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SOLUTIONS & SERVICES

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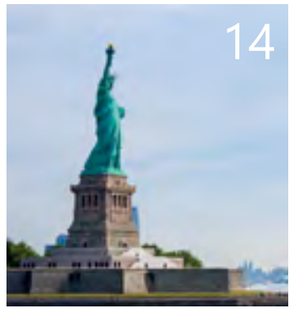
CONNECT

INSIDE

LEAD STORY

SUBMISSION PUBLISHING SERVICES

WHAT'S INSIDE



FROM THE EDITOR'S DESK

Hello all and welcome to the **Vol 3 Issue 3** 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 **"Submission Publishing Services"** 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
EDITOR

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LEAD STORY

SUBMISSION PUBLISHING SERVICES

The regulatory landscape is extremely fragmented-many regions around the world have different formats, validation tools, electronic gateways and languages for registration of pharmaceutical products. The documentation standards are not the same everywhere, while Common Technical Document (CTD) format for submissions is followed by the United States, Europe and Japan.

Global pharmaceutical companies must adhere to compliance requirements considering the growing number of acquisition and in-licensing activities. Lack of uniformity in rules being introduced by different regulators in different nations makes it difficult for the companies.

Global pharmaceutical companies face an increasingly onerous regulatory regime across different phases of their product life cycle. This makes it even harder for drug makers to accomplish regulatory compliance.

AUSTRALIA Reaches Electronic Only Submission Milestone

The Australian Therapeutic Goods Administration (TGA) has released the first final regional specification and validation criteria for eCTD format.

Since late 2014, TGA was accepting eCTD submissions based on draft specification 0.9 in a pilot phase to assess the eCTD readiness of the agency and industry stakeholders and to collect comments from stakeholders during the ongoing consultation period.

The pilot phase clearly demonstrated the feasibility of eCTD in Australia and triggered the finalization of the eCTD specification.

A bit surprisingly the first final version of the Australian eCTD was released as version 3.0 (and not 1.0 which could have been expected). Also the corresponding final eCTD validation criteria were released as version 3.0.

Submissions using version 3.0 of the eCTD specification will be valid starting 1 June 2015. Submissions using version 0.9 of the eCTD specifications are valid until 31 December 2015.

Timelines:

- The TGA will accept eCTD submissions in accordance to the final version 3.0 from 1 June 2015 onwards
- The current pilot version 0.9 will still be accepted in parallel until 31 December 2015
- Any eCTD submitted starting 2016 will need to follow the version 3.0 of the specification

In parallel, the TGA is currently revising the NeeS format to align the corresponding validation criteria with the newly released final eCTD validation criteria. Furthermore additional guidance material for NeeS is being developed and will be released by TGA in the near future. The NeeS format will still be accepted by TGA but a revision of this policy is being considered.

A time frame for transitioning from paper to NeeS/eCTD is not determined. TGA has yet to decide the transition period. Once a submission for a product is submitted in the eCTD format, all future submissions for that product must be in the eCTD format in order to take advantage of the lifecycle features of the eCTD standard.

When changing from paper or NeeS to eCTD, it is highly recommended but not mandatory to use a baseline as a start of an eCTD. A baseline submission is a compilation of the current status of the dossier, i.e. resubmission of currently valid documents that have already been provided to an agency but in another format. The baseline should normally be submitted as sequence 0000.

It should be clearly stated in the cover letter of the 'baseline eCTD sequence' that:

- Content of the previously submitted dossier has not been changed, only the format
- All the studies have previously been submitted to TGA and
- Any omissions do not render the submitted content misleading

The TGA will not convert new or existing submissions to eCTD format they will only accept validated eCTD submissions published by applicants.

TGA is accepting electronic submissions in eCTD and NeeS format. TGA is still accepting regional specification V0.9 but starting from FY 2016 only V3.0 is acceptable. The TGA is planning for RPS (eCTD 4.0).

Navigation through an electronic submission is greatly enhanced by the appropriate use of bookmarks and hypertext links. However, the overuse of hyperlinks may confuse rather than help assessors. The maximum size of an individual PDF files used for submission is 100MB. There is no maximum allowable size for the entire

submission. The TGA will encourage submission via DVD during the pilot and until they have a fully developed portal facility with capacity for upload.

Each eCTD submission should have submission identifier issued by TGA. It is required in the 'envelope' information for each submission. Submissions will be referenced by this number and therefore subsequent sequences must include this identifier. To get an eSubmission Identifier, send an email to esubmissions@tga.gov.au (link sends e-mail) with the applicant's name, the Australian Approved Name, and description of the application (trade names, dose form, strength and route of administration).

The TGA expects sponsors and applicants to use validation tools to test their own eCTD applications before submitting them to the TGA. A copy of the validation report will need to be attached to the submission. Validation tools are available from software vendors or an example tool can be downloaded from the TGA's website.

TGA will adopt a set of technical validation criteria against which all eCTD and NeeS sequences can be checked. Two categories of validation rules apply: 'Pass/Fail' and 'Best Practice'.

The technical validation of an eCTD or NeeS formatted submission is a separate activity to the content validation of a submission and takes place irrespective of the type of the submission.

Sequences which fail to meet one or more of the 'Pass/Fail' criteria will be returned to the applicant for correction and resubmission. TGA may accept sequences which fail to meet one or more of the 'Best Practice' criteria; however, the applicant should make every effort to address these areas before the eCTD is submitted to TGA.

Submissions which include STFs will be accepted but are not required. However, if STFs are included, they must pass validation. If an FDA submission containing STFs is modified by removing the STFs, the study files must be organized using node extensions.

eCTD submissions will be preserved in the TGA's computer network file storage system according to the Australian Government electronic record keeping standards. Applicants should maintain archival copies of submissions according to their business rules. TGA recommends archiving all dossiers in the format the dossier was submitted to the TGA.

The below are the envelope elements for 'AU'

XML Element	Description	Constraint	Occurrence	Defined List*
Esub-id	eSubmission Identifier	Mandatory	Single	
Applicant	Applicant	Mandatory	Single	
aan	Australian Approved Name(s)	Mandatory	Multiple	
Product-name	Product Name	Mandatory	Multiple	
Artg-number	ARTG Number	Optional	Multiple	
Sequence-type	Sequence-Type	Mandatory	Single	X
Reg-activity-lead	Regulatory-Activity-Lead	Mandatory	Single	X
Sequence-number	Sequence Number	Mandatory	Single	
Sequence-description	Sequence Description	Mandatory	Single	X
Related-sequence-number	Related Sequence Number	Mandatory	Single	

THAILAND First ASEAN Country with a National eCTD Program

Thai FDA (Thailand) electronic submission system is to be fully implemented this year. Thai FDA intends to accept dossier in eCTD format: The Drug Regulatory Authority of Thailand (Thai FDA) has initiated the acceptance of Pilot eCTD from October 2014. Formally, eCTD submissions should be accepted from May 2015.

Thai eCTD Module

Thai eCTD Module 1 has been developed based on the EU eCTD Module 1 and ICH eCTD specifications v3.2.2 for Module 2 to Module 5. The EU structure is being used as a proven structure and to increase reusability from applications already submitted in the EU region. Thai FDA has released the TH eCTD (Thai eCTD) Module 1 Specifications draft version 0.92 and validation criteria, draft version 0.92.

eSubmission and Thailand

Thailand will become the first country to publish a national eCTD specification in ASEAN.

Some of the positive aspects with the eSubmission include

- Countries with eCTD specification have increased access to medicines through ease of submitting (part of first or early wave of release)
- eSubmission also increases the ability to co-operate with agencies globally
- It promotes export as it equips local industries to compete internationally
- Offer a transparent review process thereby increasing the quality of review and also offer access to related information

Thailand's Reason's for Considering eCTD as Global Submission Strategy

- eCTD has worldwide acceptance
- Establish a single application format for all applications
- Timelines are met and is much more favorable than paper timelines
- Supports Lifecycle Management
- Harmonizing structure improves reviewing process
- There are minor differences between ACTD and eCTD

Thai eCTD Module: To Improve Reviewing Process

- Submissions are uploaded via electronic submission gateway (future) and can be available to reviewers within minutes
- Improves application review process
  - More efficient review
  - Changes and updates are easy for reviewers to identify and review
  - Bookmarks and Hyperlinks
  - Easy 24/7 access from any location
  - Everyone can access the document simultaneously
  - Document is more secure, no need to print desk copies, maintain duplicate electronic file

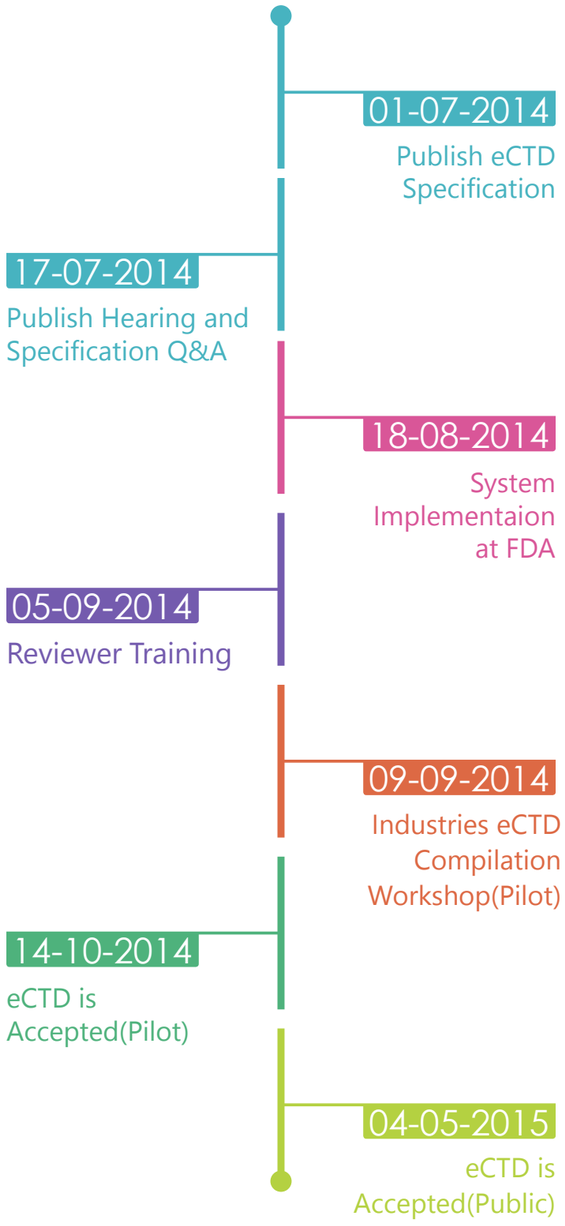
Pilot eCTD

Thai FDA is working in cohesion with several industry representatives to ascertain suitable eCTD pilot submissions (only e-submission will be accepted). The officials will conduct tests ahead of the adoption expected to be complete this year.

The following application types will be tested

- new chemical entity
- new biological
- new generic
- submissions prepared with different publishing tools

Pilot eCTD: Implementation Timeline



Thai eCTD implementation will have no impact to other or existing applications and variations.

Filing Dossier in eCTD Format

Obtaining the eSubmission Identifier:

- Prior to filing the first regulatory transaction for an application in an electronic format, the applicant should submit a request to the THAI FDA online service to obtain an eSubmission identifier.
- The request will require the following information:
  - Licensee Number
  - Description of Application
  - Dosage Form
  - INN or Generic Name
  - Strength
  - WHO ATC Code
  - Sequence Type
  - Application form (CPP)
- If the applicant wishes to provide single dossiers for the same active ingredient, dosage form and therapeutic group but has more than one strength, only one eSubmission identifier will be issued to cover all strengths.
- The eSubmission Identifier will be issued within 10 days of application. After receiving the identifier, the applicant must then make an appointment for submission within 30 days.

Validation Report

- An electronic copy of the validation report created should be submitted. A folder should be created in the application folder named after the eSubmission identifier with the naming convention of the sequence number followed by validation-report e.g. "0000-validation-report".

TH Regional Information

- The ICH Common Technical Document (CTD) specifies that Module 1 should contain region-specific administrative and product information.
- The content and numbering of Module 1 for Thailand is modeled after the EU Module 1 content as described in the 2008.
- Additional documents specifically required by Thailand not covered by the EU structure will be added to 1.A Additional Data.
- The following items listed in the Notice to Applicants may be included for an initial submission:
  - A cover letter
  - An application form(Form MA-1)
  - Product information documents
  - Information on the experts (optional)
  - Specific requirements for different types of applications (if required)
  - An environmental risk assessment
  - Information relating to pharmacovigilance (optional)
  - Information relating to clinical trials (optional)
  - Information relating to paediatrics (optional)

Future Outlook

FDA is working alongside with other regulatory agencies to facilitate improvement processes for best practices.

- eSubmission gateway to be implemented to support application process through internet
- Improve bi-directional communication over electronic communication channel
- Only eSubmission will be received by 2017
- Prepare for next iteration of eCTD 4.0 (RPS)
- RPS (Regulated Product Submission) is able to support different types of application e.g. ACTD, Medical Devices, Veterinary
- Furthermore, it is very likely that the eCTD system will also be extended to medical device applications in the next several years.

US FDA Module 1

Specifications Version 2.3 (DTD v3.3)

The US FDA has released new module 1 specifications for V2.3 which will be made mandatory to use from the third quarter of FY 2015 (which ends June 30, 2015). Using the new module 1 specifications is mandatory for advertising, promotional submissions to the Office of Prescription Drug Promotion (OPDP) and for grouped submissions. Once an application is converted to the new M1 specifications, you cannot return to an older version. So far no retirement date for the US-regional DTD v2.01 has been set, so companies can still submit using the older version that is V2.1.

Using the new module 1 specification applicants can submit a single grouped submission instead of submitting in many sequences. Grouped submissions can be "ungrouped" at any time, but one disadvantage of this grouped submission is that technical rejection of grouped submissions for any reason will lead to rejection of all applications in the group. Below is the overview of new module 1 specifications and validation criteria. Unlike other regional specifications this new module 1 specifications have different validation criteria and DTD from V2.3.

TITLE	VERSION	LATEST REVISED DATE	STATUS
USFDA Module 1 Specification	2.3	Feb-15	Final
USFDA eCTD Validation Criteria	3.1	Mar-15	Final
US Regional DTD	3.3	Feb-15	Final

Points to be noted when using new module 1:

The latest Module 1 specification is compulsory for use only for few submissions which are advertising and promotional labeling submissions, grouped submissions. Promotional labeling and advertising submissions applicants must make sure that they do not include form 356h. Differently grouped submissions require 1 form per application references in the admin section of the US-regional XML.

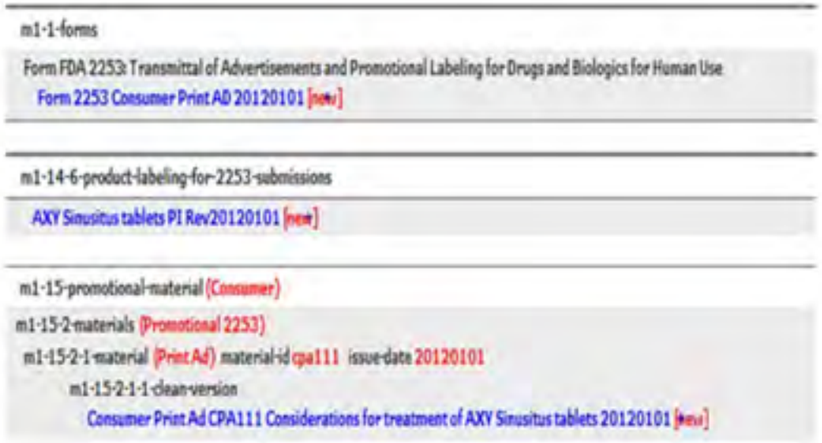
The updated Module 1 has high granularity compared to the older one, so it is asking for more attributes. One of the major changes in the updated Module 1 is the inclusion of section 1.15 promotional materials with high granularity. Applicants must note that correspondence related to promotional materials should not be included in section 1.2. Below is the screenshot of Module 1.15.

1.15 Promotional Material(promotional-material-audience – type)

- 1.15.1 Correspondence relating to promotional materials
  - 1.15.1.1 Request for advisory comments on launch materials
  - 1.15.1.2 Request for advisory comments on non-launch materials
  - 1.15.1.3 Presubmission of launch promotional materials for accelerated approval products
  - 1.15.1.4 Presubmission of non-launch promotional materials for accelerated approval products
  - 1.15.1.5 Pre-dissemination review of television ads
  - 1.15.1.6 Response to untitled letter or warning letter
  - 1.15.1.7 Response to information request
  - 1.15.1.8 Correspondence accompanying materials previously missing or rejected
  - 1.15.1.9 Withdrawal request
  - 1.15.1.10 Submission of annotated references
  - 1.15.1.11 General correspondence
- 1.15.2 Materials attribute=(promotional-material-doc-type)
  - 1.15.2.1= Material(promotional-material-type, material-id, issue-date)
    - 1.15.2.1.1 Clean version
    - 1.15.2.1.2 Annotated version
    - 1.15.2.1.3 Annotated labeling version
    - 1.15.2.1.4 Annotated references

Every submission should have form 2253 and labeling referenced to the advertising and promotional submissions should be placed in section 1.14.6.

Below is the example of a submission with form 2253.



Challenges:

- Lack of naming standards for leaf titles
- Navigation difficulties
- Insufficient headings and hierarchy
- Challenge of maintaining unique sequence numbers if 3rd parties are involved in preparation or submission

REVAMP OF

PSUR TO PBRER

Periodic Safety Update Report

Periodic Benefit Risk Evaluation Reports for Medicinal Products

It is learnt that during the drug development process and after the drug is in the market, the sponsor or market authorization holder must submit safety related information to the regulatory agencies periodically. The reports submitted periodically have different requirements.

Various Types of Safety Reports

- IND Annual Report
- Annual Safety Report (ASR)
- Development Safety Update Report (DSUR): replacing IND Annual Report and Annual Safety Report
- Investigator's Brochure (IB)
- Periodic Safety Update Reports (PSUR) and
- Periodic Benefit-Risk Evaluation Report (PBRER) which replaces PSUR

Periodic Safety Update Reports

PSURs are Pharmacovigilance documents `intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission by marketing authorization holders at defined time points during the post-authorization phase.

Periodic Benefit Risk Evaluation Reports for Medicinal Products

In 2012, the PSUR was updated and is now referred to as the PBRER in many countries. PBRER's focus is on the benefit-risk profile of the drug, which includes a review of relevant safety data compiled for a drug product since its development.

Objective and Challenges

PSUR provides only a comprehensive picture of the safety of approved medicinal products whereas PBRER provides cumulative information about benefit-risk balance of the medicines which includes evaluation of the safety, efficacy and effectiveness information of medicinal products.

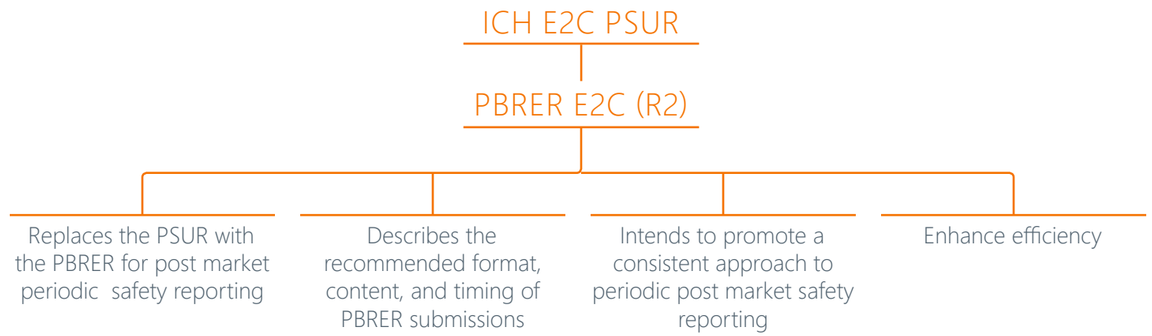
PBRER also provides

- Greater emphasis on the cumulative knowledge regarding a medicine, while retaining a focus on new information
- Minimize duplication of effort
- Interval listing no longer required in PBRER
- Free up resources by rationalizing and simplifying periodic safety update report
- "Analysis of individual case histories" has been deleted in PBRER

The new PBRERS require more evaluation and interpretation and are less of a 'data dump'. Thus the traditional data review by System Organ class, which had more emphasis on individual case review, has been replaced by a more holistic active signal detection and evaluation process necessitating a completely different approach by the MAH.

History of PSUR and PBRER

In November 1996, the ICH endorsed the ICH E2C Periodic Safety Update Report Guideline (E2C guideline), which established the PSUR as a harmonized format for post market periodic safety reporting for approved drugs and biologic products, and described the format, content and timing of PSUR submissions. The PSUR was updated in 2012 and is now referred as the Periodic Benefit Risk Evaluation report (PBRER).



Major changes from PSUR to PBRER

PSUR	PBRER
• PSUR follows ICH guidelines ICH E2C (R1) • The MAH should submit a PSUR within 60 days of the data lock point if covering interval is up to 12 months • One report for one active substance, except in fixed dose combinations (FDC) • PSUR contains 11 sections 1. Introduction 2. Worldwide market authorization status; 3. Update of regulatory authority or MAH actions taken for safety reasons; 4. Changes to reference safety information; 5. Patient exposure; 6. Presentation of individual case histories; 7. Studies; 8. Other information; 9. Overall safety evaluation; 10. Conclusion; 11. Appendix: Company Core Data Sheet	• PBRER follows ICH guidelines ICH E2C (R2) • The MAH should submit a PBRER within 70 days of the data lock point if covering interval is up to 12 months • One report for one active substance except in fixed dose combinations (FDC) • PBRER contains 20 sections 1. Introduction 2. Worldwide marketing approval status 3. Actions taken in the reporting interval for safety reasons 4. Changes to reference safety information 5. Estimated exposure and use patterns 6. Data in summary tabulations 7. Summaries of significant findings from clinical trials during the reporting period 8. Findings from non-interventional studies 9. Information from other clinical trials and sources 10. Non-clinical data 11. Literature 12. Other periodic reports 13. Lack of efficacy in controlled clinical trials 14. Late-breaking information 15. Overview of signals: New, on-going or closed 16. Signal and risk evaluation 17. Benefit evaluation 18. Integrated benefit-risk analysis for approved indications 19. Conclusions and actions 20. Appendices

Documents required for Preparation of PSUR and PBRER

PSUR	PBRER
• Information on International Birth Date (IBD) and Data Lock Point (DLP) • Countries in which the product is authorized • CCDS/SmPC • Cumulative subject exposure in clinical trials • Findings from active surveillance methodologies or Literature sources (e.g. data-mining in internal or external databases) • On-going clinical trials and other studies that the marketing authorization holder or its representative is conducting or has completed during the reporting period (Phases I - IV) • Non-clinical studies (toxicological and in vitro studies) • Any other source of relevant efficacy or safety findings for products in the same therapeutic class • Other PSURs	• Cumulative subject exposure in clinical trials • On-going clinical trials and other studies that the marketing authorization holder or its representative is conducting or has completed during the reporting period (Phases I - IV) • Non-clinical studies (toxicological and in vitro studies) • ADR reporting systems of regulatory authorities • Epidemiologic databases • Any other source of relevant efficacy or safety findings for products in the same therapeutic class • Other PSURs and DSURs

Frequencies of PSUR submission

The Marketing Authorization Holder (MAH) should submit PSUR to the Agency within 60 calendar days of the data lock point (day 0) for PSURs covering intervals up to 12 months (including intervals of exactly 12 months); or within 90 calendar days of the data lock point (day 0) for PSURs covering intervals in excess of 12 months.

PSUR India	PSUR US	PSUR EU
First 2 years, every 6 months	First 3 years, every 3 months	First 2 years, every 6 months
Next 2 years annually	Annually	Next 3 years annually
-	-	Every 5 years thereafter

Frequencies of PBRER submission

The frequencies of submission of PBRER report to regulatory authorities is subject to national or regional regulatory requirements, and usually depends on factors such as approval dates, the length of time the product has been in the market, and the extent of knowledge of the benefit-risk profile of the product.

"PBRER format and contents are intended to apply to periodic reports that cover reporting periods of 6 months or longer".

Once a drug has been marketed for several years, national or regional regulation may allow the frequency of submission to be extended to longer time intervals, e.g., greater than one year for products considered to have an established and acceptable profile or considered to be low risk; however, more frequent PBRERs may continue to be required in other regions.

As a result, the following scenarios may be encountered by MAHs:

- PBRERs may be required on 6-monthly, annual, and less frequent submission timetables simultaneously across different regions.
- Changes in reporting frequency may also apply after important additions or changes in clinical use are approved (e.g., new indication[s] and/or new population[s]). In these circumstances, it is possible that the reporting interval will be shortened, even for older products with a previously reduced frequency of PBRER submission.
- An ad hoc PBRER may be requested by a regulatory authority

Ad hoc ("for cause") PBRERs:

Ad hoc PBRERs are reports outside the routine reporting requirements, and may be requested by some regulatory authorities.

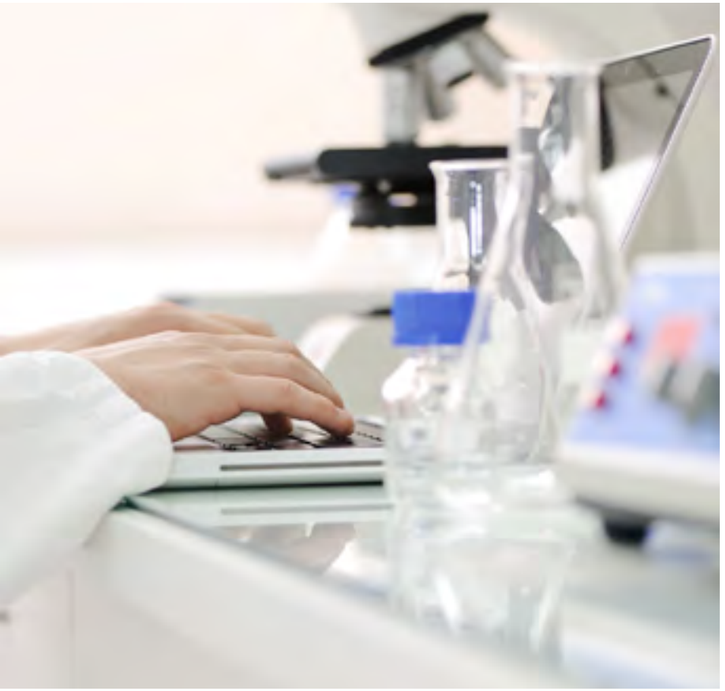
Where an ad hoc report is requested and a PBRER has not been prepared for a number of years, it is likely that a completely new report will need to be prepared by the MAH.

Independent of length and interval covered by the report:

- Each PBRER should be stand-alone and reflect new and cumulative information currently available to the MAH
- Regulators will normally accept use of the IBD to determine the DLP for PBRERs. Where national or regional requirements differ from this, the MAH may wish to discuss with the relevant regulatory authority
- Use of a single harmonized IBD and DLP for each product is important in order to reduce the burden of work involved in preparing PBRERs, and respects the original purpose of the PBRER – to prepare a single worldwide summary on a product that can be submitted to different regulatory authorities
- For newly approved products, a 6-monthly periodicity applies in many regions, for at least the first 2 years after approval
- For PBRERs submitted on a routine/regular basis, the reports should be based on cumulative data, with interval data sets of 6 months, or multiples thereof
- Sections that provide interval information are likely to be updated for each PBRER, and the content used in the previous PBRER can be reviewed and reused for sections where no new information has arisen since preparation of the last PBRER, if appropriate

Conclusion

The definition and scope of the PSUR is changing. New PBRER will put more emphasis on analysis of cumulative risk-benefit balance of a medicinal product at defined time point while minimizing the duplication and also deleting analysis of individual case histories hence rationalizing and simplifying periodic safety update report.



GLOBAL REGULATORY MEDICAL WRITING

An Integral Part of Clinical Research Organization

In today's uncompromising regulatory climate it is imperative for companies to produce accurate scientific, medical and regulatory documents. Regulatory writing- a discipline that evolves with new and updated regulations and guidelines. Medical writers are specialized in writing all kinds of high quality regulatory documents. It must be noted that a single medical writing document is the culmination of many hours of hard work by study teams, and is essential to creating high quality documents. Poorly written regulatory documents may lead to delays in regulatory approval, costing time and money for the sponsor.

It is important that all regulatory documents are presented in a clear and unbiased manner. Regulatory medical writers must adhere to stringent regulatory requirements while keeping in mind the needs, preferences and styles of sponsors/study teams. Regulatory medical writing plays a large role across the evidence generation continuum and also adds a lot of value in the production of clinical trial documentation.

The medical writers can aid in all steps right from protocol development to the submission process. In short regulatory medical writing is of key importance in developing and conveying the strategic message of the data and is an integral part of clinical research.

A clinical development program is deemed successful if it has proper documentation of research plans and results.

Regulatory Medical Writing is an activity of writing / communicating clinical and scientific data. The process involves writing regulatory documents like protocol, Clinical Study Report (CSR) narratives, Safety Update Report, Investigator Brochure (IB), Investigational New Drug (IND), New Drug Application (NDA) submissions and other documents as per Common Technical Document (CTD) or eCTD that are submitted to regulatory authorities for approval.

It also involves writing commercial documents like abstracts, manuscripts, posters, oral presentations for Congress/ Conferences/ International Meetings, educational slide sets and training modules for medical professionals.

Medical Writer

The Importance of Producing High Quality Documents

Highly skilled medical writers can play a role in every step of the data analysis and document preparation process. A medical writer can efficiently take up the writing tasks from the technical staff and help hasten the document development process. The writer must also ensure that scientific and medical communication materials are clear, concise, scientifically accurate and fully compliant with regulations, industry best practices.

Medical writer needs to produce high quality documents in a short time with respect to the CRO perspective. Client pharma companies deal with the production and testing of drugs, but presenting this information to the HA is crucial and lies in the hands of the medical writer.

Understanding Client Requirements:

Medical writing projects follow basic end-to-end steps, which typically start off with a kick-off meeting. For large or complicated projects, the internal team should first arrange and meet for the internal kick-off meeting so that the whole team is on the same page when client introductions are made. This helps every member understand the client requirements, which in turn gives the client the confidence that the team is well organized and understands the project.

The most important fundamental for both the medical writers and the client lies in here, which is the 'Expectations'. Expectations should be outlined to the extent possible before actual writing is even initiated; which include:

- The number of drafts?
- Input the client intends to provide?
- How often will the client provide input?
- Any other specific requirements?

It is also important to discuss with the client, the list of reviewers from different line functions (i.e. statistician [would assist in the statistical part], DMPK expert [Drug Metabolism and Pharmacokinetics, would assist in the PK part; etc.]). The respective timelines should also be discussed with the client:

- Database lock (DBL) point or data cut-off date, as applicable
- Availability of final source documents
- Date by when the client wants the drafts
- Date by when the client wants the final deliverable

Draft Preparation and Significance of Internal Review:

The medical writing team should work within the realistic timelines to ensure that there is no delay from their end at any instance. Usually there are one or two draft deliverables, followed by the final to client deliverable document. Mostly comprehensive templates and the corresponding source documents are provided by the client, after which medical writer needs to add relevant information into the corresponding sections of the working template.

The medical writer must have regulatory knowledge (for example, knowing what information is required in the efficacy section of a Clinical Overview); experience with client preferences (example, (1) for agency submissions, client A prefers that all data is presented individually from all phase 1 studies, not just an overall, pooled phase 1 summary; (2) when target population for a compound is an elderly population, client prefers devoting more text to adverse events that may be especially concerning to an elderly population).

Also, interpretation of the results in the form of tables, listings, figures is a skill and an aspect which needs strong attention to every detail, hence requires the medical writing expertise. In some cases, together with template, the client also provides a model document to ensure the medical writer prepares the working document in line with the model.

Any doubts which arise while preparing the draft document should be carefully handled, by initially utilizing the internal experience, best practices, lessons learnt, knowledge sharing etc. It is only then the medical writer should generate the list of queries-to-client.

An internal review to improve the quality of document always plays a significant role before the client review wherein it is checked for flow, adherence to client template and relevance of subject matter. Always impose a pre-discussed deadline to schedule a review so as to keep work on track.

Adherence to Style Guide (Client Specific)

It is the medical writer's job to prepare a clean-read (spell-check, grammar, formatting, accuracy of citations, cross-referencing etc. adhering to the client style guide) deliverable document before sending to the client for feedback.

Importance of Comment Logs and Client Review:

The writer must provide comment logs along with drafts which communicates the exact input needed from the client in a systematic manner. Through the addition of client responses to the log, any misunderstood issues if there are any can be quickly cleared ensuring the team and the client are on the same page.

A good draft should be so prepared that it may need only minor changes post-review, rather than substantial revision. Scheduling a comments resolution meeting with the client is exceptionally important to discuss 'Why and Why not' to address a major comment, in a tricky situation and a consensus is reached.

A medical writer should prepare the minutes-of-meeting (MoM), post-meeting and should circulate among all the participants so that all the members are on the same page of understanding, to keep track of the agreed points in the meeting and for documentation purpose.

Comments from multiple client reviewers 'within' a single line function should be handled sensitively and thus it is better to initially agree upon, before sending the document for review, as who will provide the comments and who will act a spectator, so that the latter could be marked in CC of the email.

Finalizing Draft and QC Review:

By the final draft, the writer must keep track of multiple versions, consolidate comments and any feedback from the client should be integrated into the document.

Before it is delivered, it should also go through a formal quality control (QC). This is where the entire content is thoroughly checked against sources for accuracy, consistency, completeness; which can be anything from an email with wording provided by the client, to the number of adverse events provided in client table, to agreed upon responses in a comment log or comment resolution meeting.

Documentation of the communication happened throughout the entire writing and reviewing period is highly important.

Conclusion:

CROs have a wide spectrum of customers who all have different requirements in terms of templates, language, presentation, etc. Such a variety of customers bring diverse indications to work on, whether it is hypertension, Alzheimer's disease, psoriasis or a vaccine. Medical writers within a CRO can therefore be exposed to a wide variety of documents (and indications) in a short timeframe.

In the end, clients will prefer to work with a CRO that have medical writers who consistently produce high quality documents in the promised time frame. A quality document delivered a week late, does no good to the client. And the converse is also true - A document completed on time, but if it's less than stellar, then the client may move their business elsewhere. With so many CROs out there, pharmaceutical companies have their pick of medical writers to work with, so the measured index of productivity is to consistently deliver quality documents in a systematic and timely fashion.

NAVIGATING Through Latin American Pharmaceutical Regulatory Environment

ABSTRACT

Obtaining marketing authorizations (MAs) for drugs in the Latin American (LATAM) countries is very country specific. Organizations must chart out a successful global regulatory strategy to understand the pharmaceutical regulatory environment in LATAM in order to address complex and evolving ad-hoc requests from reviewers in a bid to avoid expensive delays for local product launches.

From a global perspective, the commercial significance of markets is increasing and it is imperative for the pharmaceutical industry to cope with the regulatory requirements to ensure their place in the market. The registration dossier has quality, safety and efficacy data, which holds significant importance.

The International Conference on Harmonisation's (ICH) Common Technical Document (CTD) can serve as a resource for most local MA applications. In addition, a large amount of mandatory and highly country-specific documentation (related to infrastructure, legal documents, stability studies, labeling, etc.) requires strategic planning and allocation for timely local approvals.

Organizations can face challenges owing to identification of actual requirements due to frequent changes in regulations, unclear expectations, etc.

The pharmaceutical industry will benefit if they have clear visibility of the country-specific requirements and health authorities (HAs) expectations in LATAM and also improve their planning activities when submitting the global MA applications.

This will also help in managing internal expectations and offer patients in the region faster access to therapies.

INTRODUCTION

The LATAM pharmaceuticals market has seen a phenomenal rise over the last decade and has been mostly dominated by European and US-based multinational companies who have found a fertile ground here.

This has also led to growth of local drug regulations due to the rapid introduction of high-technology medicines into import, export and distribution networks. It has also become critical for each HA to guarantee medicines reaching local patients are in compliance with specific standards of quality, safety and efficacy.

Each LATAM HA has strengthened its health legislation which is a continuous evolving process; however variation in drug registration processes causes time-consuming and costly obstacles for companies. The article tries to focus on MAs for prescription drugs (including biologics/biotech).

Latin American countries must harmonize their basic vocabulary on pharmaceutical products and reach agreement on the technical procedures needed to ensure the quality of multisource products.

LATAM PHARMACEUTICAL MARKET

As of May 2012, Latin America has a market size of $66bn and it is extremely difficult to penetrate the pharmaceutical market. To gain momentum in these markets it is important to address different regulations between countries in the region and the various components required to register a product from country to country.

Adaptation and Growth

Emerging markets have long served as low cost manufacturing destinations pharmaceutical companies who pay low wages to manpower and less stringent adherence to environmental, health and safety regulations.

Countries in emerging markets are now taking steps to adapt their regulations to compete with highly regulated markets like the EU and the US. Brazil and Mexico are spearheading this growth which has given impetus to countries in Latin America to establish their place in the market.

Location

All the LATAM countries put together have a population of 582.5 million and they constitute Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama in Central America; Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Uruguay, and Venezuela in South America.

More than 20 countries and territories including Aruba, the Bahamas, Cuba, the Dominican Republic, Haiti, Jamaica and Trinidad and Tobago.

The first language of most Latin Americans is Spanish, except Brazil where Portuguese is spoken. There is a marked diversity of influences and also the politics to a certain extent contribute to the HAs' idiosyncrasies.

Pharmaceutical Trends: Growing Domain of Generics Market

Branded and unbranded generics are expected to grow faster than patent protected and non-protected branded drugs. Pharmaceutical sales in the areas of vaccines, oncology, high cost medicines, biologicals and rare diseases are rising fast.

There is an increasing demand for drugs; urging the region to increase drug access in spite of intensifying cost containment measures.

There is also an emergence of a new biosimilars market offering opportunities and consistent regulatory challenge for biopharmaceutical producers in many LATAM markets.

Pharmaceutical Market Overview

Brazil, Mexico, Argentina and Colombia are considered as the top Latin American economies and pharmaceutical powers. As a pharmaceutical market overview, Latin American sales in 2011 were at $62.9 bn (Source: WHO 2012).

Latin America also faces westernized health risk trends such as hypertension, obesity, cancer, ischemic heart diseases and diabetes posing challenges to domestic and international pharmaceutical companies catering to these markets.

Companies are looking into emerging science, new products and services, shifting demographics, evolving regulations while transformed business models trigger increased stakeholder expectations.

Drug Registration Process: Limitations

LATAM's drug registration processes are not harmonized. Through the initiative of the Pan American Health Organization (PAHO) via the Pan American Network for Drug Regulatory Harmonization (PANDRH) harmonization efforts have been ongoing for the past fifteen years.

Recommendations for a number of key topics (including Pharmacovigilance and pharmacopoeias) were generated by PANDRH to strengthen local HAs and regional regulatory harmonization however each country has its own unique regulatory requirements.

There are also country specific challenges to pharmaceutical companies seeking market penetration in the region as there is no regional "CTD" application. Each MA application must be planned and executed as per requirements of each country's HA. PAHO has recognized five national reference authorities from Argentina, Brazil, Colombia, Cuba and Mexico for the LATAM region.

The Term Generic: Different Connotations in Different Countries

The term "generic" means different things between and within countries. Most policy-makers, consumers, and many health professionals use the terms "generic" and similar interchangeably, which is confusing. Brazil has 1033 generic pharmaceuticals while rest of the Latin American countries have few drugs proven to be therapeutically equivalent or interchangeable with the proprietary product.

In Argentina, the term "generic" is used indiscriminately causing confusion. The Minister of Health- Argentina announced an initiative through a resolution 326 and law 25.549 to promote the use of generic drugs, competition and to lower prices, resulting in increased accessibility. However national and provincial medical associations opposed the policy owing to ambiguity of the term "generic" and stated that none of the drugs sold as generic drugs in the country had proven bioequivalence as required by law.

The government's initiative was to explore if expensive branded originals could be replaced with similar drugs, which were offered in markets under branded and International Nonproprietary Names (INN). Medical associations thought that the quality of the similar drugs was questionable and hence opposed the policy.

Classification of Pharmaceutical Products in LATAM Region

Some countries developed a typology that includes three types of drugs: original, similar and generic while others use a binary classification of branded and generic products. The World Health Organization (WHO) has proposed a different typology: single source and multisource pharmaceuticals.

Single source pharmaceuticals usually identified with a brand name correspond to the original drugs (usually on-patent). Multisource pharmaceuticals, identified by the INN or by brand names, can be produced by multiple pharmaceutical firms and include drugs that are pharmaceutically equivalent and may or may not be therapeutically equivalent to the original drug.

Merging of the categories of similar drugs and generic drugs offers several advantages. Drug regulatory agencies must check the efficacy of medicines supplied to ensure they are safe. For multisource drugs, currently there is no agreement on the tests that each pharmaceutical product should undergo for it to have met acceptable efficacy and safety standards.

For some products it is sufficient to document that the new product is pharmaceutically equivalent to the original drug; in other cases therapeutic equivalence needs to be proven. Clinical trials, in vitro or through pharmacodynamics studies can be used to prove therapeutic equivalence; however this has several implications in terms of costs, technical capacity and time.

Also drug companies opt for lengthy testing if they want to restrain competition while other drug companies who want to expedite availability of cheaper versions of drugs which is sufficient to guarantee efficacy and safety of drugs opt for limited testing. There is also confusion on classification of pharmaceutical products commonly used in Latin America as there is a lack of consensus on classifying these products, across pharmaceutical industry experts.

In addition, pharmaceutical industry experts had different interpretations of the word bioequivalence. As of now LATAM countries are trying to reach agreement on the type of tests to be carried out ahead of approval of commercialization of multisource drugs.

Curious Case of Brazil: Difficulties Encountered in Making These Types of Determinations

In September 1999: Resolution number 391 was passed which stated, "Bioequivalence must be proved for a product to be registered as generic."

Modification of Requirement for Proving Bioequivalence

In February 2002: Resolution 10, which mandated creation of a guide to substitute bioequivalence testing with other tests to demonstrate the interchangeability of the new product with reference drug. Resolution 10 included a list of medicines that for safety reasons could not be registered as generic drugs. (Uruguay has a similar list and Colombia is considering adopting one.)

In March 2002: Resolution 84 "modified the list of products identified in resolution 10." Other issues under discussion in Brazil include the determination of the minimum number of volunteers needed to demonstrate bioavailability and bioequivalence in clinical trials."

Furthermore, as there is a lack of consensus on the term "generic", carrying out comparative cross national studies of generic policies looks impossible.

Drug Registration

Regulatory regime in LATAM countries can be divided into three categories

Established Regulations	Less Stringent Regulations	Imperfectly formed Drug Regulations
Brazil, Mexico and Venezuela	Argentina, Chile, Columbia, Ecuador and Paraguay	Guatemala, Barbados, Bolivia, Nicaragua and Peru
To demonstrate efficacy, safety through clinical trials or Bioequivalence studies with the innovator's product in the drug approval process.	Have regulations for registration of new or generic drug but are less stringent.	These countries have imperfectly formed drug regulations for approval of drugs.

Time Frame for Product Registration

Country	Registration Time
Peru	Only 7 days. If the regulatory agency fails to prove that a particular product may be harmful during this period of time, the product is automatically registered.
Brazil and Chile	Between 8 and 14 months.
Rest of the countries	Less than 6 months to register a product.

Country	Cost of Registering a Product
Bolivia (for 5 years)	$50
Brazil	$27,000
Ecuador	National companies will be charged $535 and for essential drugs $344. Foreign companies will be charged $1,339.
Nicaragua	Charges local producers $485 for a foreign product and $166 for a nationally produced drug.
Argentina, Brazil and Chile	Charges significantly lower fees for registration of generics and similars than for registration of a new product.
Chile and Colombia	Charge a different fee for registration and re-validation.

Conclusion

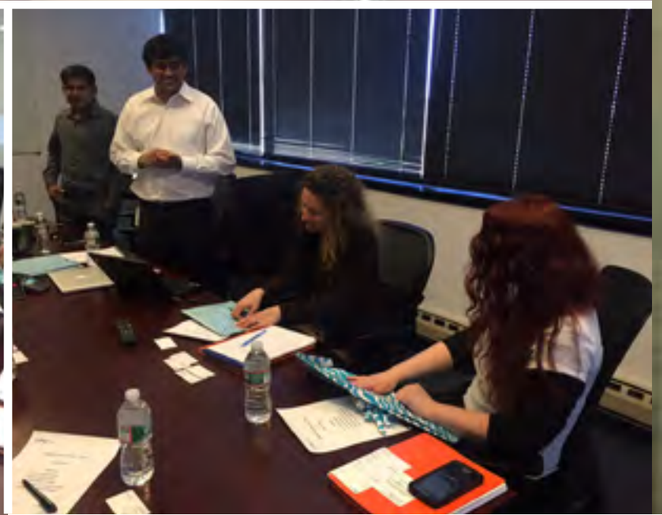
There are major differences between countries in the LATAM region as there is no centralized or harmonized procedure for drug registration. The LATAM market will continue to be the focus along with other emerging markets as quality requirements and cost of compliance continue to increase globally.

Manufacturers continue to seek ways to decrease costs and capitalize as it may lead to partnership opportunities as governments try to increase their local capabilities to decrease healthcare expenditures.

The LATAM market is expected to see regional investment and signing of new deals for biologics, high potency, and cytotoxic medications. Foreign market and established players can benefit from developing their manufacturing and expertise in this growing region.

CLIENT VISIT

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



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

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 REGULATORY INTELLIGENCE SERVICES FOR $40+BN, PHARMACEUTICAL COMPANY

- Provide strategic regulatory intelligence services for a Europe based, global $40+ Bn, pharmaceutical company
- Offer strategic support on global readability guideline for client's product portfolio along with strategy implementation

LABELING MANAGEMENT SERVICES FOR $2+BN, BIOTECHNOLOGY COMPANY

- Awarded regulatory labeling management services support contract by a US based, global $2+ Bn, biotechnology company
- In-scope activities include development and management of client's Company Core Data Sheet (CCDS) using Freyr Label, a proprietary CCDS tracking & distribution tool

STRATEGIC REGULATORY SERVICES FOR EUROPE BASED HEALTHCARE COMPANY

- Provide end-to-end regulatory services for a Europe based, fast growing healthcare company
- Regulatory services that include end-to-end product registrations (medical devices, medicinal products and food supplements) in Middle East followed by all GCC countries.
- Undertake QPPV support for medicinal product, variations submissions for medicinal products in Middle East and offshore support for regulatory activities in EU

STRATEGIC LABELING SERVICES FOR $20+ BN, BIO-PHARMA COMPANY

- Provide strategic labeling services for a US based, global $20+ Bn, bio-pharmaceutical company
- Develop and manage client's labeling management services including (LPD's, SPL)
- Leverage strong industry knowledge and expertise supporting further enhancement of global competitiveness and reduce operating cost for the multi-year project

eCTD SERVICES FOR $15+BN GLOBAL PHARMA COMPANY

- Provide eCTD submissions and publishing services for Europe based, global $15+ Bn, pharmaceutical company
- Undertaking multiple projects pertaining to NeeS and eCTD submissions services for Middle East

Kodak and Freyr Announce Technology & Implementation

PARTNERSHIP

Kodak/Design2Launch recently announced an on-going partnership with Freyr, as the technology tool provider and implementation partner of choice.

The shared vision for this partnership is to create an innovative solution offering by integrating Kodak's Workflow Automation tools with Freyr's specialized global Regulatory Artwork Change Management and Label Design Lifecycle Management services.

The partnership teams the industry-leading strengths of each company to address the key challenges and provide an integrated solution that will create enhanced Artwork Change and Label Design efficiencies for Pharma and Life Sciences companies.

Jonathan Winkel, National Business Manager for Kodak/ Design2Launch, was quoted as saying, *"We are extremely excited about the partnership opportunities that are made possible by working with Freyr. We see the combination of workflow automation tools with regulatory artwork and label services as a trend that is quickly becoming a best practice, particularly in the pharmaceutical industry. By unifying Freyr's world-class regulatory services with Kodak's "Brand Manager" platform we will have created the most agile and value added solution available in the Regulatory Artwork Services space."*

Commenting on the partnership, Sudheer Goparaju, VP Global Operations for Freyr, said, *"At Freyr, we believe in partnering with the best and pioneering regulatory solutions that create a high-value transformational effect for our clients and partners. We are very excited about our partnership with Kodak and the opportunities it will open up as a best-in-class unified solution for companies to seamlessly transition and unlock superior operational, process, and cost efficiencies across Artwork Change and Label Management lifecycles."*

EMPLOYEE APPRECIATION

Ranvijay Singh, Praveen T, Sathish Kanukutla, Varsha Salla & Chandrakala Madireddy

Marketing Team

"Would like to call out Marketing teams efforts in generating some highly qualified leads in the past few months - both in terms of quantity and quality of leads. Many of them have been converted to clients and many on the verge of being converted to Freyr clients. The outreach activities for the eCTD Webinar was a big success in building the Freyr Brand with 100+ participants for the Webinar conducted on Publishing... Keep it up!"

Rajiv Rangan
Co-CEO

Kranthi Kumar M

Sr. Associate

Software Services

"Kranthi played a major role in delivering a project which was very difficult to deliver in the set timelines from the client. His effort is commendable and appreciated. Glad to be working with you Kranthi!"

Prasanna N G
VP
Software Services

Yogi Raj, Sasi Bhushan K, Jagdish Kotikalapudi, Hemanth Reddy, Ravi Kankanala & Vivek Pokhare

Sales Team

"A shout-out to the Client Partners and BDEs for the excellent work in winning many new clients in the past few months - Both large clients & small-medium clients with potential to grow. Pipeline also looks very exciting. Keep up the great work! A key contributor to this momentum is the tremendous support and efforts from Client Services, Delivery / SMEs/ Functional heads and support departments (HR, IT/Ops, QA/ Compliance). First half of this calendar year has been truly transformational for Freyr and the second half of the year looks even better!"

Rajiv Rangan
Co-CEO

Sneha Gunjal

Trainee

RIS

"Sneha is hard working and focused and needs minimal supervision in delivering projects/tasks on time and with quality. A proactive team member, she is always willing to take up new assignments. She is a quick learner and has handled complex documents with ease."

Sathya K
VP
Regulatory Operations

NarenKumar Racha

Trainee

RIS

"Naren shows lot of enthusiasm to work on new assignments. He is very friendly and a good team player. He has so far delivered all the projects assigned to him with good quality. He has very good analytical skills and secondary research skills."

Sathya K
VP
Regulatory Operations

Anil Devunoori

Inside Sales Executive

Marketing

"Anil is a dedicated resource in the marketing team. His effort in generating qualified and prospective leads from various networks is much appreciated."

Praveen Kumar T
Asst. Manager
Marketing

Chaitanya, Sudarshan, Lavanya, Vittal, Priyanka

Software Services Team

"I would like to congratulate this young and vibrant team who worked rigorously in delivering the project in which we could achieve 92% customer satisfaction! Keep up the good work team."

Ramasrinu A
AVP
Software Services

Chandrakala Madireddy

Inside sales Executive

Marketing

"Chandrakala is a hardworking resource with good analytical and searching skills. She does her best in generating qualified leads, executing and completing Ad hoc projects on time"

Praveen Kumar T
Asst. Manager
Marketing

Varsha Salla

Senior Content Specialist

Marketing

"Would like to appreciate Varsha for her contributions in planning, leading, managing, and executing great content and special themes month after month across Freyr's internal communication channels including the newsletter, blogs, and social content. Her steadfast strive for enhancing and raising the bar for high quality Regulatory content is creating significant value across a mix of ATL & BTL outreach programs. Please keep up the excellent work!"

Ranvijay Singh
VP
Marketing

Pavan Kumar

Graphic Designer

Marketing

"Would like to call out Pavan's contribution towards enhancing the design standards of the Flagship Newsletter and Freyr branded digital assets. His passion to explore and adapt newer, contemporary style of visual design and content layout approach is a value addition to the digital outreach program."

Ranvijay Singh
VP
Marketing

Neelima Uniyal

Trainee

Regulatory Affairs

"I just wanted to let you know the things you do for the company do not go unnoticed. You're a necessary piece to this company. I appreciate your dedication and service, and I know others do too."

Phani Kumar Chintala
Manager
Regulatory Affairs

STAR ACHIEVERS OF THE QUARTER

Praveen T

Asst. Manager
Marketing

Innovation and Proactive Leadership

Outstanding organization skills are necessary to keep on top of both long-term goals and daily needs. Effective leaders stay organized and Praveen is one such leader.

Building Relationships/ Partnerships and Creating Measurable Impact

Understands the power of relationships, connection, and engages with the people in the organization openly to build mutually supportive relationships.

Attitude and Commitment

Has had a positive impact on the attitudes and performance of his fellow employees through his can-do approach to work. Praveen puts in astounding hours on marketing projects to help make them a major success.

Interpersonal Skills

Praveen possesses effective business communication and excellent interpersonal skills.

Work Performance

Praveen worked towards building Freyr's online presence and brand awareness through use of social media networks, blogs and search engine optimization. Monitored emerging social media tools to see how they can be incorporated into Freyr's business, marketing and public relation strategies.

Personal Traits

Assertive, positive and cheerful.

Kiranmai Khandavalli

Trainee - Regulatory Affairs
Regulatory Intelligence Services

Innovation and Proactive Leadership

Innovative in her approach for doing tasks which bring effective results.

Building Relationships/ Partnerships and Creating Measurable Impact

Prioritization of tasks plays a key role in creating measurable impact. Identified performance targets to support and drive the outcome measurement process.

Attitude and Commitment

Kiranmai is very competitive, who takes challenges at work head on with passion and enthusiasm.

Interpersonal Skills

A confident team player with a strong commitment to team environment.

Work Performance

She is a quick learner and completes all her assigned tasks efficiently on time while giving the best quality of work. She has met and continues to meet all the deadlines.

Personal Traits

A keen, independent, capable team member who is adaptable and confident at work.

Madhusudhan Vudugula

UI Associate
Software Services

Innovation and Proactive Leadership

Madhu has been very proactive in designing responsive User Interfaces with the latest technology which is helping the development team to reduce the UI bottlenecks and speedup the development activities.

Building Relationships/ Partnerships and Creating Measurable Impact

Madhu has been working on building better and flexible user interfaces due to which the experience the clients have and the feedback we get are really encouraging.

Attitude and Commitment

Working on some of the very complex screens and short deadlines, Madhu has proven his mettle. His sagacious attitude to the changing requirements has been commendable.

Interpersonal Skills

A confident team player with a strong commitment to team environment.

Work Performance

Madhu has been delivering all the assigned tasks as per expectations. As we all know that technology changes really fast, adapting to the new technologies and still delivering to the expectation has been the benchmark of Madhu.

Personal Traits

Cool person to work with. Enjoys every bit of life.

Madhu Sudhan K

Senior Associate
Regulatory Affairs-DP

Innovation and Proactive Leadership

Initiates and develops new ideas and strategies for the work, encourages the team to participate in problem solving and utilizes the skills of each team member and enhances productivity.

Building Relationships/ Partnerships and Creating Measurable Impact

Supports and leads team members, promotes a feeling of harmony and fairness towards the successful delivery of work.

Attitude and Commitment

He is a hard worker and very sincere.

Interpersonal Skills

Acknowledges the needs and concerns of others, promotes a positive working environment, has loyal and committed workers, manages different personalities, is tactful and sincere.

Work Performance

Meets deadlines on assigned projects within stipulated timelines.

Personal Traits

Handled multiple projects in many situations with ease, dedicated to work, comfortable with change, handles stress well, avoids confrontations and stays calm under high-pressure situations.

Pratik Japee

VP
Client Services

Innovation and Proactive Leadership

Pratik has consistently demonstrated excellent team management skills and operational/business management capabilities in order to drive successful engagements.

Building Relationships/ Partnerships and Creating Measurable Impact

Manages cross-border communication at all levels effortlessly.

Attitude and Commitment

Implements and manages best practices for people, process and performance management to ensure continual improvement and better the existing level of achievement of critical metrics.

Interpersonal Skills

Entrepreneurial spirit/mindset, flexibility toward dynamic changes.

Work Performance

Pratik has played a key role in project and delivery management. He has been effectively leading a team of ten to consistently meet the high quality of deliverables within the timelines and as per the project requirements. Since the beginning of the project, he has been instrumental in establishing and streamlining the process to create a culture of delivery excellence.

Personal Traits

Values learning by creating a climate of effective feedback, coaching, mentoring and personal development.

Rajee Priyanka Alluri

Trainee - Regulatory Affairs
Regulatory Affairs DP

Innovation and Proactive Leadership

Always comes with new ideas, copes well with unpredictability and stress for timely completion of projects.

Building Relationships/ Partnerships and Creating Measurable Impact

Works hard and is open to new ways of doing work.

Attitude and Commitment

Displays confidence with positive attitude towards the assigned goals and has been extremely productive.

Interpersonal Skills

Maintains good relations within team and creates work friendly environment.

Work Performance

Consistent in delivering work with high impact and is always enthusiastic about learning new topics.

Personal Traits

Enthusiastic, confident and goal focused.

Asha Reddy

Associate
Regulatory Operations

Innovation and Proactive

She has been proactively working with the client's manager and addressing issues independently. Takes initiative to ask, learn and seek information, rather than use the wait and see approach.

Building Relationships/ Partnerships and Creating Measurable Impact

Possesses excellent communication skills and has a professional approach in handling work. She has been appreciated by the customer several times, for her commitment.

Attitude and Commitment

She is always eager to learn new things and demonstrated flexibility to switch between projects and learning new things at work.

Interpersonal Skills

Asha is a good listener and gives lot of attention to the details, possesses excellent communication skills.

Work Performance

Asha is an impeccable resource, illustrating not only her professional demeanor, but in-depth skills, dedication, attention to details, willingness to switch gears and deliver timely results. Asha's exemplary performance is recognized and acknowledged.

Personal Traits

Asha is a very down-to-earth friendly person, a good leader as well as a good follower.

Sathish Kanukutla

Senior- Inside Sales Executive
Marketing

Innovation and Proactive Leadership

A proactive teammate who takes responsibility and is engaging and co-operative with team members.

Building Relationships/ Partnerships and Creating Measurable Impact

Has pushed beyond his introversion and has learned to relate well with others and build good relationships.

Attitude and Commitment

Embraces critique, actively seeks opportunities to take on the most demanding and difficult tasks. Focuses on what can be done, rather than on what can't be done.

Interpersonal Skills

Acknowledges the needs and concerns of others, promotes a positive working environment, has loyal and committed workers, manages different personalities, is tactful and sincere.

Work Performance

Sathish has been spearheading the work with regards to campaign management and LinkedIn leads.

Personal Traits

Sathish is a very calm and friendly person.

Ranvijay Singh

VP
Marketing

Innovation and Proactive Leadership

Ranvijay is a proactive leader who is able to see the big picture. Freyr's unique marketing approach is one of the key business growth drivers and Ran Vijay ensures that the marketing vision is executed with smooth planning and innovative approaches.

Building Relationships/Partnerships and Creating Measurable Impact

Understands how to manage risk and make decisions that are backed by research, multiple insights that are well thought out. Ran Vijay and his team has ensured that there is always a constant pipeline of highly qualified business leads for the Sales teams to chase.

Attitude and Commitment

Marketing is both an Art & Science – making it challenging to deliver consistent results (constant refinement of content, channel, context) – Ran Vijay has been able to handle this key challenge effectively, balancing and ensuring cross-platform outreach – thereby having a constant flow of leads.

Interpersonal Skills

Fosters open and honest communication to achieve better understanding of expectations thereby promoting spirit of teamwork and co-operation.

Work Performance

Ranvijay has implemented an effective lead scoring and prospect qualification program along with development and deployment of best in class SEM, Social, SEO to gain strategic leverage for improved search engine visibility. Developed and managed execution of marketing programs targeting new clients, such as online marketing, direct marketing, database development, newsletters, webinars, conference calls, sales support programs, automated nurturing programs, regionalized demand creation programs.

Personal Traits

Calm demeanor, strong communication skills and a proactive decision maker willing to take risks.

NEW EMPLOYEES

Abdul Azeemuddin
Sr.Associate - Finance

Chandana Purnima Ravula
Associate - Regulatory Affairs

Ganesh Kopusetti
Inside Sales Executive

Ravi Kumar Reddy Kankanala
Manager - Business Development

Kiran Venkata Satya Chinnalla
Manager - Regulatory Operations

Pradeep Deochand Chanekar
Sr.Associate - Regulatory Operations

Satish Sikakolu
Sr. Associate - Regulatory Affairs

Shelly Garg
Manager - Regulatory Operations

Sridhar Venkata Sarva
Sr. Manager - Compliance and Validation

Venkata Narasimha Raju
Business Development Executive

Vijaysree Podila
Trainee - Regulatory Affairs - CMC

Vinayak Mishra
Manager - Regulatory Operations

Vivek Pokhare
Associate VP - Sales

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