T LET THE PAPER BE A BURDEN.
GO LIGHT WITH ELECTRONIC SUBMISSIONS.
TURN TO FREYR SUBMIT.

FDA eCTD DEADLINE IS DRAWING CLOSE.

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Headquartered in New Jersey, USA, Freyr is a specialized full-service global Regulatory Solutions and Services Company and a specialist Consulting, Operations & Technology Services provider, exclusively focusing on the entire Regulatory value-chain of Bio-Pharma (Innovators/Generics), Consumer Healthcare and Medical Device organizations, globally.

Freyr is a Strategic Regulatory Solutions & Services Partner to 6 of the Forbes Global Top 10 Pharma, 3 of the Forbes Global Top 7 Healthcare, 2 of the Forbes Global Top 6 Biotech and many $1 Million to $10 Billion Fast growing global Life Sciences, CROs and Standards Companies.

Exclusively focusing on the entire Regulatory value-chain, Freyr leverages its Regulatory healthcare domain expertise and technology innovations to evolve hi-end next generation regulatory solutions and services that enable accelerated performance, operations excellence and significant cost of compliance benefits to clients while approaching for successful complaince

Freyr is one of the few global companies to have pioneered specialized Centers of Excellence (CoEs) exclusively focusing on the entire Regulatory value-chain which are supported by rapidly growing global teams of 400+ Regulatory Professionals. Freyr's Global Operations, Delivery and Development Centers are ISO 9001 Certifed for Quality Management and ISO 27001 for Information Security Management. Freyr has an extensive global Regulatory Affiliate Network spanning 120 countries to offer best-in-class local and regional Regulatory support services to global companies.

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