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GLOBAL REGULATORY SOLUTIONS & SERVICES
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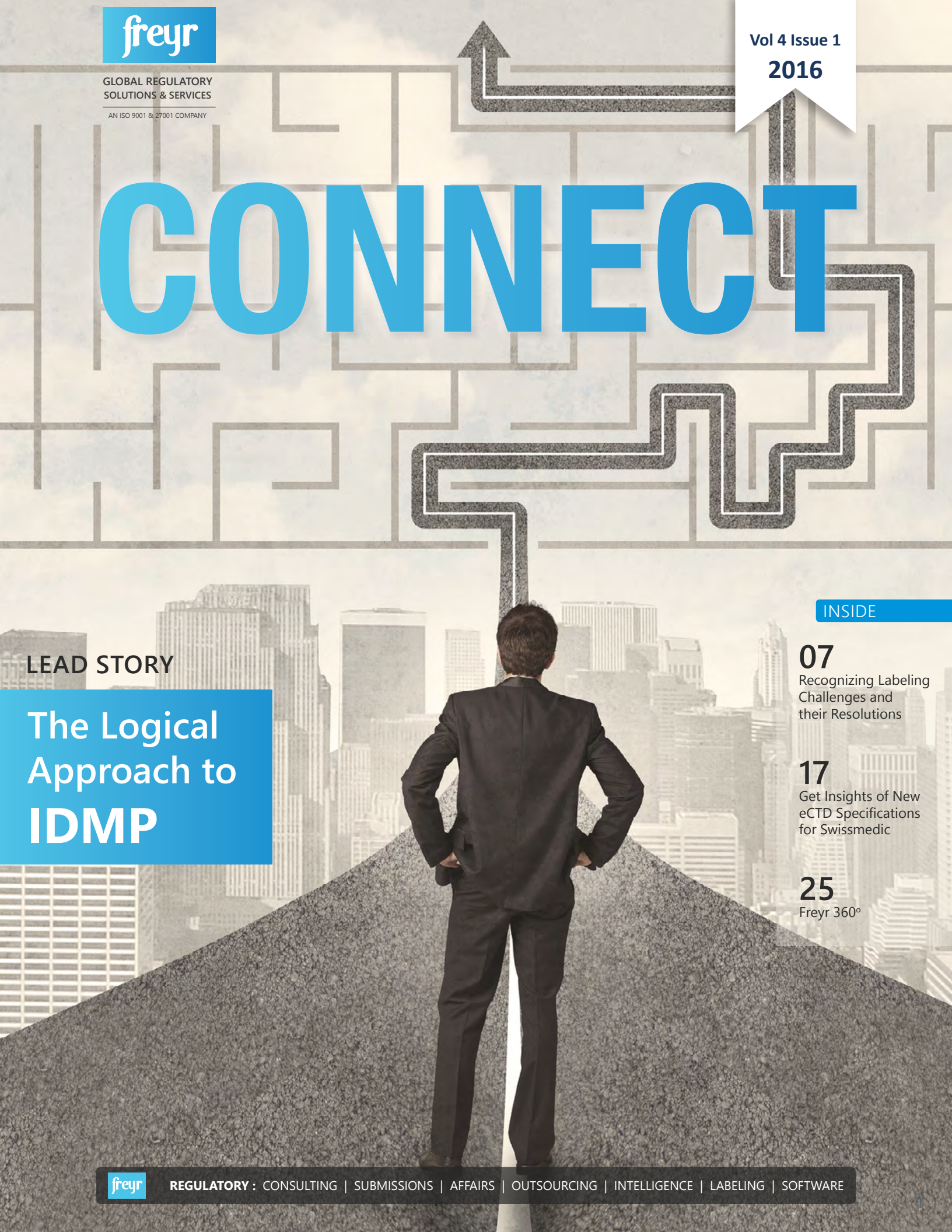
# CONNECT



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# FROM THE EDITOR'S DESK

Hello!!!

Welcome to the exciting new edition of Freyr Connect.

From jubilant January to dynamic December, the last year earmarked great accomplishments, productive ventures and bigger than before milestones for Freyr and its clients. As we make our ways into 2016, we hope to help our customers, meeting diverse challenges with our capabilities, enhance their business through our competencies and scale new heights.

This edition will take you through regulatory updates in different geographies corresponding to a wide range of regulatory operations & affairs functionalities like UDI, eCTD in Switzerland, IDMP, and much more. Don't miss the fun filled Freyr 360◦ segment that rides you across major events of last quarter.

I hope you will find this issue enjoyable and informative.

Best Regards,
**Urvashi Sharma**
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# The Logical Approach to ISO IDMP

## GET THE REALITY CHECK FOR YOUR COMPLIANCE READINESS

In 2015, when EMA announced the replacement of XEVMPD with the implementation of IDMP, it came as a big challenge for companies. The next major challenge that lies ahead for pharma companies is getting ready for IDMP while making sure that their XEVMPD obligations are achieved so that IDMP implementation is in sync with the latest upcoming regulations.


### Formation of EU Task Force for ISO IDMP Implementation

In order to develop a joint approach for implementation of ISO IDMP standards, the EMA established an ISO IDMP task force that comprised regulatory representatives across the EU network, industry associations and some interested groups. The key intentions behind formation of this task force were:

- To contribute to progress and endorsement of strategic IDMP implementation roadmap that would help companies to get complaint
- To endorse best industry practices on functional prototypes and data control for sustaining and registering medical product information in EU
- To contribute to development of EU ISO implementation guides and technical specifications aligned with the IDMP roadmap
- To function as a communication channel among all the stakeholders



### How does IDMP Implementation Influence your Regulatory Functions?

ISO IDMP is not merely just to maintain product identifier globally, but it also proves to be a great support in **pharmacovigilance**, **GMP/inspections**, **Regulatory Submissions**, and **Clinical Trials**.

### ISO IDMP & Pharmacovigilance

ISO IDMP implementation helps in assisting the key pharmacovigilance purposes such as improving the codification precision for all the medicinal products that further helps to maintain signal controlling and improves data analysis. As a result the regulatory actions associated with PSURs, literature monitoring and referrals fastens. On the bigger front, it helps to achieve the regulatory requirements of pharmacovigilance.

### ISO IDMP & GMP/Inspections

Accessing manufacturing information and streamlining the inspection on the manufacturing sites can be a stringent task especially when dealing with large product lines. However, this becomes easy with the implementation of ISO IDMP as it helps to handle emergency situations such as product recalls or product shortage. With a centralized information access point, it becomes easy for companies to deal with this crisis by seeking help from their international partners in a very short period of time.

### ISO IDMP & Clinical Trials

Since it allows to have a centralized database of medicinal product information, it supports CT process with help integrated data in annual safety report depository and EU clinical trial databank. The information exchange between EU and SUSARs can be channelized easily on a secure platform. This available information supports transparency of clinical trial information flow and augments the communication chain among all the stakeholders.

### Are We Lagging Behind to Meet the July 2016 Deadline?

The deadlines are important and failure to which costs millions to the companies. Although companies are getting ready for IDMP implementation, a gap is still observed mainly due to various practical hurdles such as overdue accessibility of ISO implementation guides. It seems these guides are still under process and being updated and revised in order to match the ongoing changes and updates on the standard itself.

Expert analysis propose that by the time the final ISO guidelines gets completed and rolled out by the agency, we might be in Aug 2016. The first guidance for medicinal products is estimated to be accessible in the first quarter of next year, whereas the guidance for medicinal substances is predicted in the second quarter of 2016. Does it mean that the old timeline needs a revision? Well that question still remains unanswered by the agency. However, the circumstances say something else. Even if European Commission approves the phased approach, IDMP implementation will require a lot of time to identify & analyze the data sources within the organization and the partners.

### Are You Ready To Cope Up with The Deadline?

There is no doubt to the fact that this entire process will demand comprehensive approach and will go for a long term. To counterpart the influence of this convergence, there should be a strategic transformation in the perspective of Regulatory Affairs. Simply gathering information, compiling and submitting it to the health agencies won't be satisfactory. Regulatory teams need to be more preemptive in terms of planning the entire IDMP implementation lifecycle by supporting the process with their strategic and rapid approach. This conjunction brings a lot of variations in terms of strategic planning and functional teams. There will be a huge influence on processes such as status tracking, data management and communication monitoring.

### Know What to Consider For IDMP Execution

Planning and successfully meeting IDMP compliance will cover the key components and activities outlined below:

- Data Elements Identification
- Data Source Identification
- Data Assessment, Gap Analysis & Process Mapping
- Develop IDMP Strategy & Roadmap
- Data Collection Repository Implementation
- Deploy Master Data
- Implement Change Management Process
- Overall Governance & Maintenance
- Data Transformation
- Submission

### Freyr For IDMP

Being a specialist provider of Regulatory Consulting, Operations & Technology Services, Freyr provides efficient and seamless IDMP implementation for its clients. Freyr IDMP software solution is developed to efficiently monitor, track, update and create XML files that are compliant with EMA requirements. As part of the solution, Freyr offers to deploy data management software solutions for IDMP assessment, data level status reports and analytics in terms of availability, accuracy and integrity. Freyr helps companies with a strategic data management approach and implementation process to meet the IDMP challenges.





# RECOGNIZING LABELING CHALLENGES AND THEIR RESOLUTIONS

It goes without saying that label creation lifecycle in the pharmaceutical industry can be a stringent task to carry out especially when there is pressure to ensure the regional requirements, global competition and adoption of new regulatory guidelines. The risks of replication of data, or missing out any critical information while maintaining the CCDS can cost millions to a company. In order to be prepared for these encounters, it is necessary to be acquainted with the challenges in first place that can interrupt the labeling lifecycle development.

### Maintaining the Local Labeling in the Global Repository

This is particularly a big challenge when a company has products being marketed in different countries that have their own way of presenting the information on the local labels (local labeling here means container labels as well as the detailed safety information document i.e., Summary of product characteristics/Product Information/ Product Information Leaflet etc). There are several leading pharma giants who are now with the help of experts taking steps to overcome this challenge. A possible and productive solution for this problem can be a centralized unit dedicated in collection of local labels from various local regulatory affairs, performing visual QC and uploading them onto the client central repository. This practice helps both the local and the global teams to ensure that the latest labeling information exists in the repository spectrum. However, the local operating companies should be informed/e-mailed periodically asking them to ensure that the latest labeling information exists in the central repository, and the dedicated unit can issue follow-up notices to overcome any discrepancies. This helps the CCDS development team to ensure that the latest safety information is taken into account while preparing the CCDS (where local labeling safety information is one of the key raw materials).

### Local Product Labeling in Alignment with CCDS Updates

The CCDS is the basic reference safety information that local operating companies needs to follow. However at times, some administrative challenges turn up that impact the alignment of local labels with the CCDS. e.g. business reasons like product already been in the markets and the batches of products released into the market. This may lead to the differences in alignment of the local labels with the current CCDS

information. To such a problem, experts can design implementation tracker that imparts huge impact and the deviations from the CCDS are now being tracked. So, for any company which requires global tracking, this model helps. This way when the local operating company wants to send an updated label to the HA (or) when the HA mandates any changes to the local label, companies can have a track of changes that are needed to be made to the existing label.

### Countries and Registration Numbers Added To the Implementation Tracker List

Labeling outsourcing service providers have come up with a new idea of providing the countries and the registration numbers on the implementation trackers. This has made a huge impact as global and the local teams now will know the status of impacted countries at the time of notification for a particular product **e.g.:** on the day of notification, the no. of countries where the product is in 'Active' stage and no. of countries the products is in 'Inactive stage'. This has helped the tracking made simple and easy.

### Queries from Local Operating Companies

Some local operating companies require information to be submitted according to the local safety presentation/ requirements rather than aligning with the CCDS safety information. Lately, a number of queries are raised from the Asia-Pacific regions in this matter. The best suited response to these queries after carrying out necessary escalations to the senior management was a creation of a Regional Work Instructions without changing the global CCDS development strategy. This work instruction within the regions is currently being developed by many companies to overcome this challenge.

### CCDS Submission Tracking Challenges

Tracking the documentation status can be a stringent task. There is a huge risk involved in terms of excluding any important information out of CCDS. Subsequently, the labeling experts provide a strategy for retrieving the 'Pending Submission to Health authorities' list for all the product CCDSs that the client rolled-out. Creating the excel sheets for 'Pending Submission to Health authorities' list has proven to be beneficial as a base excel document for tracking all the registrations and licenses for all the regions where the products are impacted/marketed. This practice has revealed constructive results in determining the status of various submissions and has turned out to be an effective way to track the submissions worldwide.

### Creation of Products List for Upcoming CCDS Development

The creation of CCDS for upcoming products list is not an easy task and it requires expertise & resources to keep it updated. Especially, it has been a challenge to identify whether it is important to take safety single actives as the basic requirement in prioritizing the products to be developed (or) would it be based on the total country impacted and the number of licenses (formally called as volume). To overcome this hurdle, several analysis are undertaken by experts within different spectrums reaching to the final decision that in the first place, CCDS would be developed for the single active products, then, the safety prioritization based on the pharmacovigilance assessment reports sent periodically by the pharmacovigilance department and lastly, the volume. A specific list is developed, providing all the information for a particular product for a CCDS.


### Creation of Consolidated List of (Product of local orientation (or) origin POLOs to be Consistent with CCDS

A consolidated list of POLOs is also created to make sure that all the impacted local operating company labels for all the CCDSs till date are updated.

### In Conclusion

In order to meet all the challenges discussed above, the CCDS for any medical product needs to be updated on the regular basis. The new information should be added to the CCDS only if it has enough scientific evidence to support the inclusion and should not be driven or influenced by any business interest of the company. This should be discussed in details in the rationale for the CCDS update and should be authored by the experts. Marketing Authorization Holders should also ensure that their promotional material is in line with the labeling. Maintaining a central repository for all the local labels and updating the safety information based on the CCDS (unless otherwise the local HA drives the content) will help overcome all the challenges.

# HEADS-UP:
# CLASS II DEVICE'S UDI COMPLIANCE IS HERE

Submissions Scheduled for Sep 24, 2016

24th September, 2015 was the scheduled UDI compliance date for the labels and packages of implantable, life-supporting, and life-sustaining devices. The UDI mandate is intended to increase the visibility and quality of information in medical device adverse event reports. The UDI guidelines proposed by FDA demands manufacturers to imply UFI complaint codes to their product labels and submit the data according to these codes to the GUDID. Therefore it becomes extremely vital for regulatory device providers to follow best practices when dealing with UDI Compliance. With the help of extensive experience of our SME's, we bring you some practices to be implemented during UDI lifecycle.

Now that the second phase of UDI compliance, for Class III I/LS/LS medical devices has been implemented, many device manufacturers, especially of Class II type, are questioning how best they could be prepared for September 24, 2016, Class II device data submission deadline. To give them heads up, at Freyr, we have identified some of the prerequisites they should consider while lining up Class II devices for compliance with FDA's UDI mandate.

The new regulation requires all class II medical devices to be labeled and packaged with a unique device identifier (UDI) and entered into the FDA's Global Unique Device Identification Database (GUDID). Given the volatility of compliance requirements coupled with shorter submission timeframes, the challenge for device manufacturers is to get to know the nitty-gritty of the compliance processes. At the same time, they must ensure that none of the key device attributes are missed out while pulling together the scattered device data across different systems and reconciling it in spreadsheets to create compliance reports.

In order to assist device manufacturers easily navigate through this time-critical and complex compliance process, with no errors, Freyr has compiled following prerequisites to be followed.

**1 Determine the UDI Compliance Date:** Since the time FDA has issued its final rule, some of the device compliance dates have been changed and extended. To meticulously plan ahead the compliance strategies and processes and to avoid hasty last-minute amendments, labelers shall determine the accurate compliance date.

For most devices, the compliance date for direct marking is different than the other requirements. Based on your product category, either intended to be reused or intended to be reprocessed, determine the direct marking UDI compliance date in the table below.

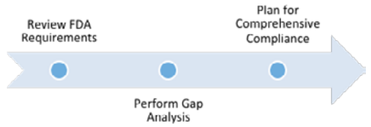
**2 Evaluate the Need of Direct Marking of UDI Number:** All medical devices which are used more than once or which are to be reprocessed before each use must have direct marking of the UDI. The exception is for implantable devices which do not require the direct marking as per the UDI rule. The devices which are for single-use, even if re-processed, are also not required to bear a permanent UDI - 21 CFR 801.45(d)(3). Thus, evaluate the need of Direct Marking based on the category of medical devices you manufacture.

| Class II Devices Compliance Date | Compliance Requirements |
|---|---|
| Sep 24, 2016 | Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. |
| | The labels and packages of class II medical devices must bear a UDI |
| | Dates on the labels of these devices must be formatted as required |
| | Class II stand-alone software must provide its UDI as required |
| | Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database |

| Direct Marking Compliance Dates | Category of Device - Reused and Reprocessed |
|---|---|
| Sep 24, 2015 | Life-sustaining and life-supporting devices, regardless of device class |
| Sep 24, 2016 | Class III devices and devices licensed under the Public Health Service Act |
| Sep 24, 2018 | Class II devices |
| Sep 24, 2020 | Class I devices and unclassified devices |



**3 Plan for Comprehensive Compliance:** Review the FDA requirements for your specific products to be complied. Perform a thorough gap analysis to find out shortfalls related to data or technology to deal with some of the major challenges in the process of meeting the strict FDA timelines. The challenges could be obtaining the DI or PI information, and handling large volumes of unstructured data from




disparate sources, etc. Instead of burning the midnight oil to reconcile all medical device data at the nick of the time, plan out for comprehensive compliance ahead of time through validated regulatory systems and tools which support data integration, data quality and data management.

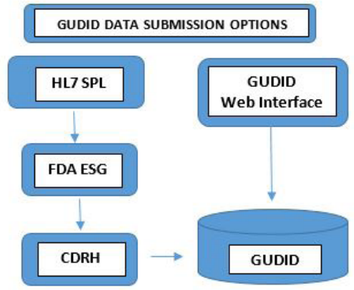
**4 Obtain DI Number and Agency Membership:** The UDI is composed of Device Identifier (DI – unique number based on version or model of device) and Product Identifier (PI – includes lot number, serial number, or expiration date). The DI portion of UDI will serve as the primary key to look up information about the device in the GUDID. To assign a DI, the FDA has accredited three Issuing Agencies – GS1, HIBCC, and ICCBBA. In this scenario, labelers must obtain membership of one of the agencies to get the DI number which needs to be entered into the FDA's GUDID.


| | Identifier | Attributes | Issuing Agencies |
|---|---|---|---|
| UDI | DI (Device Identifier - Static Data)<br>Required to be synched to GUDID | Unique Number of Manufacturer, Device Make, Device Model | GSI |
| | PI (Product Identifier - Dynamic Data)<br>Required on all levels of packaging | Lot Number, Serial Number, Manufacture Date Expiration Date, | HIBCC<br>ICCBBA |

5 **Submit the Data:** The way you submit the data to GUDID varies with the volume of product portfolios you handle. Device manufacturers with the minimum number of devices choose to submit the UDI information manually through FDA's free GUDID web interface. In this case, only one DI record could be submitted at a time through a secured GUDID web interface.

In the other case, manufacturers with a larger number of product portfolios choose HL7 SPL submission option to collect data electronically and convert the consolidated data to SPL format before submitting it to the FDA's Electronic Submission Gateway (ESG), using the DUNS number.

Kindly make a note that GUDID account is not by submission type. The account is to identify you, the labeler, to enable submission of device data through both the options.




6 **Set up a GUDID Account:** A labeler / device manufacturer requires one or more GUDID accounts basing on the number of roles to be allocated; to name a few, GUDID coordinator, Data Entry User etc. But to authorize each role for data entry, the manufacturer needs an approval from the FDA prior to account creation.

The process of creating an appropriate GUDID account involves sending an email request to FDA upon which you, the applicant, will receive an account request document to fill out. Once you send back the filled up document to the FDA via email, the agency will review the form, and then send an email back to you with GUDID account log-in information.

UDI implementation is a complex and time-consuming process. During the course, while meeting with FDA's UDI requirements, medical device manufacturers face many challenges pertaining to data management, data integration and data submission. With compliance deadline for Class II devices is just a year away, start working towards it right now.

To navigate your organization through this complex compliance process, Freyr offers the best of both worlds – on-demand, fully configurable, UDI software solution, Freyr IDENTITY, as well as a Centre of Excellence that offers best in class, cost-effective and customizable UDI outsourcing services model built around your unique and demanding requirements.



# IMPORTANT POINTS TO KNOW ABOUT NEW IND SAFETY REPORTING GUIDANCE

This article emphasizes on getaways from the guidance proposed by FDA with respect to safety assessment for IND Safety reporting.

The guidance clearly defines the guidelines for manufacturers and sponsors in order to streamline the safety information regarding investigational new drug application (IND) for biological and human products. Although these guidelines are merely recommendations from the agency, sponsors in the industry tend to abide by them since the final rules are pretty much in alignment with proposed guidance.

**Safety Information Reporting Requirements**

It is the responsibility of manufacturers and sponsors to thoroughly review the safety information and inform the agency about any potential serious risks from the drug in its report. The submitted report should entail information related to any serious and unexpected supposed adverse reactions of the drug. In addition to this, corresponding situations and circumstances that can led to these adverse reactions should also be reported.

As per this guidance, an adverse reaction is defined as "The one in which there is a reasonable possibility that the drug caused the adverse event".

In order to analyze the adverse reactions of a drug, sponsors should recurrently evaluate the information and data gathered from multiple resources including ongoing or completed studies.

**Clinical Database – An Efficient Solution**

To carry out this activity, clinical trial reports database works like a one stop solution for sponsors. Since clinical trial reports consist of great volumes of useful information to identify the behavior of a drug, it becomes easy for investigators to assemble, manage and analyze this information to prepare accurate and detailed safety reports to be submitted to the agency. It also helps sponsors to review the rate of adverse effects across different treatment groups using those drugs.

Once the reports have been submitted to the agency, the further steps are taken by reviewing committee of the agency that monitors the processes involved. Certain questions arise like:

- Can the drug dosage be modified to reduce its adverse reaction?
- Will a change in the chemical composition of the drug help to make it safer to use in all circumstances?

Thus, it is critical for companies to detect these adverse effects as early as possible and report it to the agency so that any important safety information is not left out and public health is not put in jeopardy.

Sponsors need to understand that it is not just about reporting the safety information to the agency but also following a strategic approach for safety surveillance of a drug. Agency recommends sponsors to form a safety surveillance plan and a safety assessment committee to carry out these activities smoothly.



# GET INSIGHTS OF NEW eCTD SPECIFICATIONS FOR SWISSMEDIC

**Swissmedic**

The Swiss Agency for Therapeutic Products (Swissmedic) is the Swiss surveillance authority for medicines and medical devices, registered in Berne. It started operating on 1st January 2002 as the successor of Interkantonale Kontrollstelle für Heilmittel (IKS), which was itself the successor of Schweizerische Arzneimittelnebenwirkungszentrale (SANZ). Swissmedic is affiliated with the Federal Department of Home Affairs.

All medicinal products and devices for humans and animals on the Swiss market must first be approved by Swissmedic. All clinical studies must also be reported to the institute, which works with other national and international partner authorities.

Swissmedic is a public body affiliated to the Federal Department of Home Affairs FDHA. It operates independently at an organizational and budgetary level. Every four years it receives a service mandate from the Federal Council, to which are added further specific objectives and verifiable measures each year. Swissmedic is primarily funded by charges and to a lesser extent is subsidised by the Confederation for providing a public service.

**What's New with Swiss eCTD?**

Swiss started accepting all electronic submission only in eCTD format. Similar to other countries Swiss eCTD contains 5 modules and Module 1 is country and region specific released by Swiss Authority. Module 2-5 is a current version of the ICH CTD specification which is accepted internationally.

As of 11 September 2015, new versions of the following eCTD specifications documents are available online:

- Swiss M1 Specification for eCTD v1.3
- Swiss eCTD Validation Criteria v1.3
- Questions & answers of Swissmedic eCTD Implementation v2.0
- Guidance for industry on providing regulatory information in eCTD Format v1.7
- Guidance on applications according to Paragraph 13 TPA for eCTD applications v1.3

The new versions are valid as of 1st October 2015. For the Swiss M1 Specification and the Swiss eCTD Validation Criteria, a transition period applies until 31 March 2016. During this

period, both versions are valid. Major modification was seen only in Module 1 Specification for eCTD and Swiss eCTD Validation Criteria. Other guidelines will get updated periodically.

### Changes in Module 1 Specifications

The M1 folder structure and file naming have been modified

**1. Folder and filename path length is added** - The overall folder and filename path length starting from the sequence number should not exceed 180 characters for any file in any module. This is a CH regional requirement.

**2. Many file names have been changed as following**

Eg: m1/ch/galenic-form/12-foapplvar/121-foapplvar to m1/ch/galenic-form/12-foapplvar/121-foapplvar/ch-foapplvar-VAR.EXT

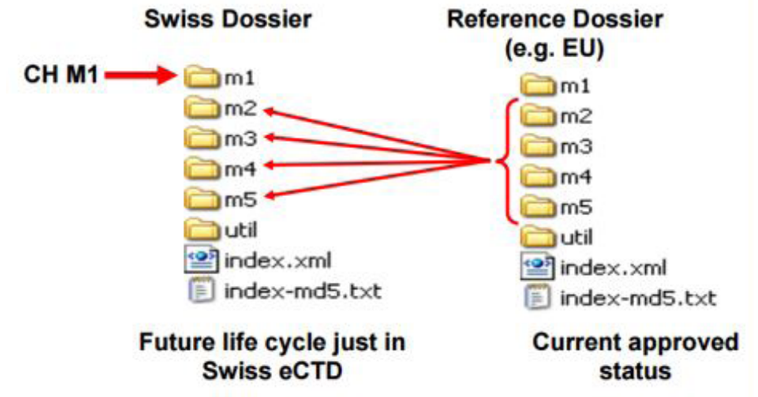
m1/ch/galenic-form/12-foapplvar/122-ann-form/1224-formvariationsrequiringnotification/ch-fovarnotif-VAR.EXT to m1/ch/galenic-form/12-foapplvar/122-ann-form/1224-formvariationrequiringnotification/ch-fovarnotif-VAR.EXT

**3. Follow-up Measure-** is included as an application type in Envelope information

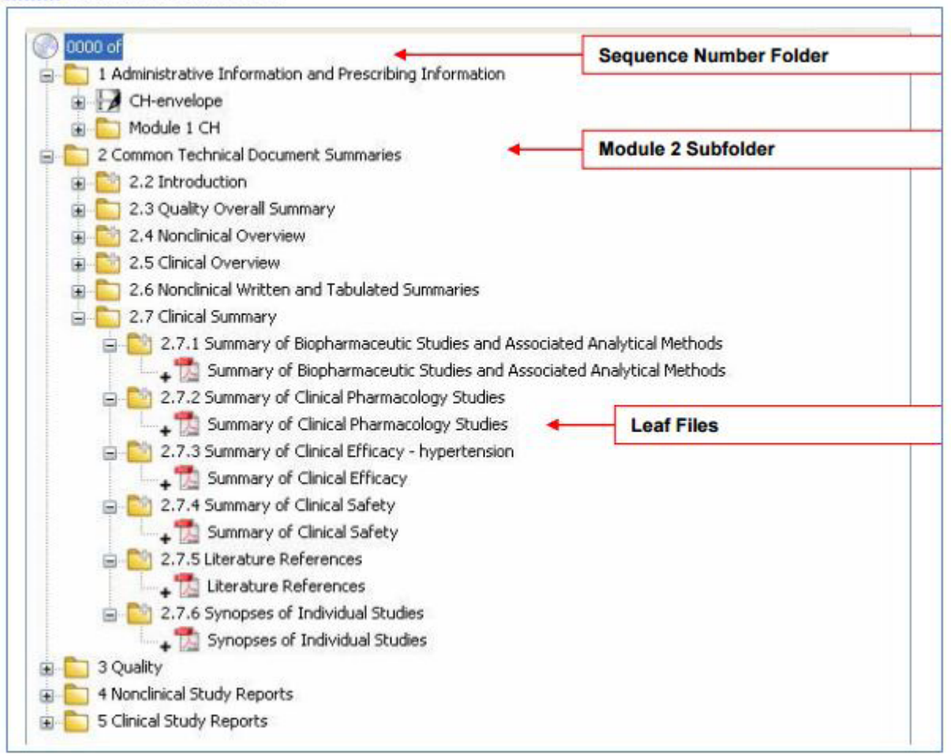
### Baseline Submission Requirements

1. A baseline submission indicates the change from a paper-based submission to an eCTD submission
2. It is recommended but not mandatory that an eCTD baseline submission is submitted in eCTD format for applications previously managed in paper or other electronic formats
3. Swissmedic encourages the submission of reformatted quality information in eCTD, in order to facilitate the handling of variations
4. A signed declaration of annex must be submitted with the cover letter stating that "The content of the submitted eCTD is identical to the currently approved documents and that there have been no changes to the dossier content as a result of the provision of the eCTD submission"
5. The submission should pass the technical validation and no review process and there is no content validation

*Fig: Incorporating the reference Modules 2-5 life cycle into the Swiss eCTD*




**eCTD Structure in XML view:**



6. The application type for the Base line submission is **Reformat**

### Guidance Paragraph 13 TPA

If the medicinal product that is already authorized abroad and gets the approval for the same product one should follow these guidelines "Guidance Paragraph 13 TPA".

If Swissmedic agrees to the application according to Paragraph 13 TPA, the applicant is required to submit a consolidation sequence. The consolidation sequence contains data from Modules 2–5 of the original, approved reference dossier, and Module 1 contains all forms and documents required for the Swiss application according to the currently valid version of the Swiss Module 1 Specification for eCTD.

Fig: Incorporating the reference Modules 2-5 life cycle into the Swiss eCTD

### Technical Validations

Technical validations are a must for every set of eCTD submissions for which various free source validation tools can be used to ensure that there is no bottleneck in technical accuracy of these submissions.

However Swissmedic has its own internal technical validation tools, companies should understand that using any other tool does not simply replace the internal Swissmedic tool. The eCTD validation standards and validation results observed with Swissmedic's tool may differ from the one that company uses.

### In Conclusion: Takeaway Points

To conclude with let's summarize key points to take into consideration while preparing for Swissmedic submissions:

- Submission should be accompanied with paper copy of cover letter
- Lifecycle operation for tracking table should be "Replace"
- Node extensions are allowed and the use of Study Tagging Files (STF) is not accepted
- Documents in PDF/A format are accepted
- Defined naming convention should be followed for the documents placed in working documents folder
- Several galenic forms of one drug product should be managed within a single eCTD lifecycle



# OUTLINING VERTICALS OF REGULATORY DATA & INFORMATION MANAGEMENT


Regulatory functions such as submission publishing, regulatory intelligence, labeling, etc. are intricate areas of regulatory spectrum that are ever evolving. This is one segment where most of the updates and changes in guidelines are announced by the health authorities. There is no doubt to the fact that some real time challenges are involved in submission processes especially now when the world is shifting from paper to electronic submissions.

For pharmaceutical and life sciences companies to be able to smoothly distribute their product line in different geographies, huge volumes of data needs to be maintained. Based on this data, the submissions are made that ultimately affects the approval timelines. Mismanagement of this data can cost millions to companies if not controlled properly.



## Background

If we go back a decade from now, companies were not much interested in regulatory information management systems, or maybe they were not conscious of the benefits associated with it. With time going by and traditional data embracing technology, companies started to recognize that it's not all about just gathering and putting the information in a centralized database. Technology offered newer avenues and gave them an opportunity to know what is happening to their product lifecycle with real-time access and monitoring capability.

Accessing information about a product might sound simple but knowing every other product in the same product family caught the attention. An easy access to information even for legacy products that may have been manufactured a decade ago was made available in a single click. That's what finally pushed the companies to go for a robust solution that is capable of holding huge volumes of data and information in an organized manner. However later, it was made mandatory by the health authorities to have a regulatory information management system for all companies.

## Why Companies need a Dedicated Data & Information System?

Now let's understand the key reasons behind health authorities demanding more and more information from companies. Well, the foremost reason is that regulatory authorities wish to have this information readily available at any instant of time. There should be a centralized location for all this data accessible from anywhere anytime.

Since there are a lot of perspectives involved in the review process by health authorities, this database helps the regulatory reviewers to be able to cross reference any information regarding

any medical product. There are other factors too that can be determined if companies have a regulatory data and information management system like:

Details about what product has been registered in which regions.

Consequently, it also helps to analyze about how the health authorities work in that particular region/country.

Whether all changes approved in one region are or need to be implemented in other regions.

A well-structured regulatory data and information strategy not only helps the health authorities but also allows companies to analyze and fill the gaps in their information which further helps to improve interactions and collaborations with partners and enhances business decision-making.

## What's at Stake?

With a technology that offers a huge pool of structured information about medical products of a company, comes the consequence of failing to adhere to regulations. For instance, regulatory controllers in Europe have authority by their legal framework to enforce severe permissions on companies that fail to comply with guided mandates or requirements.

It is for companies to have an integrated regulatory data and information management system to be able to share the info such as registration details of the product line in various regions/ countries, lifecycle processes, marketing authorization approvals, change management implementations and any other updated information with the regulatory authorities to be approved.

In European countries, any authorized regulatory individual representing a health authority organization should have direct access to all this information. The metrics associated with a strategic

information management system directly affect the brand image in the market.

- How has the company performed during submission publishing process?
- How much time did it take for a company to get approvals?
- Was any of their product got recalled?
- How many amendments were involved in submission process?

Answers to questions like these help build a basic metrics on which a company is evaluated in the regulatory market.

### What Features Should a Regulatory Data & Information System Have?

For building a successful and user-friendly data & information management system, lot of technology is involved. The performance of this system basically depends on the capabilities of the tools implemented in the system architecture.

From a company's standpoint, there are a few traits that need to be considered while choosing a regulatory data management system:

- Seamless organization of document monitoring process to ensure compliance with worldwide regulatory authorities.
- Easy management of document mode, status, and version.
- Effortlessly create, capture, manage, organize, connect, deliver and archive regulatory data and documents in a compliant, efficient and intuitive manner.
- Robust and secure tools to manage an extensive range of regulatory documents.
- Advanced search functionality and restricted access to important documents or folders.
- Ability to create groups and assign related documents to groups.
- Has a validation-ready audit environment.

These are few important features a company should look for, however, there are several other systems that are built on strong frameworks offering great features to manage huge volumes of data anytime anywhere.

### In Conclusion

It is a must for companies and regulatory experts to understand that implementation of a strong and reliable data & Information system, directly and indirectly effects all other regulatory operations and affairs. If there is a gap at any single point, it will get reflected in some or the other regulatory processes. Although there are a lot of complexities involved in this particular execution, for companies, a reliable and innovative regulatory partner can help them go in the right direction.



# CELEBRATING NEW CLIENT WINS

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

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

As always, it is a great pleasure to announce the **new wins** of this quarter.

## STRATEGIC CMC SERVICES FOR A SWITZERLAND BASED HEALTHCARE COMPANY

- Provide Variation Classification, Gap analysis for two of the products
- Develop and manage strategic CMC variations within a short duration of 3 weeks
- Provide Variation package preparation for two modules
- Assisted in Dossier Reformatting

## IN A DAY, SUCCESSFUL ECTD SUBMISSION SERVICES FOR A MULTIMILLION PHARMA COMPANY

- Provide end-to-end eCTD services for conversion of Annual report into eCTD document

## STRATEGIC SUBMISSION & PUBLISHING SERVICES FOR A US BASED PHARMA COMPANY

- Provided end-to-end support for conversion of paper submission into eCTD format

## PIVOTAL REGULATORY INTELLIGENCE SERVICES FOR A SPAIN BASED HEALTHCARE COMPANY

- Provide Patent Analysis across US, EU, ASIA
- Creating and developing patent analysis report for a multiple raw materials across different geographies



# Corporate Social Responsibility



## Freyr's Chennai Flood Relief Initiative

As Max Lucado quoted "No one can do everything, but everyone can do something", we did our bit by helping the affected whose existence were devastated in Chennai Floods. As a result of active initiative started by Madan Kumar, Freyr extended its helping hand towards victims of floods by joining forces with Thamarai Social Service Trust, providing them basic provisions of food, clothing and shelter. It was great to see the enthusiasm exhibited by Freyr Family by participating actively and aiding these civilians during their hardships.

# Client Visit

Freyr was honored by the visit from a Switzerland based, Global, $50+ Bn Pharmaceutical Company in the last quarter. The visit was envisioned to finalize future agreements with respect to the services and solutions provided by Freyr.



It was a great pleasure to welcome our US based, Global $20+ Bn, Bio-Pharma client for a much memorable visit to explore new ventures and promising developments. The visit was intended for further development and expansion of the labeling management services.

# Freyr-SEZ
# Connect Conference

Freyr participated in SEZ Connect conference organized by VSEZ (Vishakhapatnam Special Economic Zone) Zonal Office held on 17 Dec, 2015. SEZ connect is an initiative supported by Government offering a platform for potential propositions among companies from diverse domains from their respective Special Economic Zones. The event featured open discussions among companies, providing potential business opportunities.

Utilizing the platform, Freyr exhibited its competencies, proposing profitable opportunities for other companies to collaborate and delve into lucrative business endeavors. Freyr's presentation and capabilities were well received by organizers and other participants and provided us with many promising contacts to work with. The representing team bagged words of appreciation from the Chief Guest, **Mrs. Shobhana**- Zonal Development Commissioner and **Dr. Trinath** the Zonal Joint Development Commissioner for our high end next generation regulatory solutions and services.

# REWARDS AND RECOGNITIONS

Freyr gave away Rewards and Recognitions for Quarter 2 to acknowledge the employee efforts towards successful accomplishment and implementation of projects. These appreciations 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.


## TOP - Target Oriented Performance

1. Lazaruskeerthi Kumar G
2. Md. Abrar Hussain
3. Kenari Velangani Sagar
4. N.V.S Narayana Reddy
5. Sandeep Talari
6. Divvela Jagadeesh Kumar
7. Swetha Ravula
8. Balakrishna Panguluri
9. Dhiraj Kiran More
10. Sowmya Bhaskarla
11. Kankata Sairam
12. Rambabu Yakasiri
13. Manaswitha Konakanchi
14. Harinath Reddy M. V.
15. Yasmin Mohammed
16. Arey Srikanth
17. Paramesh Ragala
18. Ravi Kumar Reddy Kankanala
19. Krishna Hemanth Reddy G.
20. Bikshapathi Marri





## CIP - Critical Incident Performance

1. Satish Sikakolu
2. Pendkar Sanjay Kumar
3. Khandavalli Kiranmai
4. Katipelli Srikanth
5. Mohan Sai Mallampalli
6. Ashlesh Bodugam
7. Krishna Ranjit Devalla
8. Rajitha
9. Karunakara Rao Simhadri
10. Lavanya Jujjavarapu



## DMP - Deadline Meeting Performance

1. Appalaraju Mandanada
2. Sreedhar Dharanikota
3. Soma Naveen
4. Pratap Kumar Gouda
5. Racha Naren Kumar
6. Pethakamsetty Srujana
7. Ronanki Anil Kumar
8. Rayappa Reddy Gopu
9. Madhusudhan Vudugula
10. Vangavity Sudhir
11. Naveen Kumar Lingam


## CAP – Customer / Client Appreciated Performance

1. Pankaj Dinkarrao Burse
2. Alluri Rajee Priyanka
3. Madhadi Sowmya
4. Naga Sarath Chandra Kandi
5. Gurav Sudarshan


## IP - Innovative Performance

1. Radha Dureddy
2. Balarao Maddala


A Month-full of

# Sports

Freyr Fricco Fest took-off with a series of sports events wherein Freyr fanatics joined in with great zeal and fervor. The events filled everyone's hearts with the spirit of sportsmanship and unity with a lineup of team games like Cricket, Kabaddi, Volleyball, Throwball being few of many other endeavors. Stress busters games like playing chess, caroms, and dart board also stayed in spotlight for our employees. Winners were presented with exciting prizes on the Finale of Fricco Fest.


# freyr's Annual Bash 2015

24 December of every year marks a day that puts in a nutshell, a year packed with fun, fervor and great accomplishments. Freyrians made the Annual Day event bigger and better than before with their phenomenal contributions.

The performances presented a sight of fusion factor and cultural shades through dance and music. Few of our friends were roasted with gut-busting punches by our rowdy hosts. Just like we said earlier, everyone contributed to the successful event, Sunitha, the Managing Director got in on the act with her enthralling performance and left everyone to surprise.

To sum up the entire event, we would just say
"Everyone Rocked !!!"

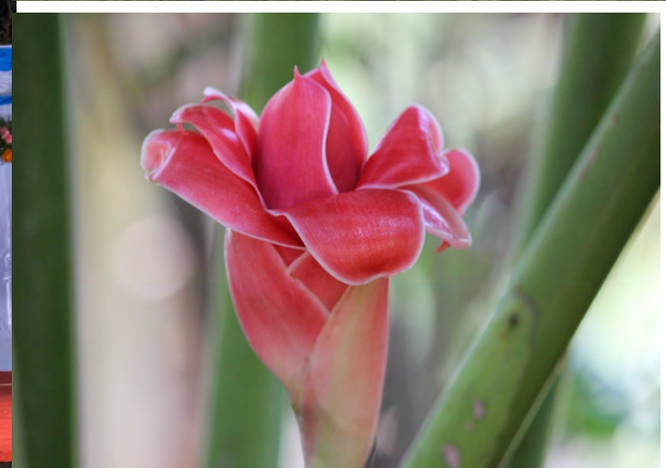
# Sieze the Moment

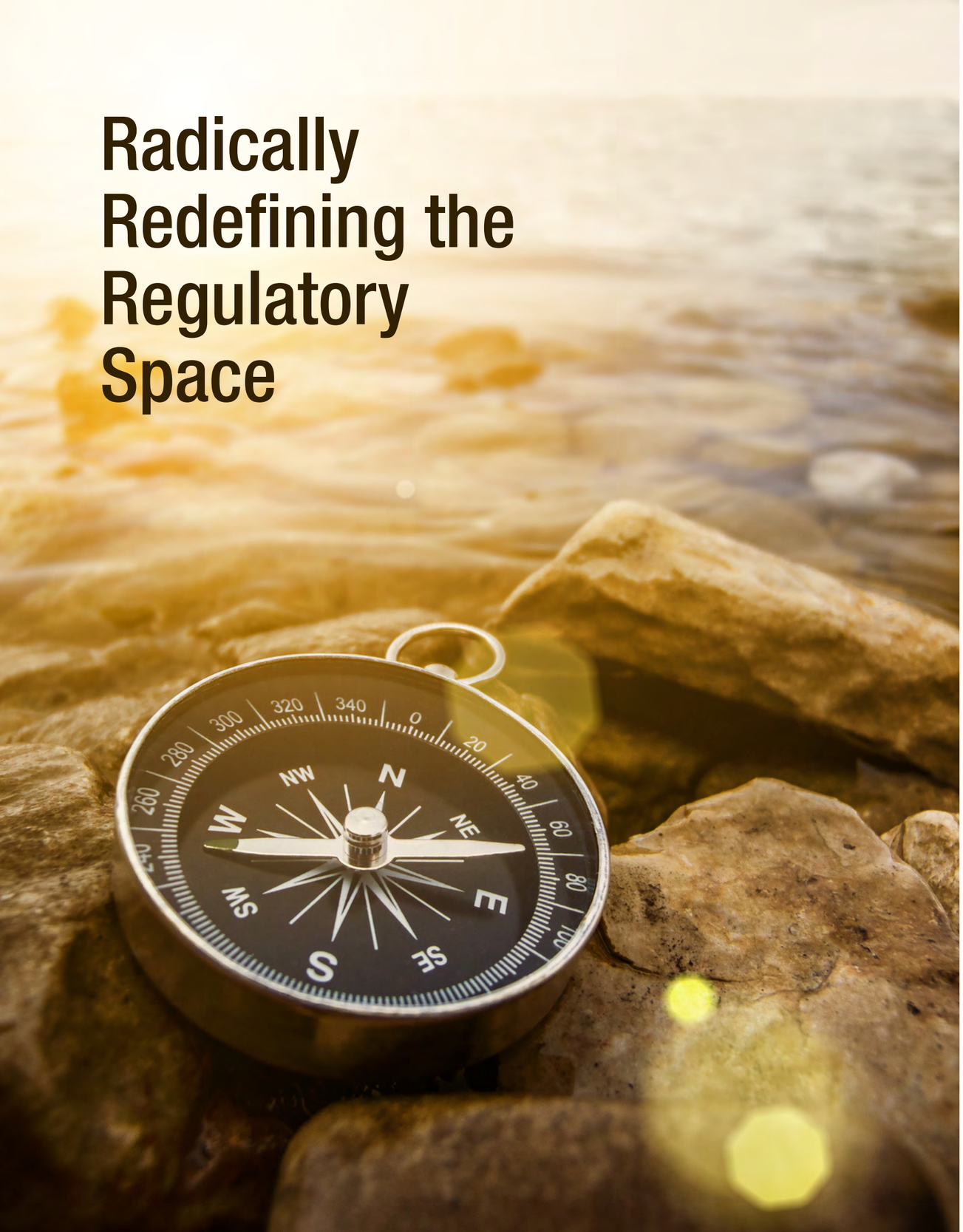
For some photography is a passion, for some a profession and for the rest, a way to capture a moment to be cherished all their lives. Heading with the idea of seizing the moment, Freyrians shared some of the breathtaking moments captured in their cameras with us. Enjoy the snapshots.

Photography by
Apparao ▼




Photography by
Sainath ▶



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# About Freyr

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 companies, 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.

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 350+ Regulatory Professionals.

Freyr's Global Operations, Delivery and Development Centers are ISO 9001 Certified 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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