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Vol 2 Issue 4, 2014

Lead Story

New Emerging Markets: A Strategic Outlook

Inside

What's Inside

From the Editor's Desk

Hello all and welcome to the Vol 2 Issue 4 edition of the newsletter!

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

What's inside this time! Freyr Connect's issue opens with the lead story "**New Emerging Markets: A Strategic Outlook**" followed by exclusive regulatory articles. Be sure to check the issue for a 360⁰ overview of Freyr's growth curve over the last quarter.

Lastly, the editorial team would like to take this opportunity to thank everyone who contributed to this edition of Freyr Connect. Please feel free to bring any comments, suggestions or new stories to our attention for future editions.

I hope you find this issue an enjoyable, informative read.

Best Regards,
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Management Speaks

As we rapidly traverse the final months of 2014 and move towards a new year, it's time for a short pause to take a fresh look at new emerging opportunities and re-align our business strategy with renewed vigor.

We are accelerating our growth and go-to-market strategies and are better positioned to deliver higher value to clients and open up significant opportunities to penetrate new markets, while offering growth opportunities to employees.

In this significant growth phase, we will focus on expanding global operations to bring into perspective the new emerging Rapid Growth Markets and the operating parameters that bring value to our clients. In our commitment towards operational excellence, we will continue to invest in infrastructure, people, training (competency development) and operations.

As we continue to move forward on the ambitious path, we must continue to sustain excellence in service delivery, grow in number and contribute across diverse levels of client engagements as well as add new dimensions to our personal and professional competence.

Looking forward to all of us working towards greater client focus, providing value added regulatory solutions and service delivery, and leading with a steadfast spirit to innovate and excel every day.

REGULATORY INTELLIGENCE:
DELIVERING A WEALTH OF INSIGHT

By Sunil Chandupatla

"Regulatory intelligence (RI) is an integral part to enhance effectiveness and guidance for the regulatory professional, and is at the heart of every well-informed regulatory decision. RI focuses on the regulatory pathways associated with the drug development and approval process, often using historic decisions of regulatory agencies as a lens for potential future decisions."

Regulatory intelligence is an essential aspect to succeed in the regulatory landscape. Regulatory data must be harnessed and turned into actionable information as regulatory documents are readily available online and the right analysis, can deliver a wealth of insight.

Regulatory intelligence can be summarized "as actionable intelligence derived from assessment of the regulatory landscape." Regulatory landscape can comprehend various types of publicly available information, such as:

- Product approvals
- Adverse event reports
- Recalls
- Guidance documents
- Recent actions taken by government agencies

Finding correlations between the massive amounts of data provided in hundreds of separate public databases that are not cross-referenced can prove strenuous but, the emerging field of regulatory intelligence has such tremendous capacity to inform the regulatory process that it should be an essential component of every regulatory professional's toolbox.

"RI can advance product lifecycle (value chain) in terms of procedural, technical, scientific and strategic input. Core roles include general information gathering and tracking legislation, followed by information dissemination and use. Procedural intelligence can include advising on marketing authorization applications (MAA) format and procedures, content and copy requirements in Europe and subsequent rest-of-the-world dossier preparation, plus compilation of internal working practice documents, templates and policies."

REGULATORY DATA: POTENTIAL USES

Some of the many ways regulatory data can be useful include:

- Identify issues that a FDA district office frequently cites in inspection reports and help industry to cover the ground
- Survey the competitive landscape to formulate regulatory strategies and gain business intelligence
- Monitor approvals of new products, provide valuable regulatory input to sales and marketing
- To be abreast of labeling changes to competitive products, to assess whether the changes might impact the market
- Analyze adverse event reports
- Assess review times for a category of product or reviewing division to detect trends and compare results
- Keeping up with warning letters that might affect the market and to see shifts in policy implementation
- Screening potential suppliers or distributors to guard against supply chain interruption
- Monitor adverse event and recall data to detect problems in similar products to better inform the design process for new ones
- Keeping current with the evolving requirements in guidance documents
- Aiding in the selection of clinical investigators

IMPACT OF REGULATORY INTELLIGENCE

RI contributes to every pharmaceutical company's bottom line by helping the RA teams provide the highest quality submissions to agencies. If the FDA or European Medicines Agency (EMEA) delays approval of a regulatory submission because of a flaw in the application, the long-term sales of the new compound could be significantly affected, particularly if the company aims to be the first to- market in a specific drug class.

BENEFITS OF REGULATORY INTELLIGENCE

- Decreased time for the approval of product
- Decrease in the cost of the development of a product
- Increased compliance
- Identifies the opportunities for broader indications and identifies the roadmap for product approval
- Identifies the hurdles like compliance hurdles and changes in requirements for specific indication
- Predict agency review times and approval requirements
- Answers specific development questions and maximizes target marks

CONCLUSION

Regulatory intelligence has become a pivotal aspect of the regulatory affairs function. Regulatory personnel constantly seek out, analyze and communicate information about new guidance's and requirements emerging from different markets.

The goal of regulatory intelligence is to help companies stay updated on the regulatory environment to align the policies and product decisions with all relevant regulatory agencies.

New regulations are also taken into consideration by the regulatory intelligence professionals, to help companies acclimatize themselves with the new requirements.

Regulatory intelligence teams can keep local teams up-to-date on country specific regulations while global teams must align their product development with every regulatory environment in which they plan to market their products. Hence regulatory intelligence is important to all surveyed teams locally at the country level and at the global level.

LEAD STORY

NEW EMERGING MARKETS: A STRATEGIC OUTLOOK

"By 2016, the emerging markets will amount to 30% of spending when compared to 20% in 2011."

GLOBAL REGULATORY STRATEGY: INFLUENCE OF EMERGING MARKETS

The US, Japan and Europe constituted as the worldwide pharmaceutical market in the early 1980s. Today developing countries in the rest of the world (ROW) are a force to reckon with, and are referred to as emerging growth markets. China is rapidly scaling competition and is poised as the number two global pharmaceutical market with other countries in Asia, Africa, LATAM and Eastern Europe following suite.

ASIA, AFRICA AND THE NEW EMERGING MARKETS

About 60% of the world's population is based in Asia - home to a population of around 4.3bn; China alone has a population of 1.3bn. If we include the other developing and growing markets - Latin America (LATAM) and Africa, where the GDP is on the rise. In addition, as the GDP increases, healthcare expenditure also increases and this makes for a huge potential market for the pharmaceutical industry.

Africa is also one of the emerging markets and comprises of 54 countries with different growth rates, infrastructure, trade and regulatory agreements and tax regulations. Owing to many operational challenges, clustering strategies may often be optimal. Although the continent remains complex and challenging, it does offer opportunities for pharmaceutical companies to adapt their business models to the region.

Pharmaceutical companies must position themselves in this market early on to take advantage. The new markets to look out for include many countries in Asia, Africa, Eastern Europe and LATAM that combine a large population and a growing GDP within the growth markets.

ALIGNING REGULATORY STRATEGY

Big pharmaceutical companies can re-align the regulatory strategy and opt for increased harmonization as their global operations calls for simultaneous global launches.

In particular, OTC Healthcare companies will benefit largely by this strategy as it will save them time and money, resulting in earlier access to medicines by patients.

In an ideal business scenario, as a drug reaches Phase 1 of the clinical trials companies should plan to initiate deliberations with global regulatory authorities, and seek to create a worldwide development program for major markets.

However, the market environments in some countries may force the companies to create country-specific programs as may be required. And once the regulatory dossier is finalized, companies must aim for a simultaneous global submission plan.

EMERGING MARKETS ARE MORE COMPLEX: UNDERSTANDING THE CHALLENGE

Harmonization is the norm for all guidelines nowadays and some specific local requirements (translations or the structure of the entire clinical trials) are becoming significant enough to shape the entire worldwide strategy.

Emerging markets are more complex as there are many local manufacturers and a staggering number of approved products, which are controlled by small regulatory agencies. Some countries will require translations (entire file or abbreviated files if the product has been approved in other regions).

Specific local clinical trials are needed for few countries which could be challenging for companies developing drugs for small populations and orphan indications.

Paper application for CTAs and new drug applications (NDA), is still the norm in some emerging markets as they do not have electronic filing systems, which further delays the process. One must also take into consideration that some populations and ethnic groups may metabolize drugs differently. These issues can have a significant impact on time lines, thus incurring delays.

THE FUTURE FORWARD LOOKS PROMISING

Emerging markets are displaying willingness to work with industry and other regulatory authorities such as the FDA and EMA in a bid to forge excellent working relationships.

Additionally, working with local manufacturing partners can help pharmaceutical companies manage different requirements for clinical trials.

As the standards for exporting products are extremely high, few local manufacturing partners are seeking US and European approval for importing products.

In many of the developing markets, the FDA has set up offices with an aim to develop standards, benchmarking, collaboration and cooperation through formal and informal workshops and meetings.

It will be imperative for companies to create a global development plan to include Asia and the developing markets. Lot of changes need to be made to make sure drugs continue to be developed and marketed within these markets.

"It will be imperative for companies to create a global development plan for the new emerging growth markets."

eCTD IMPLEMENTATION BY SFDA

By Mohammed Gous

The pharmaceutical industry is tantamount to being one of the most regulated industries in protection of health and well-being of the general public. The regulatory policies of EU and US-FDA are deemed to be standard for the regulatory agencies worldwide.

ICH brought regulatory authorities and pharmaceutical industries of Europe, Japan and US together for various aspects of drug registration.

Similarly, countries from Asia Pacific and Gulf are in process of harmonization with mutual concern as The Association of Southeast Asian Nations (ASEAN) and Gulf Co-operation Council (GCC).

The GCC region is considered as the "Emerging Market" for pharmaceutical export and bilateral trade. The Ministry of Health of GCC States (which include Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and UAE) are the regulatory authorities for the regional Pharma sector. They also regulate prices of pharmaceutical products and bring about harmonization of varying prices and the regulatory process, the GCC implemented a centralized system, Gulf Central Committee for Drug Registration (GCC-DR) in May 1999, which currently runs parallel to the regulatory regimes in the region.

The Saudi Food and Drug Authority (SFDA) is the main drug regulatory body of the Kingdom of Saudi Arabia (KSA). It is considered to be the most stringent and advanced body among GCC cooperation.

To cope up with the ever changing regulation across the globe, the SFDA has taken an initiative of adopting the efficient EMA directives and regulations. As a part of this initiative, it has started accepting submissions in the form of eCTD from Jan 2013. Now that the guidelines has been efficiently drafted and success of the eCTD submissions till date, the SFDA has brought in new regulations stating that from Jan 2015 eCTD format is mandatory for filling any applications to SFDA.

The SFDA eCTD Module1 is slightly different from EU Module1 that it contains additional information requesting the MAH to make declarations as listed below

1.7.5. ALCOHOL-CONTENT DECLARATION

- This section should contain a declaration letter in an official company letterhead stating that the product is free from alcohol

1.7.6. PORK-CONTENT DECLARATION

- This section should contain a declaration letter in an official company letterhead stating that the product is free from any materials of pork/porcine source

1.8. PRICING

- The applicant shall include the price of the product in countries listed in the SFDA Guidance for Submission

CLOUD COMPUTING IN LIFE SCIENCES

By Manoj Sree Harsha Jadapalli

LIFE SCIENCES SUPPORTING INNOVATIONS OF TOMORROW

Most of the life sciences companies now face increasing consumer, portfolio, regulatory and operating challenges on a daily basis as they carry on their search for innovative health solutions. In order to create and sustain competitive differentiation and market dominance, the life sciences sector must meet the diverse challenges of your regulatory/life cycle strategy today while supporting innovations of tomorrow.

CLOUD COMPUTING: UNDERSTANDING THE CLOUD HEMISPHERE

The super cool tech word heard in all industries today is 'The Cloud'. However most of us are concerned about the security and scared about the fringe guarding the cloud with your data in it. Few of the questions around the cloud have been addressed as below.

This article addresses to study the rise of cloud computing in the emerging life sciences domain including biotech and pharmaceutical sectors. The main objective has however been to determine the effects of cloud computing and the business impacts in an increasing global and competitive environment.

WHY SHOULD THE PHARMACY INDUSTRY EMBRACE THE CLOUD?

Cloud computing finds it applications fitting into the picture perfect pharmaceutical regulatory industry because of the following reasons

- Ever-growing datasets
- Unpredictable work packets and traffic patterns
- Demand for faster responses
- Reduced time to market
- Business continuity

WHAT IS STOPPING THE TRANSITION?

Regulatory bodies scrutinize enormous amounts of sensitive and confidential data. Cloud services have been deemed a mystery status when it comes to the visibility and security levels. Data in the cloud moves between various centres for various reasons load balancing, redundancy maintenance etc thus not making it a viable option for heavily regulated industries like the Pharma regulatory.

Especially the language of the legislation has always been slow to catch up with the socio-technological shifts. This in turn makes it more challenging for the industry and the regulators to embrace new ways of maintaining the massive volumes of data in the wake of uncertainty if the new approach is either by letter or by spirit messing with the laws.

WHAT IS THE ACTUAL GAP?

Finding and presenting the framework explaining the relation between the cloud provider and the customer has been an open challenge for the whole industry. Cloud providers are at large misinterpreted as "Outsourcing Providers".

Existing regulations dictate the interaction between service provider and their outsourcing partners, thereby impacting the ability of engaging with cloud providers. Despite of increasingly sophisticated virtual networks, many existing rules in regulated industries are mostly obsolete or hold little relevance to the security norms and standards for the new age technology.

WHERE TO START MIGRATION OF DATA TO THE CLOUD?

Not everything that is IT related about an organization has to move onto a cloud. However taking time out to segment the existing datasets and concerned work packets on criteria like frequency of change, sensitivity enables the customer to effectively use the complementary solutions available in a big data environment.

WHAT TO LOOK INTO AND HOW TO SELL CLOUD?

The cloud providers need to dive deep into potential customer requirements and understand the legislation that governs various aspects around the targeted market, specific to the client requirement and provide more insights on the relevant procedures followed.

Recommending deployment models and identifying the operational and organizational benefits would create an impact. Self-certifying the cloud would sell the confidence on the cloud solution as well as the infrastructure. Additionally explain the analogies around the cloud (these analogies on the cloud or the cloud services are unlikely to change anywhere in the near future).

BOTTOM LINE: UNDERUTILIZATION OF CLOUD SERVICES

Cloud services are being highly underutilised due to lack of transparency of security, capabilities and out-of-date legislations. It's time the Cloud service providers put to paper descriptions of the capabilities, features of their data centres also focussing on the legislation governing the target market to enable the customer learn and educate others to make right choices.

CONCLUSION

The Cloud provides increased opportunities for more efficient business operations, collaboration and innovation, but regulatory concerns continue to be a challenge for life science companies.

Freyr collaborates with clients globally to drive growth, maximize pipeline productivity to deliver and improve customer interactions. Freyr's software centre of excellence is capable of providing cloud-based regulatory compliance software solutions and services that can manage clinical and business applications simply and efficiently.

How Cross Functional Teams Help Leverage Company Core Data Sheets

By Manish Dubey

Can more than one drug name appear in a CCDS. Who is the proper party to approve CCDS updates and revisions ?

This articles offers a framework and helps in understanding the role of the cross-functional teams and their undertakings that are involved in creation of a CCDS.

IN PERSPECTIVE

The Company Core Data Sheet (CCDS) or Core Data Sheet (CDS) is an internal company document that is owned by the marketing authorization holder (MAH)/ pharmaceutical company which presents its position on the safety profile of any drug. The CCDS serves as the basis for prescribing a medication and for global advertising and promotional activities. The purpose of having a CCDS firstly is to align the labeling of any said drug product across the globe and to have the "Reference Safety Information" for the assessment of the aggregate reports for the product.

Depending on the policy and structure in the company, the CCDS is owned by regulatory or safety line functions; but in the true sense CCDS is a cross functional document, that is updated/ created with inputs from various functional groups in a pharmaceutical company.

CROSS-FUNCTIONAL TEAM LIAISES TO PERFECT COMPANY CORE DATA SHEETS

The CCDS cross-functional team would comprise of experts from Global Labeling, Chemistry, Manufacturing and Controls (CMC), Clinical, Safety/Pharmacovigilance, Pharmacokinetics and Pharmacodynamics (PKPD) functions and also legal and marketing in special cases.

In a cross functional labeling team, the regulatory or the global labeling group plays the role of the leader to drive the process by ensuring the other teams provide input on time and bringing consensus on the new content.

Members of the cross functional teams are responsible for finalizing the content of sections pertaining to their area of expertise.

A GUIDE FOR UNDERSTANDING CCDS CLASSIFICATION:

Given below are the classification of the CCDS sections based on the responsible function:

CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC):

"Name Of The Medicinal Product", "Qualitative and Quantitative Composition", "Pharmaceutical Form"

CLINICAL:

"Therapeutic Indications", "Posology and Method of Administration"

SAFETY/ PHARMACOVIGILANCE:

"Contraindications", "Special warnings and precautions for use", "Interaction with other medicinal products and other forms of interaction", "Fertility, Pregnancy and Lactation", "Effects on Ability to Drive or Use Machines", "Undesirable Effects", "Overdose"

PHARMACOKINETICS AND PHARMACODYNAMICS:

Pharmacodynamic properties, Pharmacokinetic Properties

TOXICOLOGY (ANIMAL STUDIES):

Pre-clinical Safety Data (Acute and chronic toxicity, carcinogenicity, teratogenecity, fertility).

MULTIPLE STAKEHOLDER EXPERTISE HELPS IN COLLABORATIVE PROCESS

Various functional groups perform indepth data research and evaluation to provide textual input for sections they are responsible for in the CCDS. Sections in the CCDS require input from multiple line functions as the information in these sections may impact other sections; information may have a cross-reference to other sections in the CCDS as applicable.

For example, "Posology and method of administration" would have information pertaining to the normal adult population as well as the special population like pediatrics, geriatrics, patients with renal impairment and patients with hepatic impairment, as applicable. Information on these special populations would depend on the PK/PD parameters of the drug. The details of PKPD data would be discussed in the pharmacokinetics and pharmacodynamics section of the CCDS.

The effect on dosing would be calculated by the clinical expert, based on the data and would be mentioned in the section "Posology and Method of Administration". If the safety expert on analysis of PKPD data finds any activity which can cause adverse event in any of the special populations, then a caution statement must be added in "Warnings and Precautions" section of the CCDS.

UNDERSTANDING DIVERSE VIEWPOINTS & IMPACTS

As the same information would impact three sections of the CCDS which are owned by Clinical (Posology and Method of Administration), Safety (Warnings and Precautions) and PKPD (Pharmacokinetics and Pharmacodynamics section) experts, the final text in these sections should be discussed and agreed-upon by these experts.

Hence it is important that all the concerned functions agree on the content in the overlapping sections. This process will also aid in constant review of the document.

Moreover, working with cross-functional teams allows diverse perspective on any topic and helps in having in-depth discussions. It also provides an opportunity to look in to the overall risk-benefit ratio of the product instead of looking into risk and benefit in isolation, as both Clinical and Safety functions work in cohesion in the cross functional team.

In conclusion, the cross functional team provides diversity of knowledge, thinking perspectives, additional review of the content from other functions and in depth data analysis while ensuring consistency of information in the CCDS.

REGULATED PRODUCT SUBMISSION (RPS):

AN EVOLUTIONARY UPGRADE FROM eCTD

by Naveen Chand Vudimudi

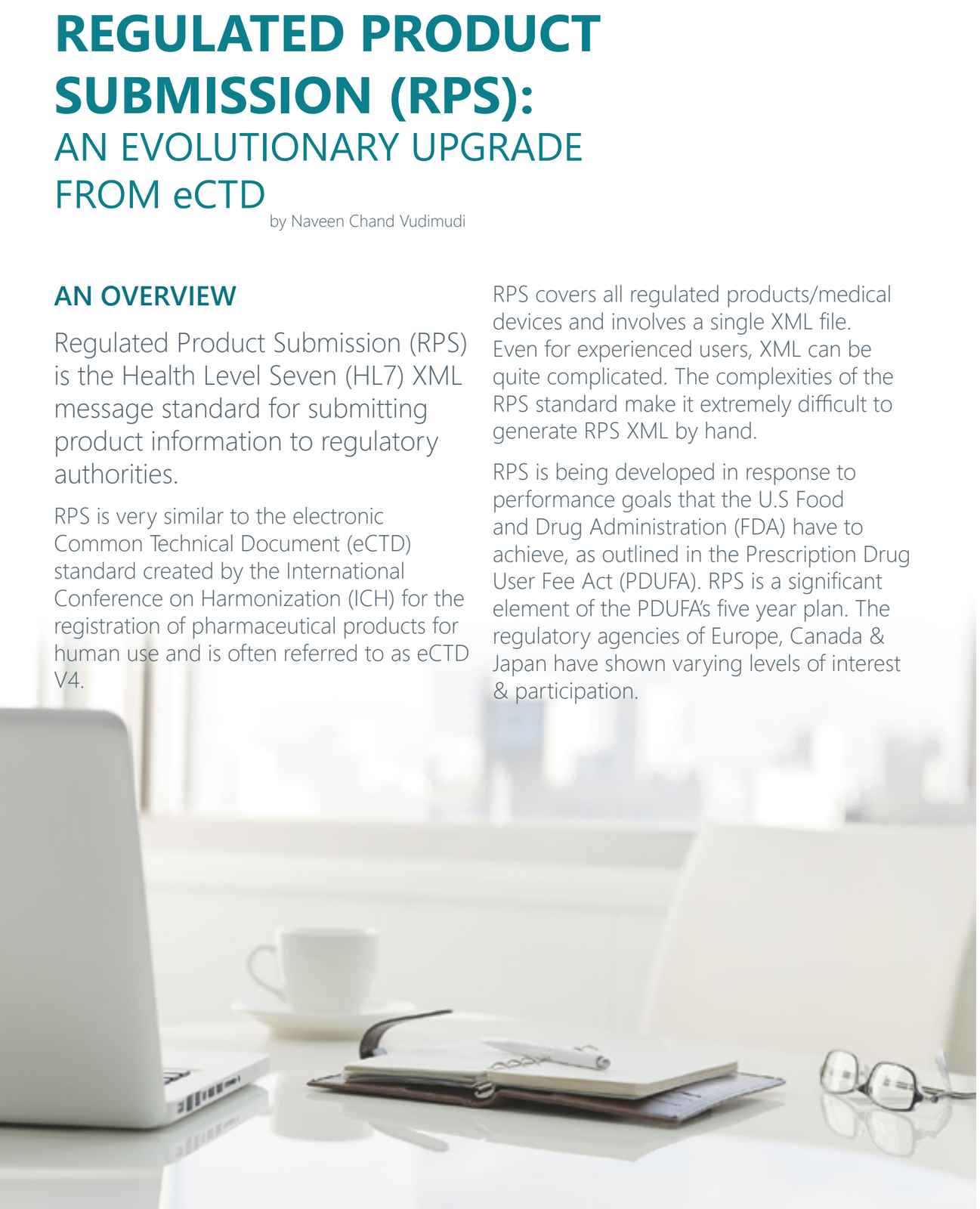
AN OVERVIEW

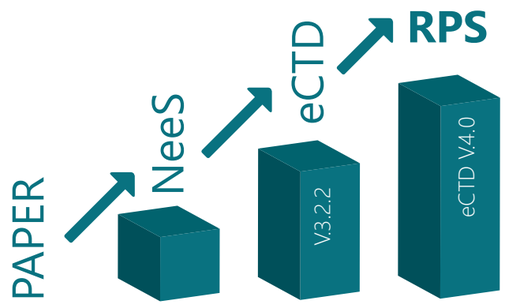
Regulated Product Submission (RPS) is the Health Level Seven (HL7) XML message standard for submitting product information to regulatory authorities.

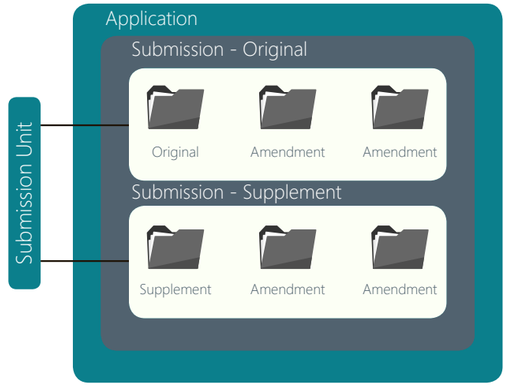
RPS is very similar to the electronic Common Technical Document (eCTD) standard created by the International Conference on Harmonization (ICH) for the registration of pharmaceutical products for human use and is often referred to as eCTD V4.

RPS covers all regulated products/medical devices and involves a single XML file. Even for experienced users, XML can be quite complicated. The complexities of the RPS standard make it extremely difficult to generate RPS XML by hand.

RPS is being developed in response to performance goals that the U.S Food and Drug Administration (FDA) have to achieve, as outlined in the Prescription Drug User Fee Act (PDUFA). RPS is a significant element of the PDUFA's five year plan. The regulatory agencies of Europe, Canada & Japan have shown varying levels of interest & participation.





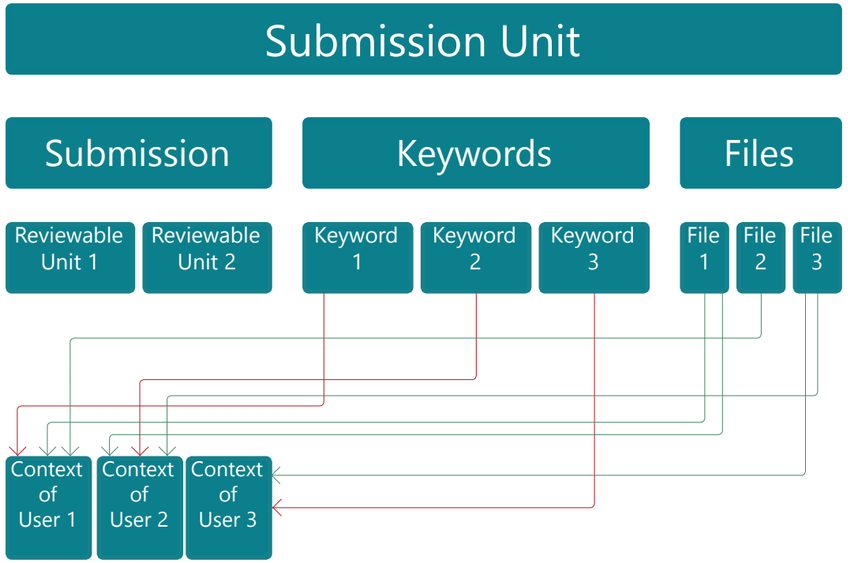


RPS Vs eCTD

Organize applications and regulatory activities	Flat structure
Single XML File	Multiple XML Files
Folder structure undefined	Folder hierarchy and names defined by guidance
Attributes globally defined and assigned at the file level	Attributes assigned at folder level – some at file level
Attributes can be corrected	Attributes cannot be corrected
Virtual TOC: Documents appear in a browse-able structure based purely on their metadata	Electronic TOC: Documents appear in a browse-able structure based largely on how their leaf nodes are linked into an overall hierarchy of leaves
Structure created externally by a viewing tool – otherwise only a flat file list would be seen	Structure inherently part of the XML and appears within any web browser
Allows for regional or product differences in organizing documents into a TOC	Cannot easily add new content for regional differences or other regulated products
Re-use documents across applications formalized	Re-use documents across applications not formally described and subject to specific regulators' rules

GOAL OF RPS

- To create an HL7 XML message standard for submitting information to regulatory authorities
- The Refined Message Information Model (R-MIM) shows the structure of a message as a color-coded diagram



RPS RELEASE 1

The project to develop a RPS standard was initiated on 22 June 2005. RPS RELEASE 1 was spearheaded by Jason Rock of Global Submit, a US-based company dedicated to facilitating electronic regulatory submissions between life science companies and regulatory agencies worldwide. The aim was to create one standardized submission format to support all of the FDA's electronic product submissions.

RPS RELEASE 1 provides the capability to cross-reference previously submitted material owned by the sponsor as well as append, replace and delete parts of the document lifecycle. RELEASE 1 was approved in 2008, but was not suitable for EU and Japan.

RPS RELEASE 2

RELEASE 2 was led by Peggy Leizear of the Office of Planning at the FDA. RPS RELEASE 2 grants the ability to exchange contact information, classify submission content and handle multi-region submissions.

RELEASE 2 of RPS also handles two-way communication-between the Regulatory Authority and the Submitter. Both the parties involved will use RPS to send correspondence (e.g. request for additional information, meeting minutes and application approval).

RPS RELEASE 2: WINS VOTE at HL7 TO BECOME NORMATIVE STANDARD

The Regulated Product Submissions (RPS) standard, in development since 2005, is a normative standard as of 8th September 2014, following its win at the Health Level Seven (HL7) summit.

When the votes were counted, RPS Release 2 didn't get a single negative vote and is well on its way to become an ANSI standard in future.

This is the first major step towards the creation of the electronic Common Technical Document (eCTD) version 4.

RPS IMPLEMENTATION TIMELINE

RPS will be implemented in the US in 2016 and EU and Canada in 2017, according to industry sources.

FUTURE RELEASES AND IMPLEMENTATION RPS RELEASE 3

Beyond HL7/ANSI accreditation, they need implementation guides from ICH and regulatory agencies, and approval as an ISO standard. With those guidelines RPS RELEASE 2 will come out as RPS RELEASE 3, which is likely to happen in 2016 or early 2017.

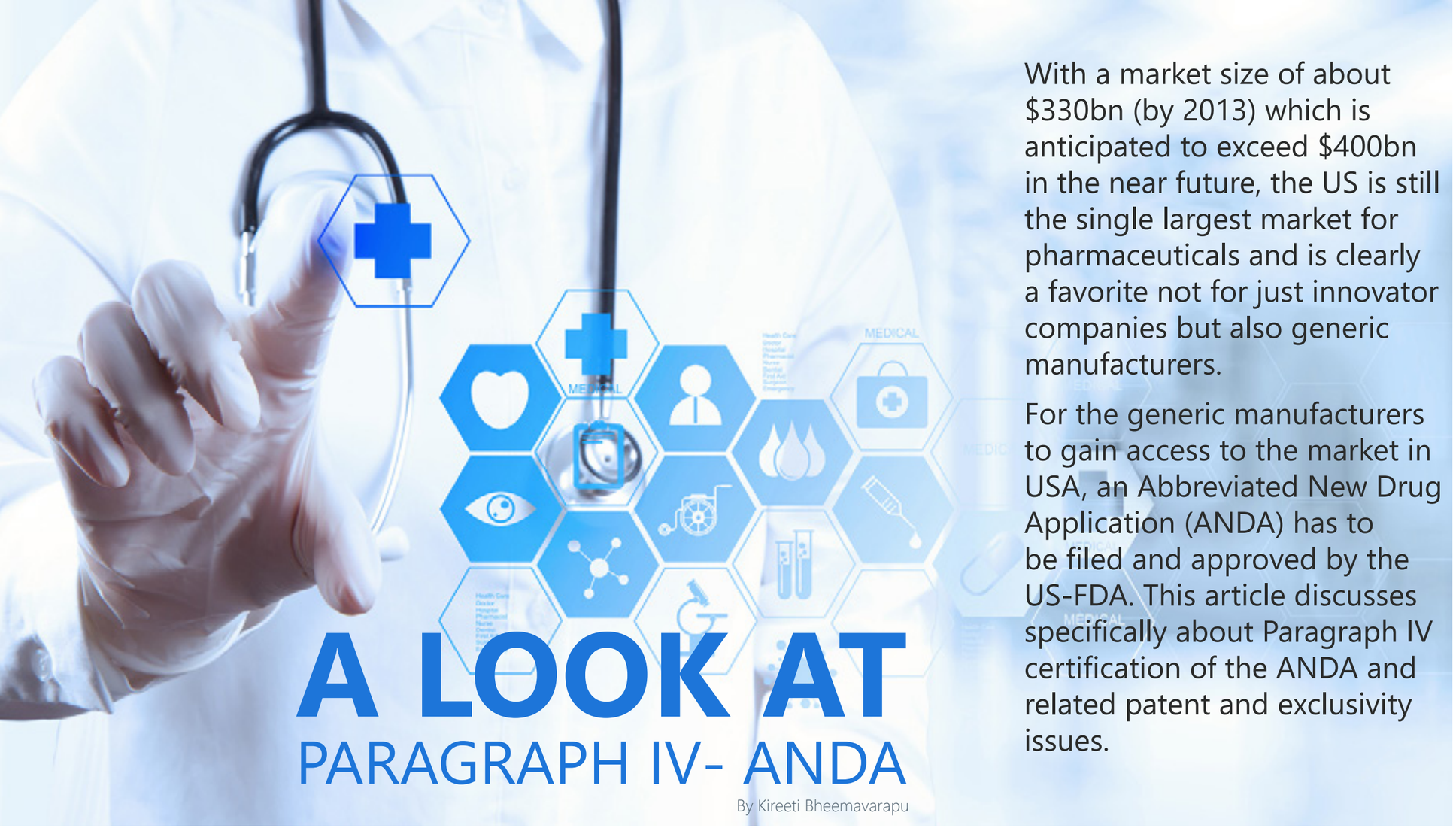
- It will be headed by ICH
- The goal of **RPS RELEASE 3** is to have more international requirements

RPS ADOPTION FOR A PHARMACEUTICAL COMPANY

Adoption of an electronic submission process that leverages RPS means a pharmaceutical company can

- Increase their profitability goals
- Automate their inefficient paper processes and
- Significantly reduce their costs

> "RPS is the highly anticipated replacement for eCTD, which is currently the electronic standard for submissions to the FDA."



A LOOK AT PARAGRAPH IV- ANDA

By Kireeti Bheemavarapu

With a market size of about $330bn (by 2013) which is anticipated to exceed $400bn in the near future, the US is still the single largest market for pharmaceuticals and is clearly a favorite not for just innovator companies but also generic manufacturers.

For the generic manufacturers to gain access to the market in USA, an Abbreviated New Drug Application (ANDA) has to be filed and approved by the US-FDA. This article discusses specifically about Paragraph IV certification of the ANDA and related patent and exclusivity issues.

Section 505 (b) of FD&C act which lays out regulations for the new drug applications, codified as 21 USC § 355 (b) (1) states that : "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

Now, all the list of patents that claims that are submitted to FDA during NDA/ANDA submissions are published with their code names in Approved Drug Products with Therapeutic Equivalence Evaluations (the list) also known as "Orange Book"

The following are the examples of Types of Patents: Composition/Molecule (API) (Listable)

- Formulation (Listable)
- Dosage Form (Listable)
- Method of Treatment (Listable, Section viii carve out)
- Only Compositions and Method of Treatments can be listed in the Orange Book
- Method of Manufacture (Not Listable)

(Note: Out of these, listable patents are the ones that are published in the Orange book.)

Hatch-Waxman Act:

Drug Price competition and patent restoration act also known as Hatch –Waxman act, is a 1984 federal law designed to encourage the manufacture of generic drugs and established a modern regulation of the generic drugs in the USA.

Hatch-Waxman amended Section 505(j) of the Act, codified as 21 U.S.C. § 355(j), which prescribes the process for pharmaceutical manufacturers to file an Abbreviated New Drug Application (ANDA) for approval of a generic drug by the US-FDA.

21 USC § 355(j)(2)(A)(vii)) specifically lays out the details of the patent certification required for the ANDA which states that an ANDA application shall contain "certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to ….or which claims a use for such listed drug for which the applicant is seeking approval"

- That such patent information have not been filed, also called as paragraph I certification
- That such patent has expired, also called as Paragraph II certification
- Of the date on which such patent will expire, also called as Paragraph III certification or
- That such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted also called paragraph certification.

The ANDA application filed with Paragraph I or II certification will be taken up for review once the applications are deemed complete by the FDA. In case of application filed with a Paragraph III certification, its review and subsequent approval depends on the expiry of the patents claiming the listed drug or its use. However, ANDAs filed with Paragraph IV certification are most lucrative, expensive & time consuming.

Market Exclusivity:

Generic manufacturers who first file Paragraph IV certifications, challenging patents that may be invalid or unenforceable thereby triggering a patent action against them by the owner of the patent are provided with an incentive in the form of 180 day market exclusivity under Section 505(j) (5) (B) (iv), meaning FDA shall not approve any other ANDA having paragraph IV certification during the exclusivity period.

The 180 day exclusivity is financially very rewarding for the first applicant as the price of generic

drug decreases with multiple competitors and with less competition the ANDA applicant can make better profits and also can aggressively pursue to establish the product in the market directly competing with the innovator by the end of exclusivity period.

Serving Notice to the Patent Holder:

The applicant who files an ANDA with paragraph IV certification should serve a notice to the patent holder/his representative for each patent that claims the listed drug or use for such listed drug for which the applicant is seeking approval within 20 days upon filing of such ANDA.

Under FDA's implementing regulations (21 C.F.R 314.95) based on FDC Act (§ 505(j) (2)(B)) & Medicare Modernization Act (2003) such a notice must:

- State that an application that contains data from bio-availability or bio-equivalence studies has been submitted under this sub-section for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and
- Include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

Confidential Access:

In addition, FDC Act § 505(j)(5)(C) provides that a Paragraph IV notice letter may include an Offer of Confidential Access (OCA) to provide the NDA holder/patent owner confidential access to certain information from an ANDA "for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the [Paragraph IV certification] and for no other purpose." An OCA must "contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Moreover, "[a]ny person provided an offer of confidential access . . . may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an [OCA]."

Once FDA is convinced that notice is sufficient and complete, a 45 day period for the patent owner to legally challenge the applicant for patent infringement will be triggered from the date of receipt of the notice or any later date that applicant chooses and submits to the FDA in a written statement failing which ANDA will be approved and applicant shall be entitled to 180 day exclusivity.

If the patent holder sues the applicant for patent infringement then there will be a 30-month stay on the FDA's approval of an ANDA. However this duration can be lengthened or shortened by the court "and ends when law suit is resolved.

There are three possible scenarios as to what can happen during 30-month stay:

- Patent expires, then FDA may approve ANDA and more than one generic version may be on the market.
- Patent claim of the patent still holds and court rules in favour of the patent holder (innovator) so FDA cannot approve any generic drug until the patent expires. Moreover, no ANDA applicant is entitled to 180-day market exclusivity challenging the same patent.
- Court may rule in favour of the applicant so FDA may approve ANDA and the first applicant is entitled to 180-day exclusivity.

Exclusivity Forfeiture:

- However, the exclusivity comes with conditions failing which it will be forfeited. A first applicant may forfeit 180-day exclusivity if:
- He fails to market the approved generic drug by later than 75 days after final approval of the ANDA or 30-months after the ANDA filing (whichever is earlier).
- If the applicant amends /withdraws the paragraph IV
- NDA holder withdraws the patent information

Multiple first applicant approach: After the district court's ruling in the case of "Mova Pharmaceutical Corp Vs Shalala" FDA's approach has changed in the way it identifies the first applicant who filed ANDA with a Paragraph IV certification. Currently, FDA applies a multiple first applicant approach wherein FDA "intends to treat all ANDAs containing a paragraph IV certification to a listed patent that are submitted on the same day as being submitted at the same time for purposes of 180-day exclusivity when no ANDA for the same drug product containing a paragraph IV certification to the same patent has been submitted on a previous day." Implying none of the same day ANDA with Para-IV submissions would be considered as previously submitted and all the applicant who fulfil the requirements are considered as first applicants.

Exclusivity begins to run, independent of the approval, with the commercial marketing of that drug product or with a court decision on the patent, whichever comes first. Exclusivity will be triggered for all of the first applicants for a specific listed patent by the earlier of commercial marketing by one of the first applicants or by a court decision (regarding the patent as to which the applicant is a first applicant) finding the patent invalid, unenforceable, or not infringed. The commercial marketing trigger will begin exclusivity as to all of the listed patents; a court decision will only begin the running of exclusivity as to the patents addressed in the decision.

During the exclusivity period, FDA may approve any other first applicant's ANDA, but no other ANDAs. Any first applicant whose ANDA is approved after the exclusivity has been triggered will share in the remaining period of exclusivity. Once the 180-day exclusivity period has run, FDA may approve all subsequent ANDAs.

Authorized Generics:

An Authorized Generic is the brand company's (innovator) own product which is repackaged and marketed as a generic drug through either a subsidiary or a third party. This type of generic is a brand name drug already approved as a New Drug Application (NDA) by the FDA and marketed as a generic product under a private label. An Authorized Generic has the identical colour, size, shape, flavor, dosage form, and strength, route of administration, active ingredients, and inactive ingredients as the brand drug. Authorized generics are exempt from the 180-day period exclusivity, meaning they CAN be sold in the market during the first applicant's exclusivity period.

Involvement of Attorneys: We now know that the notice served to the patent holder should "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid unenforceable or will not be infringed."

This opinion of the applicant comes from Attorneys, API Suppliers (if API is sourced from other parties). However, this should come early in development process. Although it is understood that the detailed statement to have some rational reasonable basis there is little guidance on how detailed is "Detailed Statement".

Now`, fewer facts, detail and argument in the detailed statement may provoke lawsuit.

Whereas as detailed statement with more facts, detail and argument may avoid lawsuit by showing strength of case so firms which who wish to file ANDAs (with Paragraph –IV certification) it would be better to involve attorneys from the early in the development process to avoid or handle the legal litigations.

freyr 360°

Global Regulatory Solutions & Services

NEW SERVICES LAUNCH

FREYR'S SPECIALIZED REGULATORY SERVICES FOR NEW STRATEGIC MARKETS -AFRICA & SUB SAHARA COUNTRIES

Freyr unveiled its suite of specialized regulatory services for new strategic markets that will cover Africa including South Africa, Sub Saharan and North African regions like – South Africa, Ghana, Kenya, Nigeria, Angola, Uganda, Namibia, Zimbabwe, Zambia, Mauritius, Tanzania, Botswana and Malawi.

Freyr's specialized regulatory services suite is aimed at supporting Large and SMB Pharma/ Bio tech/ Consumer and Medical devices companies with end-to-end strategic regulatory services for their strategic regulatory needs across new emerging markets. Identifying a promising opportunity, Freyr has created a new regulatory market intelligence service that would help the pharmaceutical industry make crucial decisions and capitalize on unmet customer needs.

Freyr's specialized regulatory services suite will offer - Medicine Registration, GMP Roadmap, CTD Conversion and Dossier Harmonization for new MAA.

PHARMACEUTICAL REGULATORY & MARKET INTELLIGENCE REPORTS – SUB SAHARAN AFRICAN REGION

Strategic Pharmaceutical Regulatory and Market Intelligence Reports with the latest insights, analysis and forecasts within the Sub Saharan African Region at the country level, with a practical evaluation of new market opportunities and risks.

The reports will help to:

- **Improve new market expansion planning** with key regional and sector focused market insights
- **Take well-informed decisions** with key regulatory data and detailed regulatory market analysis
- **Understand the competitors,** their product strategy and market position
- **De-risk the market strategy** by comparing the strengths and weaknesses of the country's market

FREYR ANNOUNCES LAUNCH OF MEDICAL WRITING SERVICES

Freyr has launched its professional medical writing services across a spectrum of domains to the global bio-pharmaceutical industry. The services include writing/editing of regulatory submission documents, consulting and training and document template solutions across therapeutic areas, such as: Oncology, Neurosciences, Cardiovascular, Diabetes, Endocrinology, Antiviral, Anti-infective, Biological, Gastroenterology and Orthopedics.

Regulatory Writing: Comprehensive understanding of various regulatory guidelines such as ICH-GCP, FDA, EMEA, TGA and CDSCO-DCGI guidelines.

Scientific Writing: Typical scientific writers are well-versed in all aspects of Good Publication Practice (GPP), International Committee of Medical Journal Editors (ICMJE) guidelines & CONSORT statement which they routinely apply in preparation of scientific documents.

Commercial Writing: Experience in medico-marketing communication writing which includes development of marketing material including posters, newsletters etc.

FREYR LAUNCHES ENTERPRISE COSMETIC REGULATORY SERVICES FOR EAA, US AND ASIAN COUNTRIES

Freyr announced the global launch of its full-services Enterprise Cosmetic Regulatory suite targeted to comprehensively cover countries in the EEA, US and Asian regions.

Freyr services will offer faster, cost-effective and accurate Cosmetic Product Safety (CPSR) & Toxicology Reports providing end-to-end retrospective assessments that will comprehensively cover – Safety & Toxicology Assessments, Margins of Safety (MoS) calculations, Threshold Toxicological Concern (TTC), Chemical Structure & Profile, Levels of Exposure, Overall Toxicology Issues & Summary, as well as INCI (International Nomenclature) for ingredient safety, listing, warning & labeling-relevant information for both – Cosmetic Raw Materials as well as Finished Cosmetic Products.

Backed by a global team of professional toxicologists, Freyr services are slated to provide assessment reports that will cover hundreds of products, ranging from simple to complex cosmetic formulations and will be in themselves a certification of the safety of the products, within the intended application and its compliance to the various annexes of the EU cosmetics regulation.

All Freyr provided Safety & Toxicology Reports will be valid across countries in the EEA, US and Asian regions.

CELEBRATING NEW CLIENT WINS

As an organization, we at Freyr, have always placed the highest value on our business associations and partnerships. It has been our guiding principle to identify newer opportunities and create exceptional engagement excellence for our clients that transform into long-term relationships. As always, it is a great pleasure to announce the New Wins of this quarter.

GLOBAL REG INTELLIGENCE SERVICES FOR $71bn TOP-5 CONSUMER HEALTH COMPANY

- Designed a product version for a global Top 5 Multinational Pharmaceutical and Consumer Healthcare Company
- Completed an Africa related Pharmaceutical Regulatory and Market Intelligence project comprehensively covering deep insights across 7 Sub Saharan Regions
- Freyr has a pipeline of 4-5 potential global business leads in the Regulatory Intelligence space

CMC REGULATORY SERVICES FOR $1bn GLOBAL R&D FIRM

- Provide strategic services in the CMC Regulatory Services space for an independent associated company
- Freyr's CMC Regulatory Affairs consultants will identify critical path activities and timelines to begin work on the project soon
- The client has also engaged with Freyr for another EVMPD project, which is currently operational

STRATEGIC eCTD SERVICES FOR $10m INTEGRATED PHARMA COMPANY

- Provide non-clinical documentation services using eCTD software for an Indian based integrated pharmaceutical company
- Freyr undertook the task of compiling the non-clinical overview report (Module 2.4)
- Worked in tandem with a medical practitioner, to review and successfully submit the report within the stringent timelines

GLOBAL REGULATORY SERVICES FOR $57bn TOP 5 GLOBAL PHARMA COMPANY

- Awarded regulatory services support contract by a Top 5 Global Pharmaceutical Company for its Drug Regulatory Affairs division for Middle East & African Countries (AMAC) and Latin America & Canada (LaCan) regions
- In-scope activities include delivery of critical regulatory materials including regulatory components for product license renewals, registration samples & certificates
- Liaised with global translation services core team and delivered operational support to regulatory activities related to new product planning for the regions

UDI Compliance Services for BSD Medical Corp

- Provide end-to-end UDI compliance solution and support for BSD Medical Corp to meet the fast approaching deadline for GUDID submissions
- Deploy "Freyr IDENTITY", its indigenous UDI compliance solution application, to streamline, collate, compile and validate all the respective GUDID attributes and enable smoother and error-free submission
- Freyr IDENTITY will enable an efficient UDI compliance Lifecycle Management System through its advanced Data Tracking, Management and Validation

STAR ACHIEVERS OF THE QUARTER

Balarao M V
Technical Lead

What was your reaction to being named as the "Star Achiever of the Quarter"?

I felt very happy and elated at the news.

What has been your greatest challenge at Freyr?

The transition phase, when I moved to web technology from mobile technology.

What do you like most about your job?

Learning new technologies is what I most love about my job.

What is the one thing people would be surprised to know about you?

I am a father of two wonderful sons.

Complete this sentence -If I could do it all over again, I would:

I would want to do lot of things differently to achieve my goals.

Your hobbies and/or interests.

Music.

Favorite sports or pastimes.

Cricket.

Prateek Kulshrestha
Regulatory Affairs Associate

What was your reaction to being named as the "Star Achiever of the Quarter"?

I felt privileged and happy at the same time.

What has been your greatest challenge at Freyr?

I consider every task as a challenge. But I feel the greatest challenge so far while working on global change controls was to close the pending change controls and to consistently meet the client requirements.

What do you like most about your job?

The experience and knowledge, which I gain at the end of each task.

What is the one thing people would be surprised to know about you?

I am very easy going and very witty.

Complete this sentence -If I could do it all over again, I would:

I would have worked in research and development or established a business of my own.

Your hobbies and/or interests.

Listening to music, playing console games and reading articles on inventions and discoveries.

Favorite sports or pastimes.

Table tennis.

I would like to extend my gratitude to Vikas Bhardwaj and Anklesh Raut for their consistent support and motivation. Additionally, I would also like to thank Vishnu Teja M V N and Gautam Kalagara who supported and encouraged me to face the challenging tasks during the projects.

I would like to express thanks to all the people who have inspired me and led by example. Firstly, I thank my parents who are my greatest strength, next would like to thank Vikas Bharadwaj and Gautam Kalagara who always backed me up during the tough phase of my project. I also want to thank my team mate Prateek Kulshrestha for his support. Best learning in this year is: All progress takes place outside the "COMFORT ZONE".

Vishnu Teja M V N
Regulatory Affairs Associate

What was your reaction to being named as the "Star Achiever of the Quarter"?

I was surprised and overjoyed at the news.

What has been your greatest challenge at Freyr?

I believe that each project, that I have been involved has been a learning experience. However my greatest challenge has been the APR/PQR project which requires strict adherence to timelines in line with client expectations.

What do you like most about your job?

I love that my job challenges me every day in different ways. It also gives me great job satisfaction that significantly outweighs the hours, the stress and the hard work. All I can say is give me MCP: mission, challenge and purpose, I'll be set for the day.

What is the one thing people would be surprised to know about you?

I am very pious and intuitive.

Complete this sentence -If I could do it all over again, I would:

I would be a professional basketball player or a successful entrepreneur.

Your hobbies and/or interests.

I love gardening and visiting new places.

Favorite sports or pastimes.

Swimming, basketball and table tennis.

Arey Venkata Srikanth
Facility Manager

What was your reaction to being named as the "Star Achiever of the Quarter"?

I was shocked and ecstatic at the announcement; I would like to thank the management for this recognition.

What has been your greatest challenge at Freyr?

Today facility management is a highly evolved specialization, where every facility manager is supposed to be an expert in every aspect right from purchasing products and services to maintaining infrastructure. I believe that gaining information from all directions and filling out knowledge gaps has been my greatest challenge at Freyr.

What do you like most about your job?

I'd say that I enjoy giving direct support to senior management in a way that really makes a difference. It is not now just about getting the day job done, it is about thinking more strategically about the general business environment.

What is the one thing people would be surprised to know about you?

I am a big car enthusiast; they are both beautiful and utilitarian.

Complete this sentence -If I could do it all over again, I would:

I would make all my parents' wishes come true.

Your hobbies and/or interests.

Listening to music and staying abreast of technology.

Favorite sports or pastimes.

Swimming, basketball and table tennis.

Yogi Raj
Business Development Manager

To “be” is the answer, “how” is the question.

What was your reaction to being named as the “Star Achiever of the Quarter”?

I was humbled.

What has been your greatest challenge at Freyr?

Being in business development, I need to work with multiple stakeholders including clients and people from all departments within Freyr, which is the most challenging aspect.

What do you like most about your job?

I like meeting new people, understanding new challenges, trying to find solutions, working with people for greater good, push my abilities, test them, create, express and explore. My profile offers me these opportunities to excel.

What is the one thing people would be surprised to know about you?

My attitude of “living every day as it comes” leaves me with enough room to experiment and thus I often end up surprising myself.

Complete this sentence -If I could do it all over again, I would:

Stop procrastinating.

Your hobbies and/or interests.

Writing is a passion along with dancing and traveling. I take a lot of interest in reading about history and cultures – following new art, scientific advancements and global political development.

Favorite sports or pastimes.

Swimming and riding horses, I like to read and take long walks.

Sajed Ali Khan
Manager – Regulatory Affairs

“My talents and imperfections are a blessing from God and I lay them both at his feet.”

What was your reaction to being named as the “Star Achiever of the Quarter”?

I was thrilled and delighted; it is a great honor that sets you in good stead in the workplace. Getting to this point required some genuine forethought and careful execution on my behalf.

What has been your greatest challenge at Freyr?

A chance to learn how to think outside the box and always find new ways to achieve the best results.

What do you like most about your job?

The challenging situations, tight time lines and the last minute surprises from the customer, which comes every now and then during the job.

What is the one thing people would be surprised to know about you?

I am an all-rounder who believes in all shades of life.

Complete this sentence -If I could do it all over again, I would:

I would not change a single thing.

Your hobbies and/or interests.

Fitness, playing cricket, table tennis, badminton and drawing.

Favorite sports or pastimes.

Cricket, table tennis, badminton and TV.

Varsha Salla
Sr Content Specialist

What was your reaction to being named as the "Star Achiever of the Quarter"?

I was very happy to hear the news.

What has been your greatest challenge at Freyr?

I wouldn't say it is a challenge, I love working at Freyr, which allows me to divide my time between creative and technical tasks. I love having that duality, because when I get stuck on the creative stuff, I can switch gears and do the technical stuff.

What do you like most about your job?

My team and the positive environment at work.

What is the one thing people would be surprised to know about you?

I'm great at carroms.

Complete this sentence -If I could do it all over again, I would:

Take everything you have learned over the years and apply it. Fix the mistakes. Right the wrongs. And make better choices this time. It would be the ultimate do-over.

Your hobbies and/or interests.

A passion for period literature, abstract poetry, learning Korean.

Favorite sports or pastimes.

I only like watching tennis else and I'm not very inclined towards sports.

"Right now is your chance to fix tomorrow before it becomes yesterday."

Anantha Kumar Mahendran
Business Development Executive

What was your reaction to being named as the "Star Achiever of the Quarter"?

It is indeed an honor to have been chosen as the "Star Achiever of the Quarter". This gives me the motivation to go the extra-mile in the future.

What has been your greatest challenge at Freyr?

Coming from a core IT background it has been challenging for me to align to this consultative sales role within a Pharma Regulatory Services Company. But the team and management have been really supportive in helping me align to the process.

What do you like most about your job?

The challenges that I face on a day-day basis and the opportunity to take ownership of different aspects involved in managing an account, is what makes every day different and interesting.

What is the one thing people would be surprised to know about you?

I was a certified micro-flight pilot during my NCC days.

Complete this sentence -If I could do it all over again, I would:

Manage some of the accounts that I handled during my initial months in the company in a more consultative way, as I have a better grasp of the subject right now.

Your hobbies and/or interests.

Movies, history and aviation.

Favorite sports or pastimes.

Cricket.

Khoreng Boro Ovong
Admin Associate

What was your reaction to being named as the "Star Achiever of the Quarter"?

I'm honored to be recognized as a star achiever.

What has been your greatest challenge at Freyr?

This is exactly the working environment in which people can develop and make a difference! Whenever there's an opportunity or challenge coming our way we can adjust and jump right in.

What do you like most about your job?

Freyr offers an enjoyable atmosphere where you can really see results and progress every single day. For me it's energizing to have a flexible, reliable and experienced management team who I can support in my own individual capacity.

What is the one thing people would be surprised to know about you?

I play the guitar.

Complete this sentence -If I could do it all over again, I would:

Not change a single thing. I'm happy with the way things are.

Your hobbies and/or interests.

Music and singing.

Favorite sports or pastimes.

Cricket, football and table tennis.

"Freyr is a company where you will be inspired, feel energized and be happy."

CORPORATE SOCIAL RESPONSIBILITY

By Vasu Ranabothu

FREYR PLANTING SEEDS OF GROWTH FOR STRENGTHENING THE FUTURE

Civilization began with agriculture when our nomadic ancestors began to settle and grow their own food, human society was forever changed. The urban world however has forgotten this factor, insulated by the apparent abundance of food which has been gained through new technologies for growing. Other factors include transportation and storage of food, humanity's fundamental dependence on agriculture and the importance of farmers in society is often overlooked.

Our organization has voiced its support through i4Farmers; a US-based non-profit 501(c) organization established by the core Freyr management team, as an ongoing corporate social responsibility initiative. Freyr continually challenges itself to apply its enterprising spirit, passion for innovation and can-do attitude to make a difference in vital areas essential to meet these challenges of the future like helping poor farmers to lay a strong foundation for growth.

FREYR HELPING FARMERS ENGAGE IN SUSTAINABLE FARMING PRACTICES

The Freyr management team has been actively involved in helping farmers take part in sustainable farming practices for growing cotton in Adilabad district located in the state of Telangana, India. The project is aimed to reduce the input costs of growing cotton which will in-turn reduce the losses when crop fails and maintain the same profitability when crop sustains. The most probable solution is to reduce the input costs in order to reduce all these losses.

PARTNERING FOR GROWTH

i4Farmers in collaboration with US-based Center for Sustainable Agriculture (CSA) has identified five villages in Adilabad. Through this partnership farmers will be educated on ways to reduce input costs while knowledge about alternative seeds, fertilizers and non-conventional pesticides will also be imparted.

All the farmers from these remote and backward tribal villages grow cotton for their livelihood which is cost intensive; however the farmers don't have enough resources and education on advanced farming practices.

THE PROJECT BASELINE SURVEY

The project began early this year; a baseline survey was conducted in Punuguda, Shekguda, Kapperdevi, Charlapally and Umri villages located in Talamadugu Mandal (Township) of Adilabad district to identify potential farmers who can participate in this project. Once the farmers were identified, they were taken to an innovative farmer's field in Yavatmal district of Maharastra to show them few progressive methods in farming.

PROJECT OUTCOME: NON-B.T COTTON SEEDS VS B.T COTTON SEEDS

Farmers participating in the project received non-B.T. cotton seeds from the Central Institute of Cotton Research (CICR). The non-B.T cotton seeds are priced at INR 150 ($2.440) in comparison to B.T cotton seeds INR 1,700 ($27.674) – 1,800 ($29.29), which helped in reducing the input costs for farmers tremendously. Furthermore some farmers had to plant seeds thrice owing to scanty rainfall this season which further raised the seed costs.

It is interesting to note that farmers who used B.T. Cotton seeds spent INR 2,500 ($40.66) per acre on seeds while the project participants spent INR 250 ($4) per acre. Surprisingly non-B.T seeds fared much better than B.T seeds during the tough season.

In addition, a field training session was arranged to showcase methods of preparation of organic pesticides using animal waste and plant leaves available around the field area. Project participants prepared organic pesticides and sprayed it on their fields to reduce pest attacks. The low-cost, chemical free organic pesticide further reduced the input costs.

HERE IS AN EXAMPLE OF SAVINGS PER ACRE, SO FAR FOR THE FARMERS IN THIS PROJECT.

INPUT / ACTIVITY	CONVENTIONAL (B.T. COTTON)	PROJECT PARTICIPANTS (NON B.T COTTON WITH NPM)
Soil Preparation	INR 1,000 ($16)	INR 1,000 ($16.26)
Seeds	INR 2,500 ($40.66)	INR 250 ($4)
Inter-Cultivation	INR. 800 ($13)	INR 800 ($13)
Fertilizers (DAP)	INR 3,600 ($58.55)	INR 1,200 ($19.53)
Plant Protection / Pesticides	INR 3,200 ($52.08)	INR. 400 ($6.50)
TOTAL INPUT COST, SO FAR	**INR 11,100 ($180.72)**	**INR 3,650 ($59.36)**

**NPM = No Pesticides Management Practices*
*** This table shows almost 3 times the savings for farmers, on a conservative estimate*

CURRENT STATUS OF PROJECT

The crop has reached the picking stage and the yield is good as B.T Cotton and chemical intensive farms yield in the area. Farmers who earlier didn't opt for the project are now enthused looking at the result which gives them impetus to try this pocket friendly option for the next crop season.

> "Combined power of human collaboration and networked connections."

FUTURE STEP

At the end of three year project period, Freyr anticipates that farmers could adopt these cost-effective farming practices and reduce input costs and increase their profitability.

Once the project reaches a profitable stage, Freyr intends to initiate diversification practices in cropping pattern rather than cotton mono-cropping. The main aim is to make a smooth transition for farmers from growing commercial crops to food crops, which they can also eat. Growing food crops are a sustainable and economical and can help reduce the financial burden on the farmer.

"Caring for those who feed the nation."

GREAT PLACE TO WORK

Here are few glimpses of the fun activities conducted by the Great Place to Work (GPW) fun committee over the last quarter.

THE BALLOON TOWER:

Teams were tasked with an activity to build a tower of balloons and make it the highest peak amongst the participating teams.

ANTAKSHARI (A SPOKEN PARLOR GAME):

A game in which participants sings the first verse of a song that begins with the Hindustani consonant on which the previous contestant's song selection ended. Participants were divided into teams and the contest saw beautiful rendition of songs. So now when in doubt, sing your heart out!

EARN YOUR CHOCOLATE & MAD ADS:

On the occasion of Ganesh Chaturthi (A Hindu festival), two fun events were conducted, the first was "EARN YOUR CHOCOLATE" and the second was MAD ADS.

EARN YOUR CHOCOLATE:

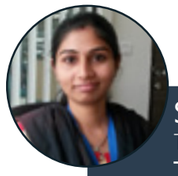
Freyrians gathered for the event were presented with a sweet treat, if they complete a certain task. Spontaneity and presence of mind was the key here.

EMPLOYEE APPRECIATION

Dr. Madhukiran P
Trainee – Regulatory Operations

Dr. Madhu was instrumental in completing the very first services project in UDI. He has excellent understanding and research capabilities. Keep up your good work Madhu.

Prasanna N G
VP – Software Services



Sneha Bhalerao
Trainee – Regulatory Operations

Sneha joined the team as a trainee and was put to test with the very new UDI initiative. She performed very well in completing the very first services project in UDI.

Prasanna N G
VP – Software Services

Chandana Shilpa
Trainee- Regulatory Affairs

Shilpa always strives to achieve the highest level of quality in the tasks assigned to her. Her dedication and diligence is very much appreciated.

Sunil Chandupatla
Associate Manager

Hemanth Reddy
Business Development Executive

A winning effort begins with preparation, Hemanth's proactive approach in supporting the pre-sales activities and arranging very important business meetings is highly appreciated. A great team player, he has always extended his shift beyond his regular work window to support to his colleagues. A quick learner even though he is not from the Life Sciences background.

Sudheer Sagar Goparaju
VP – Operations

Avinash Bhalki
Sr. Associate – Software Services

Avinash has worked extremely well in a technology which was new to him and successfully delivered the first phase of the project. He has not only shown his ability to learn a new skill and deliver on time, but was also adept at managing multiple projects efficiently. Good job Avinash and keep it up.

Prasanna N G
VP – Software Services

Freyr Publishing Team

Freyr Publishing team has been instrumental in proving that team work mingled with dedication can take you a long way. The unswerving team has shown that the secret of success is constancy of purpose and perseverance.

Mallikaarjunan R
Sr Manager – Regulatory Operations

Yogi Raj
Business Development Manager

Yogi has made a positive impact in the business development operations over the past few months. He has quickly ramped-up his knowledge about the regulatory space while operating holistically, in addition to being a great team player.

Rajiv Rangan
Co - Founder

Anantha Kumar
Business Development Executive

Although Anantha joined as a junior Business Development Executive, he has showed promise and is now handing prospects independently. He has scaled up quickly with a focused effort in understanding the regulatory space, especially UDI.

Rajiv Rangan
Co - Founder

Ranvijay Singh
VP - Marketing

Ranvijay has been instrumental in pioneering our marketing vision and strategy to a well-defined execution and management model. Furthermore he has spearheaded Freyr's innovative marketing programs and metrics which have helped improved our brand visibility significantly.

Rajiv Rangan
Co - Founder

Praveen T
Assistant Manager - Marketing

Praveen has been an effective contributor to our marketing accomplishments this year. His SEO and email lead-generation skills have played an important role in Freyr's success. Several new prospective clients were generated due to his strong arm marketing efforts; all in all it has been a great year of transformation for Freyr.

Rajiv Rangan
Co - Founder

Soumya Pippiri
Trainee- Regulatory Affairs

Soumya is a very sincere, dedicated and hardworking professional. She is open to suggestions/discussions and has great ability to deliver quality work as per the requirements.

Sunil Chandupatla
Associate Manager

NEW EMPLOYEES IN FREYR FAMILY

As an organization committed to growth and development, Freyr has further augmented its employee strength this quarter by adding over 40+ regulatory professionals.

Additionally Freyr has also stepped up expansion plans in terms of new geography coverage to offer our clients best-in-class engagement experience across the regulatory value chain.

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