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GLOBAL REGULATORY SOLUTIONS & SERVICES
AN ISO 9001 & 27001 COMPANY

Vol 3 Issue 2
2015

CONNECT

LEAD STORY

LABELING & ARTWORK

REGULATORY & COMPLIANCE IMPACT

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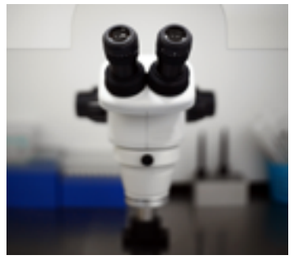

FROM THE EDITOR'S DESK

Hello all and welcome to the latest edition of the newsletter!

This latest edition of Freyr Connect provides the employees and partners with a 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 **"Labeling & Artwork - Regulatory & Compliance Impact"** 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,
Varsha Salla
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LABELING & ARTWORK

REGULATORY & COMPLIANCE IMPACT

Artwork and labeling plays an important role in the marketing process of any drug product. For any Life Science Company, labeling and artwork management process is very critical and must be managed effectively. The cumulative end-to-end labeling and artwork management function spans Commercial, Research and Supply Chain divisions in the Life Science company and requires proactive intervention, process design and cross divisional governance.

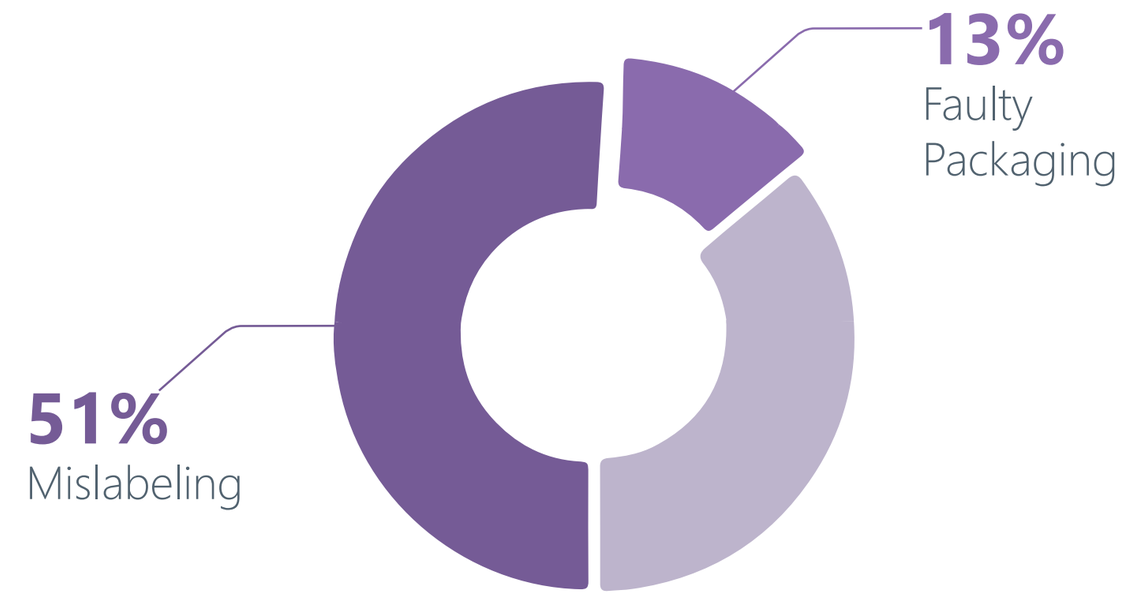
The need of the hour is to create a de-risked Labeling & Artwork Center of Excellence (CoE) to successfully manage the entire lifecycles and mitigate all non-compliance or misbranding instances.

DEVELOPING AND SUSTAINING
RIGHT FIRST TIME ARTWORK CAPABILITIES

Artwork design is an essential process in the supply of a pharmaceutical product which basically ensures patient safety while reducing recall risk.

Artwork and labeling functions are an intrinsic part for the supply of a pharmaceutical product, and are under constant pressure to deliver an increasing number of projects in a compressed time frame. In the current business scenario, companies strive to differentiate themselves by reducing time to market, deliver quick product mix and quickly change products to market needs. Pharmaceutical and Life Science companies are governed by FDA validation, stringent quality norms and GMP. Miniscule errors can be costly, damaging and puts companies at risk owing to the threat of product recalls, health authority warnings and fines.

The overall commercial success of a drug or pharmaceutical company is dependent on the right first time artwork, prior to entering a new market. Costs associated with pharmaceutical packaging amounts up to 70% of the cost of the finished product. It is also reported that 35-40% of product recalls are attributed to packaging and labeling errors and omissions. There have been a total of 455 product recall notices out of which 51% were attributed to mislabeling and 13% because of faulty packaging, according to data covered over a six month period by the Food and Drug Administration (US FDA).



GLOBALIZATION AND PHARMACEUTICAL COMPANIES

Owing to the expanding global markets, pharmaceutical companies must combat localization issues which include language, cultural and regulatory requirements. Emerging pharmaceutical markets also pose a challenge to the pharmaceutical companies which are trying to gain a foothold in the market. Delivering the Right First Time Artwork will help Pharmaceutical companies introduce new drugs and gain some ground in the new emerging market landscape.

IMPORTANCE OF ARTWORK MANAGEMENT: SUPPORTING PRODUCT LAUNCH AND PATIENT SAFETY

Producing artwork for pharmaceutical products is a significantly more disciplined process with the need for compliance, quality standards and validation which is of utmost importance.

Pharmaceutical products can only be sold if they are packaged properly, shipping will only happen if the text on the packaging is absolutely correct. If incorrect text is printed on the product, the pharmaceutical company's reputation and profit take a severe setback.

Artwork as a function is critical as it enables a Pharma company in supporting product launch and patient safety. The function although does not offer a direct strategic competitive advantage, however it offers the GxP attention as the efficacy of an active, packing line clearance and change control.

Pharmaceutical product faces a tough test, and artwork design errors however minimal do have catastrophic results and also serve as the basis of the highest cause of product recall. Typically, artwork design involves coordinating information from many different sources.

PRODUCT RECALL: AN INDUSTRY ESTIMATE

- 35-40% pharmaceutical product recalls are endorsed to pack labeling errors and omissions
- 2-3 product recall leads to higher costs
- Lack of process standardization
- Staffing issues lead to delay in artwork release
- Number of rework iterations ranging between 7 to 8 cycles

APPROACH: PROCESS IMPROVEMENT COMPLIMENTED BY TECHNOLOGY

Artwork processes are still managed by manual process; Artwork management is nothing but a combination of good project management, repository management, version and label regulatory control and actual authoring process.

Pharmaceutical companies must strategically build a streamlined process to avoid the perils of outsourcing to contractors which adds to compliance risks leading to fines, product recalls etc.

ROBUST ARTWORK PROCESS

There has been a petition owing to which there have been innovations in technology, stringent quality control and the need to streamline systems for creating an accurate automated workflow process.

- Build an integrated and closed loop procedure for artwork management while continuously update and build the processes
- Establish standard operating procedure and governance processes in product development processes
- Set up appropriate artwork infrastructure and software solution to adhere to compliance
- Build knowledge ebase repository of Artwork to avoid rework and repetitive mistakes
- Integrate Artwork process with R&D and supply chain

ARTWORK MANAGEMENT SOLUTION

Streamlining artwork management processes has been the core focus of Pharmaceutical industry, which invests heavily in packing every year.

A trusted custom software solution has been the need of the hour, which can replace the manual process, which is prone to defects, delays in the design of lay outs, forms and approvals.

An automated solution, aids in plugging loop-holes, closing the gaps and fast tracking the entire process right from design to print.

COLLABORATION CHALLENGES

Artwork and Labeling involves collaboration with various internal and external units. This includes

- Product Development
- Regulatory Affairs and Labeling Management
- Artwork Management and Vendor Collaboration
- Change Control
- Package Product Manufacturing

In addition, interaction with so many departments brings its own challenges

- Redundant and repeat process
- Absence of visibility across the chain
- Lack of coordination

TECHNICAL CHALLENGES & POSSIBLE SOLUTIONS:

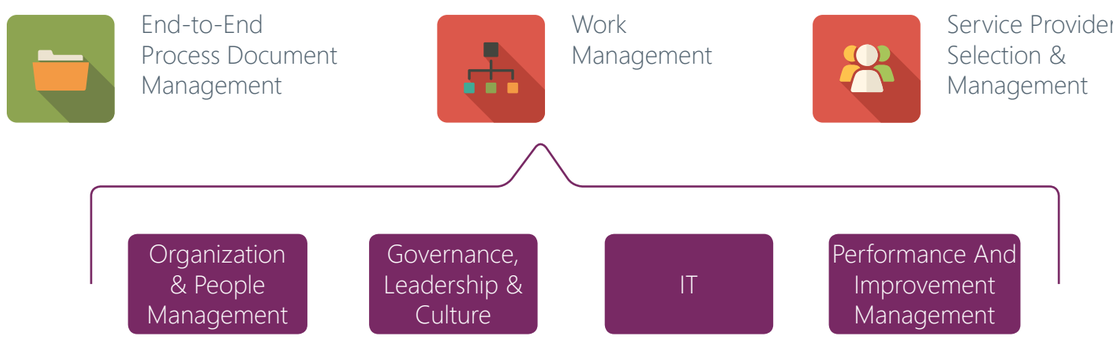
- Understanding the Current Artwork Process and Business Scenarios
- Assessing functional groups involved in the current artwork review and approval process
- Assessing number of artwork studios involved in the artwork creation
- Assessing current systems, software/applications and tools used in artwork process
- Assess current artwork repository
- Assessing the scope in terms of number of markets, manufacturing sites, print suppliers, third party manufacturers and third party markets
- Understanding the scope in terms of volumes – Number of SKU's, Brands/Products etc…
- Assessing the current business challenges and constraints in the artwork process
- Define scope and success criteria of the pilot
  - Current state assessment report
  - GAP analysis report
  - Recommendations in terms of Target- People, Process and System implementation
  - Pilot scope specification

DEFINED ARTWORK MANAGEMENT PROCESS ASSURES RIGHT FIRST TIME ARTWORK

Example model process with defined control points to ensure error free networks

Create Source text → Define Change → Produce Artwork → Produce Printer Proof → Implement

Make sure the text is right, proof read and verify for final printing. Elements required for a successful artwork capability



IMPROVEMENTS TO ARTWORK CAPABILITIES: A PHASED APPROACH

1

IN CONTROL

- Compliant GxP process
- Formal approvals at key control points
- Meeting critical artwork change milestones

2

EFFICIENT & EFFECTIVE

- Meeting performance requirements of business
- Optimal use of resources
- Processes tuned to ensure effective execution

3

WORLD CLASS

- Appropriate use of best practices
- Benchmarked with external capability
- Agile adaptation to changing business models

BUSINESS ADVANTAGES OF STREAMLINED ARTWORK FUNCTION

A streamlined artwork function offers increased quality through reduction of product recalls or critical incidents & product launch due to Artwork errors. It also improves branding consistency among the artworks in terms of design, color and text while giving creditability to product and brand.

As it will be audit and compliance driven - One process will be followed across the globe, thus reducing compliance driven penalties. In addition, it gives companies opportunities to plan ahead around staffing and has measurable SLA's around each step of the Artwork process. Furthermore, artworks can be reused for similar markets, thus significantly reducing time and cost; product launch schedule timelines can be planned accordingly. Overall Pharmaceutical companies can understand the triggers of artwork changes and business dynamics around it.

OTHER BENEFITS

0
Recall

97%
Scheduled Adherence

99%
Proof reading accuracy

90%
RFT (right first time)

0
Total non-compliance issues since the last two years

75%
Productivity improved

24X7
Operational capability

Multi-lingual support

Conclusion

Delivering quality artwork is a complex endeavor involving many moving parts in addition packaging and artwork presents a significant compliance risk. Artwork management is critical to delivery of a Pharmaceutical company's business strategy.

Right First Time Artwork can be achieved once the company undertakes the assessment of the current situation and base it against a comprehensive assessment model. Thorough gap analysis can also be done to understand key improvement areas across the organization.

LABELING

STRATEGIZE AND STREAMLINE PROCESSES TO MEET COMPLIANCE NORMS

Pharmaceutical and Medical Device industries are constantly changing with developing supply chain themes and technological advancements due to which labeling must be looked upon with a new perspective. A host of latest trends have compelled Pharmaceutical and Medical Device industries to rethink, strategize and streamline processes, meet compliance norms and start and learn best practices. Here are some of the latest trends in Labeling.

IMPACT OF REGULATIONS ON LABELING

Labeling regulations keep changing and it's especially critical for those industries where labeling and identifying parts and packages play a pivotal role in consumer's safety. In the Medical Device industry, companies now have to adhere to the changing norms/standards such as Unique Device Identification (UDI) and change the way products are labeled.

The Pharmaceutical industry is making companies reconsider the way they do business owing to the ePedigree and the more current Drug Quality Security Act (DQSA). Companies must now get in line with standards and evolving regulations to change their supply-chain processes and adopt new labeling standards. Companies must either comply or face the consequences including hefty fines and loss of business. Some of the major regulations and standards in labeling are

ePedigree

Most of the states in the US, have decreed pedigree requirement to protect consumers from contaminated medicine or counterfeit drugs. The law which was first initiated in the State of California seeks to track and serialize unit-level saleable packages (e.g; bottle of pills) throughout the supply chain. Bar code and RFID technologies are employed for implementing traceability.

DQSA

The law intends to strive for improvements in supply-chain efficiencies and control, as well as brand/product integrity. DQSA's law establishes standards for interoperable exchange of transaction information, including documenting the history of product movement, among all trading partners using unique numerical identifiers for each unit of sale.

GS1

The GS1 Systems of Standards offers global standards to fundamentally improve efficiencies and visibility of supply chain and applies to multiple industries ranging from healthcare to food and beverage and retail. To support safety initiatives bar codes are being implemented and to have a quick response to product recalls. GS1 also provides an EPCglobal (www.gs1.org/epcglob al) Drug Pedigree Standard and certification.

UDI

According to The Food and Drug Administration (FDA) final ruling, medical devices distributed in the US, must carry a unique device identifier. This includes Class III medical devices, which must meet UDI requirements and also include submission to the GUDID by September 24, 2014. A UDI system has the potential to improve the quality of information in medical device adverse event reports, better target recalls and improve patient safety.

CENTRALIZATION: THE NEXT NORM IN LABELING

In a bid to improve consistency and to streamline processes across their supply chains, many businesses are centralizing bar code labeling across all locations and geographies. Centralization supports business continuity and lowers the IT cost of maintaining multiple labeling systems. Owing to the recent innovation in enterprise labeling technology, it becomes imperative to move to a centralized labeling model. Here are three main reasons for centralization

Labeling Consistency

Organizations are trying to ensure their global locations produce labels in line with corporate standards with respect to formatting and data content perspective to improve supply chain efficiency. Marketing departments are becoming increasingly involved in making sure corporate brand standards are incorporated.

Business Continuity

Global organizations can swiftly shift labeling to support operations and removes risk in replicating labels which may be facility or region specific thereby supporting business continuity in the event of natural disasters and geopolitical unrest.

IT Maintenance Costs

Managing multiple, different labeling solutions across global operations becomes increasingly difficult. However a single, centralized solution can be deployed by organizations to reduce IT maintenance costs while allowing businesses to meet customer and regulatory labeling requirements.

CUSTOMER RESPONSIVENESS : ADHERENCE TO LABELING REQUIREMENTS

Suppliers and partners must be flexible to meet unique customer labeling requirements to show customer responsiveness. Customers are now seeking providers to meet their own labeling requirements for data content, images, symbologies and languages. Advances in enterprise labeling have made sure companies gain new customers while catering to the needs of the existing customers. Customer responsiveness in labeling must ideally meet the following expectations:

Specific Data Content Inclusion

Unique data attributes are now sought by customers on labels provided by their suppliers in a bid to streamline their processes and limit relabeling when goods are received. The unique data attributes include transactional data like quantities, lot numbers or expiration dates to actual data from the customer's enterprise applications including product codes or purchase order numbers.

Formatting Standards

Customers are looking to get their preferred label format delivered by suppliers; this desire is stoked with an aim to control label formatting across multiple suppliers. Also customers want to maintain brand consistency and simplify the receipt of goods and are specifying where data elements appear, images to be used and incorporation of bar code symbologies. Once these are incorporated, customers are satisfied to receive goods that align with their internal labeling standards.

Regulations

Customers want their supplier and partners to include necessary data in the appropriate language for subsequent local processing. In addition, the ever changing standards/regulations dictate which language needs to be applied to labels where goods are going through their supply chain.

LABELING: DATA-DRIVEN AND INTEGRATED

Critical need for label accuracy compels the adoption of automated, transactional-based labeling by companies to improve operational efficiency. A data-driven approach will help companies replace static and dynamic label templates which can simplify maintenance and ensure accuracy. The move towards data-driven labeling is because of

Integrated Labeling

Most companies are replacing manual labeling processes with automated, integrated labeling which is the best practice of initiating labeling from their transactional system.

Importance of Big Data

Data-driven approach to labeling enables support for all labeling needs by making fields on a label dynamic and variable. Using a single update a change can be initiated to all labels without making changes to numerous templates.

Integration: Product Lifecycle Management and Content Management Systems

Product Lifecycle Management (PLM) and Content Management Systems (CMC) are the main definitive sources of data which can appear on a label. Data-driven integration with an enterprise labeling system is paramount and by taking content from PLM and CMS, companies can ensure that label content is accurate and up-to-date.

ROLE OF SUPPLIERS

Increasingly companies are looking towards suppliers and partners to be meet their labeling requirements thereby increasing supply chain collaboration and streamlining operations. This will lead to accuracy and immediate deployment of labels.

Relabeling Costs

Companies must ensure that suppliers adhere to corporate labeling standards which allow compliance and costly relabeling work is avoided. Although relabeling process ensures proper bar code symbologies, images, branding and data content to support subsequent processing, it is a very costly process.

Supply-Chain Association

Forecasting, inventory level management and on-time delivery rates- technology is leveraged by customers, suppliers and partners to show tangible benefits. Supply-chain collaboration is increasingly becoming important.

Labeling Errors Reduction

Enterprise labeling technology can help companies to combat supplier label change errors by making them use their labeling solution to print accurate and current labels in line with labeling standards.

eCTD TRENDS FOR EMERGING MARKETS

Organizations are now adopting eCTD for local compliance reasons and for the strategic advantage to reduce their time to market, while increasing internal efficiency and accuracy.

Companies can leverage eCTD in new markets while simultaneously leverage their existing working practices for eCTD management in other markets. In addition, the ability to re-use approved dossiers and to build efficient business processes is one of the biggest efficiency gains associated with electronic submissions.

Regulatory authorities in emerging markets have now started looking at the better drug approval processes. Hence it's imperative that eCTD holds a great deal of advantage for these markets which are primarily paper based.

WHY ARE EMERGING MARKETS ADOPTING eCTD?

MARKET & REVENUE EXPANSION

Revenue Base, Product Portfolio and new market expansion by global Pharma industry in emerging markets

PROCESS STANDARDIZATION

Standardization of process and better services to Pharma industry for tracking, tracing, managing content

PAPER TO ELECTRONIC EFFECIENCIES

Hassle-free, less physical documentation volume and easy electronic submission process

DECREASED TIMELINES, FASTER APROVALS

Re-usability of approved module data/ content for faster approvals for more number of drugs

THE IMPLEMENTATION OF

ELECTRONIC SUBMISSIONS IN eCTD FORMAT IN JAPAN

In November 2000, the CTD guideline1 was harmonized and was implemented in June 2001 in Japan. In September 2002, the electronic Common Technical Document (eCTD) guideline was harmonized in the ICH regions with notification on eCTD specifications issued in June 2003.

Post that there have been numerous notifications of updates of specifications and guidance on eCTD preparation3-7, which were issued. There are still some differences among ICH regions, although the legislation is harmonized.

CURRENT STATUS OF eCTD IN JAPAN

Since 2004, Pharmaceutical companies have been able to submit eCTD applications and there has been a steady rise in the number of companies submitting in eCTD format yearly.

Earlier eCTD was not mandatory; applicants could either submit it as the original (official) dossier or as a reference eCTD. Applicants chose to submit paper dossiers as the official application owing to little knowledge about eCTD and most of the eCTDs submitted were as reference documents.

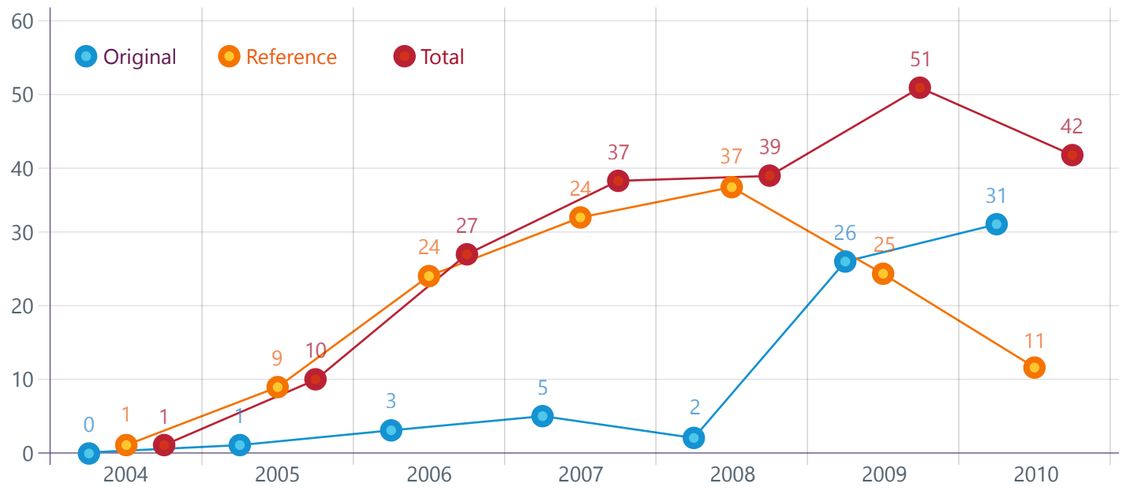
In April 2009, Japan's Ministry of Health, Labour and Welfare (MHLW) issued a notification that if applicants submitted the eCTD as the original dossier, then paper dossiers were not required.

Earlier, if the applicants submitted the eCTD as the original dossier, then paper dossiers were requested as well.

When the eCTD is submitted as the original dossier it is not necessary to submit paper Modules 3, 4 and 5 although paper Modules 1 and 2 are still required for review.

As we see in the below figure, the number of applications in eCTD format as the original dossier have increased incrementally as the benefits of the eCTD have been understood better.

Number of eCTD Submissions to PMDA, 2004 - 2010



Total Number of Submissions | 68 | 139 | 207

Source: PMDA Website

DIFFERENCES IN ECTD: JAPAN VS OTHER REGIONS

The Japanese authorities do not accept the eCTD submitted to other countries' regulatory agencies.

Some of the differences include. JNDA is the only dossier accepted in eCTD format in Japan.

1. In Japan for Module 1, the XML Schema is used; In EU and the US the Document Type Definition (DTD) is used.
2. Structure of M5.3.7 is significantly different in Japan when compared to the EU and the US.

Hence it is not feasible to use an eCTD created by an external (overseas) eCTD application tool for submission of a Japanese new drug application (J-NDA).

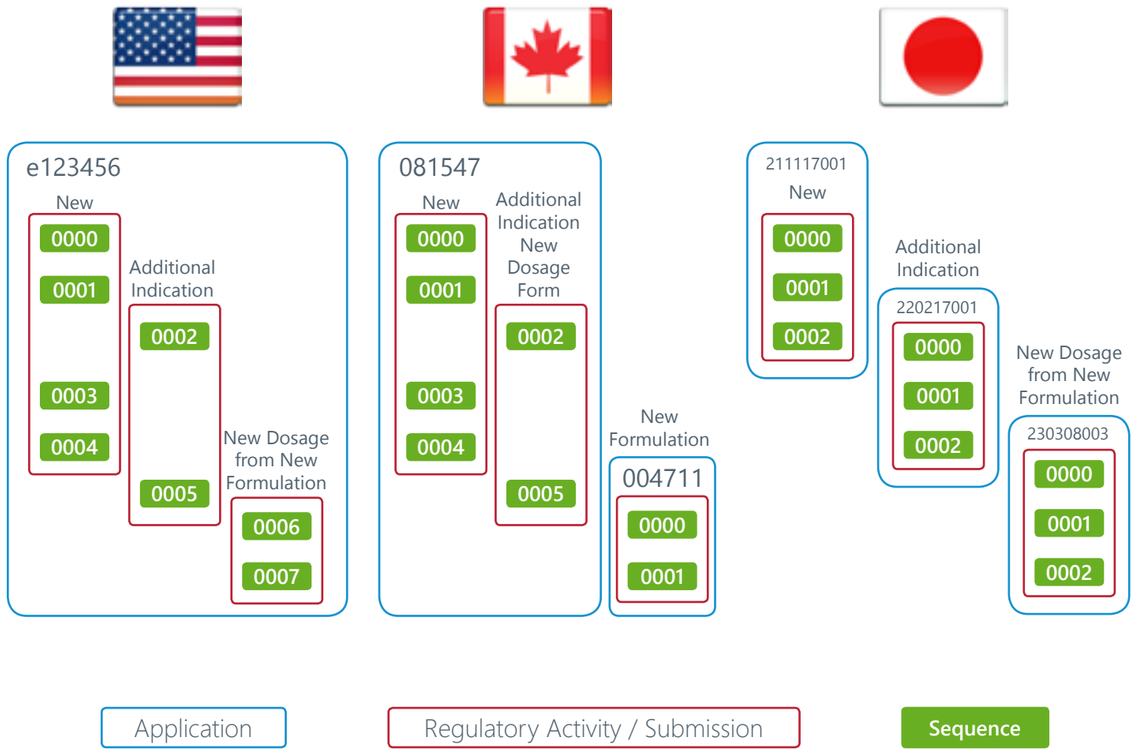
eCTD LIFECYCLE MANAGEMENT: ANOTHER MAJOR DIFFERENCE

Lifecycle management in Japan involves managing additions/ amendments to application data within individual applications from submission to approval however it does not specify collective management of new applications/ partial change applications for a single product.

For e.g; A new eCTD must be created without referring to the original eCTD if a company intends to file for additional indications for a product.

Furthermore the original Module 2 should be included in the new eCTD.

Concept of lifecycle of J-eCTD is different from the US/EU.



ANOTHER VARIANCE POST J-NDA SUBMISSION

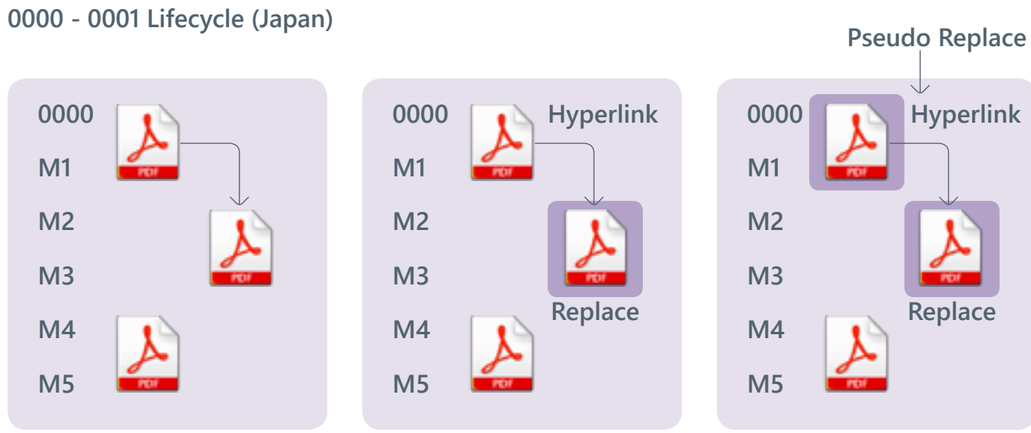
Companies must submit entire XML including variations in eCTD including the first eCTD document data in "0000" for the duration of the regulatory review period of a marketing approval application.

The Pharmaceuticals and Medical Devices Agency (PMDA), Japan's regulatory agency checks the original eCTD "0000" relevant document data when it reviews revised documents for the duration of the regulatory review period of the eCTD.

Companies must set up all of the hyperlinks again owing to the review procedure. When revised versions with file amendments are being submitted and if those files have been set up as a link related to other files, in such a case it is not possible to show the correct links.

Therefore all files affected by the changes need to be submitted in that revised version, this action is known as "pseudo replace"

Lifecycle Management in Japan



"Pseudo replace" is a manual procedure consisting of several steps

1st Search for hyperlink referring to the replaced document

2nd Description of XML to which it refers is replaced simultaneously the leaf ID of the document is changed

3rd "Checksum" is set, followed by all documents related to the lifecycle

The entire procedure is expected to be completed within five days in compliance with the time line required by the PMDA. Owing to the strict timeline, many companies use eCTD application tools to create their eCTDs.

Paper CTD	eCTD
Printed materials are checked visually. • To check - if pages are in consecutive order • For missing pages	It is imperative to check if the documents are correct electronically. An eCTD validation tool to check submissions is provided by PMDA website, (which may also seek correction if needed). Validation is sought even if the submission has been done through PMDA website.* Electronic document data must be submitted in a PDF format(specific unified style) that meets eCTD specifications Eg; eCTD requires the use of version 1.4 to set up web optimization when saving pdf files.

WORKFLOW OF eCTD COMPILATION: JAPAN

Japanese pharmaceutical companies must now acclimatize the change from paper to eCTD and must optimize workflow management including changes in writing and review processes of documents.

Currently, proofing is done onscreen via network systems when compared to visual proof reading of paper documents and amendments are electronically recorded.

Document management systems are in consonance with eCTD management but the level of risk in amendments to documents varies.

Initial stage- it is very easy to modify documents because companies can allocate time ahead of making the submission however at the later stages, time constraints hamper progress and it becomes difficult to amend or replace documents.

So in order to minimize risk it is important to prepare documentation ahead of schedule.

CHANGES IN COMPANIES' WORKFLOWS

eCTD compilation can be done efficiently in a well organized network environment including electronic writing and document management systems and the workflow of marketing approval applications.

Japanese companies can cut down the cost, resources, effort and time if they engage in cross functional communication and adapt to the rapid change to produce an eCTD.

Companies face a variety of problems like working with a network system requires rules, such as setting access limits and agreeing the remit of management in terms of oversight of any submission application.

Furthermore companies have tried to incorporate the workflow of the eCTD into the entire timeline of the J-NDA submission.

Companies must understand how an effective system is created right from planning to initiation of eCTD workflow to CROs providing study data and use of other service providers to build the eCTD, when systems creation was done in house previously.

It is vital that all stake holders come together to work cohesively in the completion of an eCTD, which is a tool to aid pharmaceutical companies secure Japanese marketing authorizations for all of their products

POINTS TO REMEMBER IN PREPARING JAPANESE CTD

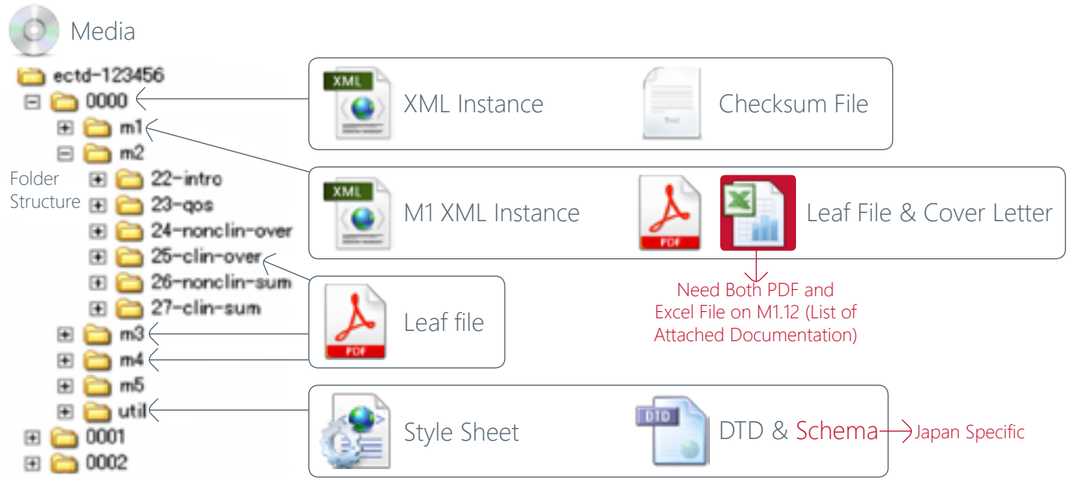
1. M1 + M2 must be written in Japanese
2. Especially information on AEs, adverse events, should be translated and also presented in same manner as Japanese studies (Administrative Notice, Jan 17, 2011)
3. M2, especially M2.7.6 is written more detail than US/EU. Because PMDA mainly review M2. So only translated US/ES M2 is not good for PMDA.
4. Cannot use STF
5. Cannot use Node Extension
6. For M5, need specific folder and files "5.3.7. Patient Data Listings and Patient
7. Records Patient listings".

In accordance with the CTD Notification, the patient listings and figures indicated below are to be submitted as part of

Module 5 '5.3.7. Patient Data Listings and Patient Records'.

1. Patient listings for main efficacy verification studies, and patient listings for main studies which formed the basis for setting the dosage
2. Patient listings for all implemented clinical studies where adverse reactions were observed
3. Patient listings for all implemented clinical studies where serious adverse events were observed
4. Patient listings for all clinical laboratory test
5. Figures appropriately in all implemented clinical

JAPANESE eCTD STRUCTURE



CLINICAL TRIAL DISCLOSURE

EVER-CHANGING LANDSCAPE AND IMPACT

Clinical trials are research studies that explore whether a medical strategy, treatment or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people.

IMPORTANCE OF CLINICAL TRIAL DISCLOSURE

Clinical Trial Disclosure is making clinical trial information widely available to the general public and provides transparency in the clinical trials process. Life sciences organizations are enabled to efficiently manage clinical trial registration and reporting of results to clinicaltrials.gov, EudraCT and other registries.

CLINICALTRIALS.gov

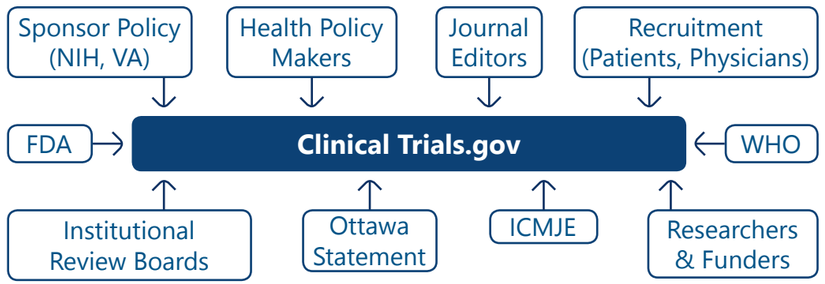
ClinicalTrials.gov is a web-based resource that provides patients, their family members, health care professionals, researchers and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions, **which is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH).**

ClinicalTrials.gov contains information about medical studies in human volunteers. This web site and database of clinical studies is commonly referred to as a **"registry" and "results database."**

ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered. ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and was made available to the public in February 2000.

The ClinicalTrials.gov registration requirements were expanded after the **FDA Amendments Act of 2007 (FDAAA).** The results database was made available to the public in September 2008. FDAAA 801 also established penalties for failing to register or submit the results of trials.

In the US, a sponsor needs to submit the data for protocol results to CTGOV and independently goes to the FDA asking for approval to conduct the trial.



RESULTS ENTRY AHEAD OF CLINICAL TRIAL

Depending on the development stage of product, the phase of study and location, study results, including a description of the design and methodology, results of primary and secondary outcome measures, and safety, will be published. In general, the law requires study sponsors or designated principal investigators (PIs) to report summary results information within one year of completing data collection for the prespecified primary outcome, regardless of sponsor or funding source.

RESULTS DATABASE

The ClinicalTrials.gov results database was launched in September 2008 to implement Section 801 of the Food and Drug Administration Amendments Act of 2007 FDAAA 801, which requires the submission of "basic results" for certain clinical trials, generally not later than 1 year after their completion date.

Results information for registered and completed studies is submitted by the study sponsor or principal investigator in a standard, tabular format without discussions or conclusions. The results information that is submitted includes the following:

- **Participant Flow:** A tabular summary of progress of participants through each stage of a study, by study arm or comparison group. It includes number of participants who started, completed and dropped out of each period of the study based on the sequence in which interventions were assigned.
- **Baseline Characteristics:** A tabular summary of data collected at the beginning of a study for all participants, by study arm or comparison group. This data includes demographics, such as age and gender and study-specific measures.
- **Outcome Measures and Statistical Analysis:** A tabular summary of outcome measure values, by study arm or comparison group. It includes tables for each pre-specified Primary Outcome and Secondary Outcome and may also include other pre-specified outcomes, post hoc outcomes and any appropriate statistical analysis.
- **Adverse Events:** A tabular summary of all anticipated and unanticipated serious adverse events and a tabular summary of anticipated and unanticipated other adverse events exceeding a specific frequency threshold. For each serious or other adverse event, it includes the adverse event term, affected organ system, number of participants at risk, and number of participants affected, by study arm or comparison group. [4]

GENERAL RESULTS AHEAD OF CLINICAL TRIAL

Participant Flow: Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial.

Recruitment Details: Key information relevant to recruitment process for overall study, such as dates of recruitment period and types of location (e.g., medical clinic).

Pre-assignment Details: Definition: Description of any significant events and approaches for overall study (e.g., wash out, run-in, transition) following participant enrolment, but prior to group assignment.

Arm/Group: Arm/Group Title: Label used to identify the arm or comparison group.

Arm/Group Description: Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.

Period(s): Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported (There is no limit to the number of periods).

Period Title: Title describing a stage of the trial. Number of participants required at the beginning of the period. Baseline Characteristics: A table of demographic and baseline data (study specific) for the entire trial population and for each arm or comparison group.

Results Described During/After Clinical Trial

Results of applicable clinical trials must be reported within 12 months following the primary completion date. Primary Completion Date is the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. “Study Completion Date” is the final date on which data was collected.

Regardless of the outcome, after completion or termination of a clinical trial in patients, the results of the trial are posted according to current laws and regulations.

GENERAL RESULTS DESCRIBED DURING TRIAL

Enrolment details: Participant enrolment into study details.

Completed: Number of participants completed the study.

Discontinuation details: Number of patients discontinued from the study.

Reason Not Completed: Additional information about participants who did not complete the period, if any.

Demographics of participants: (Ex., age, sex, race, etc.)

Laboratory results: Haematology, biochemistry and serological results of all the participants.

Safety parameters: Safety parameters include laboratory and other vital check-ups for all the participants.

Efficacy parameters: Efficacy details of the IMP and significant changes with the comparator drug.

Comments: Additional information about the completed milestone.

Adverse Events: Two types of adverse event data are to be reported

- **Serious Adverse Events:** A table of all anticipated and unanticipated serious adverse events, grouped by organ system, with number and frequency of such events in each arm of the clinical trial.
- **Other (Not Including Serious) Adverse Events:** A table of anticipated and unanticipated events that exceed a frequency threshold within any arm of the clinical trial, grouped by organ system, with number and frequency of such events in each arm of the clinical trial.

Details of Serious Adverse Event (per arm/group): Overall number of participants affected by one or more Serious Adverse Events.

Overall Limitations and Caveats: If appropriate, describe significant limitations of the trial.

CLINICAL TRIAL REGISTRATION PROCESS

The sponsor of clinical trial or principal investigator is responsible for conducting the trial and has the right to publish results of the trial.

- A sponsor-investigator means an individual who both initiates and actually conducts a clinical investigation under them the test article is administered or dispensed involving, a subject.
- Data providers use a web-based data entry system called the Protocol Registration and Results System (PRS) to register clinical studies and to submit results information for registered studies.
- Before applying for a PRS account, one should ensure that the appropriate individual has submitted clinical study information to ClinicalTrials.gov.
- Protocol information must be clear and informative. It must be consistent with the ClinicalTrials.gov Protocol Data Element Definitions.

Content Courtesy: ClinicalTrials.gov

REGULATORY AFFAIRS CONSULTING

Are you deriving value out of your Regulatory Outsourcing engagement?

The Life Sciences industry is undergoing a plethora of dynamic changes on a global scale. With globalization opening immense potential for huge business gains across rapidly growing markets, the strategic move to manufacture, market and operate in global economies is increasingly meeting the complex challenges of stringent regulatory adherence requirements.

In such a scenario, companies are increasingly looking to engage with the right Consulting Partner who can help them successfully navigate the regulatory challenges. The aim is to achieve optimized Regulatory and Compliance procedures with minimal risks through an optimal cost effective option.

The Regulatory Affairs consultation provides necessary assistance during the pharmaceutical development process, which in turn helps companies in the implementation of a Global Regulatory Strategy. The major concern is how well a consultant analyses the Regulatory Compliance obligations and values the company's needs.

Here are some of the common parameters that, in principle, help a company measure the credibility and derive value out of its consultative engagement.

RIGHT PARTNER Vs. RIGHT VALUE

Identifying the right consultant, possessing the expertise, knowhow and experience, is the most critical aspect. Solution partners with industry expertise can leverage their consultative and solution implementing experience to ensure a company streamlines the regulatory processes to meet the objectives, within mandated timelines and also saves significantly on cost of compliance.

They also impart knowledge regarding the current standards and latest rules of regulatory agencies, analyze the gaps and the needs to meet them and provide the action points to publish the submissions within the stipulated time.

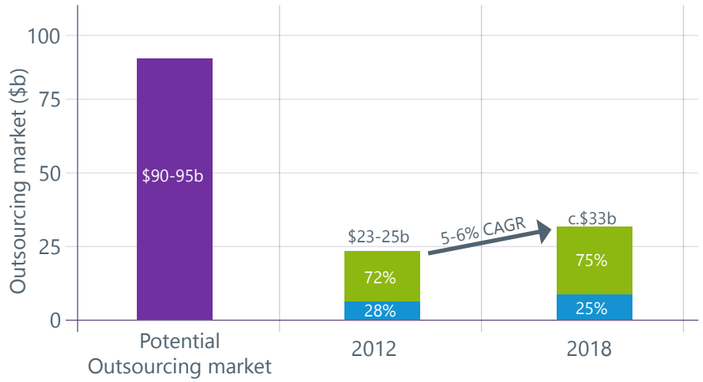
Look out for some of the few challenge areas mentioned below that a Consultant should address effectively:

- Follow mandatory processes like development, preparation, assembly and submission of technical documentation for the purpose of marketing authorization applications
- Meet requirements of regulated, semi regulated and non-regulated standards
- Understand all centralized, decentralized, national and mutual recognition procedures
- Handle all pre-submission activities, including the orphan drug designation
- Compile all types of drug submissions like NDS, NDA, BLA and MAA
- Convert paper or non-eCTD electronic submissions (NeeS) documents into electronic form through upgraded eCTD software
- Communicate with the Regulatory authorities and acknowledge comment letters, assessment reports and quality control reports within stipulated time
- Organize scientific advice meetings with Regulatory agencies for smooth drug development process
- Follow the European Clinical Trial Authorization (CTA) and ethics committee applications submission protocols
- Provide diligent data evaluations and risk management plan
- Evaluate and effectively handle change controls for EU and other regions

There are other critical areas that will demand your attention during a compliance life cycle. And, if you find yourself asking all the questions but getting no definitive solution roadmap, it's time to look for a partner who brings the experience, the expertise and, more importantly, who brings value to you!

GLOBAL REGULATORY AFFAIRS CONSULTING MARKET OVERVIEW:

Biopharmaceutical industries are highly synchronized by various regulatory authorities across the globe. It is learnt that for the protection of public health, medical devices and pharmaceutical products are subject to strict regulations. Pharmaceutical companies are planning to outsource their regulatory affairs operations to various competent contract research organizations (CROs) and contract manufacturing organizations (CMOs) to secure approval. CRO's offer definitive cost efficiencies, process improvement and utilization of the expertise which helps in the growth of the regulatory affairs outsourcing market.



- Current outsourcing penetration is only 24-28% of potential market
- Late-stage services account for the lion share of market by value
- Late-stage has been recovering faster from the financial crisis than early - stage
- As of 3Q13, several large CPO's have been reporting a recovery in early - stage

Large market poised for steady growth – 2013 Published report

In 2013, the regulatory writing and publishing services segment reportedly took 40% share out of the total regulatory affairs outsourcing market owing to growing need for rapid approval and submission of drug applications. In addition, the understanding of global and domestic regulatory requirements by regulatory writers helps in driving the growth of the regulatory writing and publishing services market.

It is reported that during 2014 to 2020, the regulatory consulting and legal representation services segment is estimated to have the fastest growth rate in the regulatory affairs outsourcing market. This is owing to growing pressure for regulatory consulting and increasing need of client interaction with various regulatory agencies.

The global regulatory affairs outsourcing market is segmented by services into regulatory affairs; clinical trial applications and product registrations; regulatory writing and publishing; regulatory consulting and legal representation; and others (post approval maintenance, reimbursement consulting etc.).

In 2013, the regulatory writing and publishing services segment reportedly took 40% share out of the total regulatory affairs outsourcing market and is expected to maintain its lead during the forecast period through 2014 to 2020. Increasing need for user/reviewer friendly and complete drug application submissions and sound knowledge for drug development services are some of the factors which have contributed towards the large market size of the regulatory writing and publishing services. Furthermore a well-written clinical study report (CSR) adds a lot of value in the final production of clinical trial documentation, which is in compliance with stringent regulatory requirements of the drug development process.

It is also stated that the regulatory consulting and legal representation services segment is expected to increase at a compound annual growth rate (CAGR) of above 14% owing to growing demand of drug manufacturing companies for product safety and efficacy evaluations. In addition, growth of the regulatory consulting and legal representation services segment can be increased if pharmaceutical companies try and minimize business impacts such as product recalls and loss of sales ensuring global environmental compliance.

In 2013, North America took the largest market share for the global regulatory affairs outsourcing market owing to increased number of clinical trial activities, vast presence of research units and cost benefits incurred by shifting high costs of in-house resources for various regulatory activities. Asia Pacific is predicted to have the highest growth rate over the forecast period that is attributed to availability of large population base and skilled workforce. Over the next few years, there is scope of increased contract manufacturing activities in emerging nations such as China, India, Malaysia and Vietnam which will give rise to growth of the global regulatory affairs outsourcing market in Asia Pacific region.

Conclusion

The FDA intends to enable product development and manufacturing flexibility and supports advancement of innovative ways to lower the cost of drug development while advancing the critical path for drug products. It is likely that third-party outsourcing service providers will play a pivotal role in delivery of business functions like drug development, sales and marketing and regulatory compliance services.

Pharmaceutical companies must strategize the execution of services they need to outsource and select a supplier/partner with good track record, in-depth industry knowledge and must possess excellent business relationships with regulatory agencies. The ideal service provider should also have the staff capacity to perform the developmental and registration activities. In 2013, the global regulatory affairs outsourcing market was valued at $1.56 billion stated a recent industry report. It is expected to grow at a CAGR of 14.6% from 2014 to 2020 to reach an estimated value of $4.49 billion.

As Regulatory consultant and global solutions partner to several Top 10 Fortune companies, handling end-to-end multi-geo Regulatory Affairs responsibilities across their Top 20 global brands, Freyr is best positioned to provide proven expertise and tailored services that put you in total control of your entire global Regulatory compliance obligations.

SOUTH AFRICAN CMC COMPLIANCE LANDSCAPE

A PERSPECTIVE ON PREVAILING CHALLENGES FACING REGULATORY CMC PROFESSIONALS

Introduction

"The Republic of South Africa is the largest market on the African continent and is a member of the "BRICS" group of emerging world economies. It has a population of 51 million and a gross domestic product (GDP) of $384 billion in 2012."

Life expectancy at birth is quite low 57 years and 60 years for males and females respectively when compared to other nations. The standard of care offered in the public and private healthcare systems in South Africa is inconsistent leading to a disparity in the over-stretched public health sector.

The nation's government hopes that people will adopt private health insurance policies, in order to reduce the burden on the state.

South Africa and the African continent are plagued by the HIV/AIDS virus, the Department of Health in South Africa is working towards combating the spread.

It is estimated that 5.4 million people over the age of 15 are carrying the virus in South Africa, which is also tackling other infectious diseases such as Cholera and Malaria.

Summary

Pharmaceutical companies can thrive in South Africa owing to the legislative framework for regulation of medicines and a burgeoning market for unmet medical need among sufferers of HIV/AIDS and those inflicted with other infectious diseases.

If drug companies intend to take advantage of the market opportunity and deliver medicines to patients, they must firstly focus on the effective lifecycle management of medicinal product registrations. In South Africa, post-approval maintenance is achieved under a change classification system of type A, B and C amendments, with the quality and performance of a dosage form that influences the filing mechanism.

The 730 day approval timeline for a change, harmonization of dossier content to common technical document (CTD) format by 2016 poses a big challenge to chemistry, manufacturing and controls (CMC) regulatory professionals.

"CMC professionals must collaborate with all stakeholders including regulatory affairs, manufacturing, supply chain and marketing to achieve compliance of product portfolios in this market."

SOUTH AFRICA REGULATORY FRAMEWORK FOR REGULATION OF MEDICINAL PRODUCTS

South Africa's regulatory agency, the Medicines Control Council (MCC, "the Council") assesses applications for new product registrations and post-approval amendment applications.

The MCC was established in 1965 as a consequence of the Medicines and Related Substances Act No 101.7 and has associated itself with other participating health agencies and countries of the Pharmaceutical Inspection Convention and Co-operation Scheme (PIC/S).

The PIC/S facilitates exchange of information and mutual recognition of inspections with regard to good manufacturing practice (GMP). The association is beneficial to companies who wish to import pharmaceutical goods into South Africa from sites in other PIC/S-affiliated countries.

If MCC gives a good opinion of a new application for a medicinal product, it will lead to issuance of a registration certificate by the Department of Health (DoH). If an amendment application which affects the registration certificate is lodged by the Holder of the Certificate of Registration (HCR), a new registration certificate is issued with the approval.

HCR is South African equivalent of the marketing authorization holder (MAH) under European legislature.

HCR's must notify any changes to manufacturing practice to the Registrar of Medicines at the Council, for assessment by the Post Registration Unit (also known as the Pharmaceutical and Analytical (P&A) Unit). The amendments guideline and the P&A guideline are valuable sources of information to CMC professionals, with reference to product dossier requirements.

POST-APPROVAL AMENDMENTS

In South Africa, a change to a registration dossier is known as an "amendment", which is further classified into categories "Type A", "Type B' or 'Type C' and "Type D', which is used for new applications. Nature of the amendment which will impact the quality or performance of a dosage form will dictate the category in which it is evaluated. It will also determine the filing mechanism, the approval timeline (if any) and the documentation requirements that must be met.

AMENDMENT CATEGORIES AND EU CLASSIFICATION SYSTEM

Let's consider each amendment categories and contrast them with the EU classification system.

Type "A" Amendments

The most minor change category - Type "A" amendments do not affect the quality or performance of a dosage form, hence can be implemented without prior notification to the MCC. Type "A" amendments are similar to EU type IA "do and tell" category, however applicants are not mandated to notify the health authority (HA) of the change within 12 months of the date of implementation. This type of change is not notified until there is a need for another amendment which falls under the type B or C categories.

For an established product, where the level of post-authorization change is low, the MCC is notified of a type "A" change only after several years. Furthermore there is no renewal process in South Africa which restricts filing minor updates to the dossier. Such amendments are captured in the "Amendment Schedule", which is found under CTD section 1.2.1. The Amendment Schedule lists all changes made to the dossier from the date on which the registration certificate was granted through to the present day.

In order for the dossier to be free from compliance gaps, the relevant CTD Module 2 quality summaries and Module 3 sections should also be updated, which will help it in passing an agency inspection. Type "A" category changes e g; include legal entity name change of an active pharmaceutical ingredient (API) manufacturer, reduction in shelf-life of a drug product due to a commercial, as opposed to a product quality issue or a minor change to finished pharmaceutical product (FPP) manufacturing process. Also MCC must be first notified of the amendments ahead of the implementation at site level, although it does not require prior approval.

Type "B" Amendments

The MCC attests these changes can impact product quality and they may fall under the type B "prior notification" category. The MCC must be notified 30 days prior to the intended date of implementation. If the MCC does not pose any queries in the intervening period, approval is granted at day 30 (but no formal approval letter is received). The Type "B" Amendments category therefore resembles the type IB category used to file minor "tell and do" variations in the EU.

HCR mostly receives queries regarding type B changes after the 30-day period has elapsed. Type "B" category changes e g; addition of a new supplier of API with pre-condition that new plant is part of same group of companies as existing manufacturer and also the processes and specifications to be employed at the two sites are identical. Other type B amendments considered by the MCC include a scale-up or down of the batch size used for drug product manufacturing, up to and including ten times.

Type "C" Amendments

Major changes to an approved registration file are assessed under the type C category in South Africa. These changes are expected to impact the quality and performance of a dosage form, hence prior approval from the MCC is required ahead of the implementation.

This kind of change can be used without submitting a new application (type D) and is similar to the Type II classification used to assess major variations in Europe. Type "C" category changes e g; increase in shelf-life of a drug product, widening of specification limits for either drug substance or drug product and changes to route of synthesis of an API.

In the EU, approval of a type II variation by the MAH can be obtained after 60 days and in South Africa the change takes two years, which poses a significant challenge. The regulatory CMC professional must factor in the longer approval timelines when they chart their strategic planning and communicate to manufacturing, supply chain and marketing departments.

Type "D" Amendments

In South Africa, filing a new application is a Type "D" Amendment which is similar to a line extension in the EU. In Europe, changes to formulation to add or add or replace an API, or a switch to a different dosage form are examples of modifications to a medicinal product which would be assessed under this classification.

POST-APPROVAL AMENDMENT CLASSIFICATIONS IN SOUTH AFRICA

Post-approval amendment classification	Filing type	Resembling EU category(a)	Approval time
Type A	Prior notification not required	Type IA	0 days(b)
Type B	Notification required 30 days prior to intended implementation date	Type IB	30 days(c)
Type C	Prior written approval	Type II	Approximately 2 years11

- This is the EU classification type which bears similarity in terms of filing mechanism and approval time.
- Amendment is "approved" immediately and can be implemented at plant level. The change must be submitted at the time of the next type B or C amendment.
- Approval is implicit. After 30 days have elapsed from the filing date, the change can be implemented, assuming that no agency queries have been received. It has been known, however, for the HCR to receive queries after this time.

SOUTH AFRICA'S RELATIONSHIP WITH NEIGHBORING COUNTRIES

Botswana, Malawi, Namibia, Zambia and Zimbabwe import their pharmaceutical products from South Africa, including Mauritius, which earlier imported stock from France. The South African export markets are becoming increasingly autonomous for e g; Botswana and Namibia. However in these countries the key hurdle for lifecycle maintenance is to get approval from the country of origin (COO), i e; South Africa.

Botswana's national competent authority (NCA), the Drugs Advisory Board, published the first version of its "Guideline on Dossier Requirements for Variations" in June 2009. The Namibia Medicines Regulatory Council has its "Post Registration Amendment Guidelines".

POST APPROVAL SUBMISSIONS IN SOUTH AFRICAN EXPORT MARKETS

Usually taken as notification filings with immediate implementation of change thereafter, approval evidence from the MCC is needed by the importing country to assure of product quality. Therefore time taken to process a post-approval amendment in a South African export market is thus determined by the time taken for the MCC to approve the change.

OPPORTUNITIES AND FUTURE OUTLOOK

Companies possessing pharmaceutical product licences in South Africa must convert their dossiers from existing format to the South African CTD (ZA CTD). Since 1 July 2010, the applications in ZA CTD format have been accepted and MCC has set a deadline of 1 June 2016 for harmonization of all dossiers.

The ZA CTD structure is based on ICH M4Q guideline and there are minor differences in naming conventions for e g; the 3.2.P.4 section is known as "Control of Inactive Pharmaceutical Ingredients" as opposed to "Control of Excipients".

The ZA CTD file is similar to an EU dossier in terms of content than the US dossier. For a CMC regulatory professional with respect to older products that may have seen a relatively low level of CMC change, conversion to the ZA CTD (less similarity in terms of section granularity to the previously used Medicines Registration Form (MRF1) represents an enormous volume of work.

The CMC regulatory professional must undertake a complete re-write of the dossier, to include the registered information under the relevant CTD sections. Alternatively, a contemporary dossier can be supplied, and a thorough gap analysis against the current file must then be undertaken and followed up with any necessary remediation actions, which may include the filing of "missing" amendments.

Both approaches are time-consuming and require due diligence and attention to detail, however the CMC function must focus on achieving fully compliant dossiers which are reflective of current manufacturing practice.

SCENARIO POST-2016: USE OF ECTD FORMAT IN SOUTH AFRICA

By 2016, the use of use of the electronic CTD (eCTD) format in South Africa may increase, which requires additional training for professionals involved in publication of dossiers. Currently, paper-only filing

The lengthy approval timelines for major (type C) amendments in South Africa, poses a challenge. It takes two years from the filing date to approval date for a type "C" change in South Africa while a type II variation for a product licensed through the centralized procedure (CP) in the EU is approved by the European Medicines Agency (EMA) after 60 days.

Strategic planning between regulatory affairs, manufacturing, supply chain and marketing is critical if timely delivery of the project is to be achieved. Manufacturing sites must either wait for approval in South Africa and other trailing markets prior to implementing the change or must run the current and proposed processes simultaneously in the gap between submission and approval.

A large inventory of compliant stock must be built up and will remain in shelf-life until manufacturing sites wait for approval of the change in South Africa. The other approach leads to the site incurring significant extra cost while stock building poses its own challenges.

Manufacturing sites are apprehensive to manufacture additional batches for market with long evaluation periods if the number of stock-keeping units (SKUs) exported is relatively low. Even if sufficient stock can be compiled, a short shelf-life can limit the time available for sale.

Stakeholder input must be taken into consideration when undertaking site transfers, manufacturing processing changes and other major variations which must be carefully managed and budgeted properly. Long approval timelines will also lead to "blocking" of variations; the South African regulatory framework has no provision for parallel assessment of changes affecting same parts of the dossier.

So if an amendment to widen a drug product specification (a type C, prior approval change) is submitted with an updated 3.2.P.5 CTD section. A future change to introduce a new drug product analytical testing methodology can't be filed until the previous specification change is approved.

For products undergoing rapid CMC evolution, this can quickly lead to a backlog of amendments and presents the risk that HCRs find their product becomes out of compliance. HCRs may submit a complete CTD dossier in support of a relatively minor change owing to requirement for CTD conversion.

This will enable the MCC assess and approve the CTD upgrade filing and prevents the certificate holder from making any further changes. The MCC's Post Registration Unit is responsible for assessing all amendment applications.

The MCC's inspectorate unit will assess amendments which affect the registration certificate and issue an updated certificate. Amendments to those sites involved in drug product manufacturing, packing or final product release control (FPRC), or plants with a final product release responsibility (FPRR).

These changes are categorized as type C prior approval amendments with a concomitant two-year approval time. The MCC may review a change to the name of a batch release site for around two years before its approval.

However in EU, for a change to the name of a batch release site, the MAH's are mandated to submit a type IA IN variation within 30 days of implementation.

Conclusion

Regulatory professionals engaged in CMC lifecycle activities in South Africa face such pressing challenges like lengthy approval timelines for major variations and full conversion of product dossiers to the CTD format.

In addition, HCR's have a long standing goal to achieve CMC regulatory compliance across the entire product portfolio. It is imperative to understand the regulatory requirements to deliver the CMC submission packages and human resource must be managed to meet the harmonization deadline in 2016.

Content Courtesy - www.topra.org

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.

STRATEGIC LABELING MANAGEMENT PROJECT FOR GLOBAL $1+Bn, PHARMA COMPANY

- Develop and manage client's Company Core Data Sheet (CCDS)
- Deploy a technology solution for management of CCDS by leveraging the "OpenText" platform
- Manage client's global labeling management activities
- Leverage strong industry knowledge and expertise supporting further enhancement of global competitiveness and reduce operating costs

NEW SERVICES LAUNCH

FREYR LAUNCHES SPECIALIZED MEDICAL WRITING SERVICES

Freyr now offers strategic medical writing services across a spectrum of domains to the global Bio-pharmaceutical industry. Freyr also provides a full range of writing services in medical writing that include writing scientific documents of diverse nature covering all regulatory and research-related documents, disease or drug-related educational and promotional literature, publication articles like journal manuscripts and abstracts, content for healthcare websites, health-related magazines or news articles.

Freyr also offers end-to-end medical writing services to clients in Pharmaceutical and Medical Device industries.

Freyr's Services include:

- Writing/editing of regulatory submission documents
- Consulting and training
- Document template solutions

Freyr is uniquely positioned to provide best-in-class services based on similar successful partnership experiences, therapeutic area expertise, and delivery rigor. Freyr's medical writing associates have extensive experience in medical writing & publishing for more than 120 studies across a broad range of therapeutic areas.

FREYR INTRODUCES MEDICAL DEVICES REGULATORY SERVICES

Freyr announced the launch of new medical devices regulatory services designed to provide a focused, market-driven approach to ensure compliance with global regulatory requirements.

The new service offers an effective regulatory strategy to medical device companies to gain competitive edge in meeting the regulatory requirements.

In addition, Freyr provides end-to-end services starting from device classification to market approval which includes appointing legal representative and offering guidance in attaining certifications like QMS etc.

Freyr will assist in navigating across any regulatory issues and offers a path to approval across multiple jurisdictions through implementations of a strategic plan in registering the device for different agencies which makes the approval process easier.

Freyr's specialized services will enable the device companies efficiently address the increased scrutiny from national regulatory agencies while minimizing downstream risks.

CLIENT VISIT

Client partners meet the management team @ Freyr headquarters in New Jersey, US.

Client delegation meets Freyr core group @ Global Operations Center in India

CORPORATE SOCIAL RESPONSIBILITY

Client Partners: Supporting Good Causes Worldwide

Freyr is sharing it's CSR programs with our client partners to extend the outreach of the CSR initiatives.

Freyr as an 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.

EMPLOYEE APPRECIATION

Samadhan N. Aldar
Assistant Manager
Regulatory Affairs - CMC

"Worked steadfastly to complete project tasks while coordinating with stakeholders in parallel to provide quality output. "

Prateek Kulshrestha
Regulatory Affairs Associate
CMC- Regulatory Affairs

"Careful attention to detail and proactive approach towards work. "

Prashanth Chilka
Associate
Regulatory Affairs - CMC

"Greatly delighted at the shared sense of team spirit and hard work that has been the leading light to countless successful projects for the year. "

Parimal Limburkar
Manager
Regulatory Affairs - CMC

Venkanna Bandaru
Senior Program Analyst
Software Services

"A hardworking and dedicated person, he has proven his capabilities in various technical application developments. projects"

Ramasrinu Akula
Practice Lead
Software Services

Senior RIS Team

"Proud of the hard work and dedicated determination in achieving the best results. I acknowledge and thank you for all your efforts and dedication."

Junior RIS Team

"The team's commitment, hard work and dedication has brought excellent results which helped the team deliver some critical projects on time."

Sunil Chandupatla
Associate Manager
RIS and Regulatory Affairs

Sandeep Reddy Kondam
Regulatory Affairs Associate
Artwork & Labeling

"Worked on critical projects and delivered on time without any issues. Has been a consistent good performer throughout his tenure."

Sagar Kenari
Trainee Regulatory Services
Artwork & Labeling

"Good performance and gained good knowledge in non-labeling projects. Has been able to handle huge volumes and later trained another resource."

Venugopal Vadla
Assistant Manager
Artwork & Labeling

Anand Chincholi
Associate Regulatory Operations
Regulatory Operations

"Thank you for the fantastic job you do every day. No job is too big or too small for you. You are a great contributor. "

Vikrant Mahajan
Senior Consultant – Regulatory AffairsRegulatory Operations

Dossier Management Team

"Outstanding contribution by the team in supporting cross-functional teams/colleagues and enabling in providing timely deliverables."

Sajed Ali Khan
Manager - Dossier Management
Regulatory Affairs

Global Labeling Management team

"The Global Labeling Management team is doing commendable work to support the client's global labeling processes. The team has been able to provide quality output within the tight timelines. Keep up the good work."

Manish Dubey
Manager Regulatory Affairs
Regulatory Operations

Varsha Salla
Sr Content Specialist
Marketing

"The past year has seen 'Freyr Connect', our flagship newsletter, transform into a powerhouse of regulatory and corporate information showcasing Freyr's thought leadership, domain expertise and customer-centric solutions focus. Today, the newsletter is eagerly awaited and highly appreciated by our clients as well as our wider circle of business prospects.

It gives me a great pleasure to appreciate Varsha who has singlehandedly and diligently made this transformation possible through her unrelenting dedication for researching emerging hot regulatory topics, collating compelling content, and creating highly informative articles.

Great job Varsha for raising the bar high with every new edition! "

Ranvijay Singh
VP - Marketing

Freyr Label Development Team

I would like to appreciate "Freyr Label Development Team", for their hard work, dedication in completing a strategic project on time.

Uma Mahesh Gorle
Technical Lead
Product Engineering

STAR ACHIEVERS OF THE QUARTER

Y Yogi Raj

Business Development Manager
Sales

Innovation and Proactive Leadership

Yogi's positive approach towards Business Development has been instrumental in bringing new clients on board. He exhibits proactive leadership characteristics and tends to successfully prioritize and implement activities accordingly.

Building Relationships/Partnerships and Creating Measurable Impact

Has built strong relationship with clients and able to successfully mine existing accounts and added value to both clients and the organization.

Attitude and Commitment

His persistent attitude makes him a key team player who is able to perform independently under all circumstances.

Interpersonal Skills

Possesses excellent interpersonal skills and effectively communicates and interacts well individually and in groups.

Work Performance

He has played a positive role in the Business Development operations and delivered high quality results. He is able to handle the prospects independently and effectively.

Personal Traits

He is always full of positive energy and is approachable all the time.

Sasi Kuchibhotla

Business Development Manager
Sales

Innovation and Proactive Leadership

Sasi's patient and continuous focused approach towards the organization is remarkable that makes him successful in adding multiple accounts.

Building Relationships/Partnerships and Creating Measurable Impact

His relationship with customers is outstanding. He has capabilities of nurturing the accounts he handles and is able to successfully add more value to the organization.

Attitude and Commitment

His tenacious and never say die attitude makes him operate holistically in the Regulatory space.

Interpersonal Skills

He is always approachable and possesses excellent interpersonal and communication skills; because of these attributes he has built excellent rapport with his clients.

Work Performance

He is a great team player and delivers high quality results even under pressure situations. He has been able to show quick promise and independently handle prospects

Personal Traits

He is available whenever there is a need and doesn't hesitate to extend beyond his regular work window. He provides valuable suggestions and inputs whenever required

Chandra Sekhar Chukka

Trainee
DM- Regulatory Affairs

Innovation and Proactive Leadership

Manages it the right way and is in the best position to cultivate creative ideas in the team.

Building Relationships/Partnerships and Creating Measurable Impact

Organized with the ability to plan and think strategically to develop relationships to drive results.

Attitude and Commitment

Has the ability to adapt quickly to changing environments.

Interpersonal Skills

Strong interpersonal skills in the workplace are a great value addition to the team.

Work Performance

Chandra Sekhar supported in all activities of submission and was instrumental in effective handling a critical task which resulted in a steep rise in productivity and time management.

Personal Traits

Good natured and soft spoken individual.

Damodar Renati

Trainee Regulatory Associate
Regulatory Affairs-RIS and Medical Writing

Innovation and Proactive Leadership

Adheres to organization's vision and policies to provide high quality of work. Works effectively on assigned projects to meet deadlines.

Building Relationships/Partnerships and Creating Measurable Impact

Works with others and builds effective relationships to accomplish common team goals and objectives.

Attitude and Commitment

Has positive attitude and has productive relationships with others; displays interpersonal skills; is continuously looking for ways to improve his skills.

Interpersonal Skills

Hard worker and result oriented.

Work Performance

Demonstrates an attitude of interest and care for each situation with a positive outlook. Responds in an open and respective manner towards concerns in assigned projects.

Personal Traits

Goal focused.

Mahesh Chandra Kalyanam

Sr. Regulatory Associate
Regulatory Affairs-RIS and Medical Writing

Innovation and Proactive Leadership

Follows through on commitments to resolve client issues and assigned projects in a timely manner; takes initiative to uncover client needs; responds in a positive manner to the needs of internal and external clients.

Building Relationships/Partnerships and Creating Measurable Impact

Works with others and builds effective relationships to accomplish common team goals and objectives. Shares ideas freely and openly and receives inputs from others.

Attitude and Commitment

Produces an acceptable level of work in a timely and consistent manner; is accurate and thorough; consistently meets deadlines.

Interpersonal Skills

Communicative, hard worker and result oriented.

Work Performance

Uses independent judgment and innovation within his limits of authority; uses time effectively and productively; requires minimal supervision to complete tasks.

Personal Traits

Persistent and self-confident...

Ramesh Ramagundam

Technical Lead
Software Services

Innovation and Proactive Leadership

Ramesh has natural leadership abilities which are evident in the projects he led with good success rate.

Building Relationships/Partnerships and Creating Measurable Impact

Due to Ramesh's application structure the team could deliver multiple repeat orders for similar work in an efficient and cost effective manner.

Attitude and Commitment

Ramesh could learn new technologies and skills on the job in spite of having extensive experience and also educated team members to deliver the projects.

Interpersonal Skills

An easy going person who can gel equally with superiors and subordinates.

Work Performance

Able to adopt new technologies easily and delivered projects within time.

Personal Traits

Honest, responsible and fun to work with.

Ravi Mishra

Sr. Associate
CMC Regulatory

Innovation and Proactive Leadership

He not only provided his review support for strategic projects but also streamlined the authorization process for documentation in a short span.

Building Relationships/Partnerships and Creating Measurable Impact

He adjusted to Freyr's new environment and also built a positive relationship with the team mates.

Attitude and Commitment

He has the right attitude and is committed to his work. Ravi took initiative to liaise with sub-ordinates and assisted in process enhancement and provided a swift resolution.

Interpersonal Skills

Ravi possesses good interpersonal skills, developed good camaraderie with his team mates.

Work Performance

He is very good at work; he not only understood the system and processes but also provided his excellent support in multiple accounts.

Personal Traits

A very hard working associate, earnest and willing to learn always.

Sandeep Talari

CDPM
EMEA - CDPM

Innovation and Proactive Leadership

A real capability to listen and integrate the function's inputs so that the projects get enriched & solid while progressing in its development.

Building Relationships/Partnerships and Creating Measurable Impact

Able to build, maintain and engage internal and external communication to provide new sources of insights, experiences and ideas.

Attitude and Commitment

Showed utmost commitment for the support needed to progress the Asia Pacific Region jobs prioritizing them with very good quality while doing the regular jobs for EMEA region, received appreciation from clients as well.

Work Performance

Has been doing a good job and always asks for immediate feedback.

Narayana Reddy Tadi

Regulatory Associate
CDPM

Innovation and Proactive Leadership

Intrinsic interest in work with problem solving skills and the ability to solve conflicts.

Building Relationships/Partnerships and Creating Measurable Impact

Fosters collaboration and communication across all organizational structures and hierarchies.

Attitude and Commitment

Narayana is eager to learn and has a positive attitude towards work and delivers the job as committed on time with good quality. Possesses good knowledge on the process and takes feedback positively.

Interpersonal Skills

He has got good interpersonal skills. He works well in a team and communicates effectively with colleagues.

Work Performance

An extremely hard working individual who works on multiple brands and delivers good quality of work. His overall performance so far has been good.

Personal Traits

An obedient, observant and confident individual.

Sridhar Kalwa

Trainee
UK - Regulatory Affairs

Innovation and Proactive Leadership

Sridhar creates a team-oriented environment. He thinks in terms of desired outcomes and not just reactive quick solutions.

Building Relationships/Partnerships and Creating Measurable Impact

Sridhar has good rapport with his fellow colleagues; he is attentive and expresses his ideas/ views freely.

Attitude and Commitment

He is dedicated, sincere and a committed resource with right attitude and strives to achieve excellence in every given task.

Interpersonal Skills

Has good interpersonal skills, works well in a team and effectively communicates his work related matters with client/seniors.

Work Performance

Sridhar is proactive and manages his assigned work independently with minimum supervision. He is always available to take up other urgent work related matters. He delivers high-standard quality works most of the time.

Personal Traits

He is quick learner, hard-worker and sincere.

NEW EMPLOYEES

Avinash Akula
Executive
TPO

Benjamin Franklin
Trainee
Regulatory Affairs - CMC

C Ramprasad
Trainee
Regulatory Affairs - CMC

Harisha Mothe
Trainee
Regulatory Affairs - CMC

Kalyan Reddy
Manager
Regulatory Affairs - DP

Karri Pavani
Trainee
Regulatory Operations

Koppula Tejaswini
Trainee
Regulatory Affairs - CMC

Maneesha Reddy
Trainee
Regulatory Affairs - CMC

Mohammed Azeem
Assistant Manager
Artwork Design

Nageshwararao Dane
Executive
TPO

Neerukonda Vamsi
Trainee
Regulatory Affairs - CMC

Pankaj Burse
Manager
Regulatory Affairs - DP

Ponamala Mahesh
Associate
Proof Reading

Rakesh Kannam
Associate
IT System Admin

K Ramesh kumar
Assistant Manager
Regulatory Affairs - DP

Ravi Mishra
Sr. Associate
Regulatory Affairs - CMC

Shivajee Vaghmare
Assistant Manager
Artwork Design

Spandana Suddala
Trainee
Regulatory Affairs - CMC

Sravani Kancharla
Associate
Regulatory Operations

Srujana penthakamsetty
Trainee
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Zeeshan Ahmed
Sr.Associate
Regulatory Operations

Sudhir Vangaveeti
Trainee
Regulatory Affairs - CMC

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About Freyr

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

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

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

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

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