freyr CONNECT

INSPIRING INNOVATIVE THOUGHTS

Vol 2 Issue 3

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From the Editor's Desk

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Hello all and welcome to the Q2, 2014 edition of the newsletter!

Much has happened since the last newsletter went out in April 2014, so we hope you will find this an useful overview on how far we've come and where we are headed. Freyr Connect's July 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-"Social media: New voice of an enterprise employee" which is a cogent call to transform the employee and work place paradigm into a progressive one. The general and industry articles cover new subjects which are sophisticated and pragmatic frameworks rooted in social and conjectural imperatives. Be sure to check the issue for a 360° 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



Management Speaks

As most of you are aware, the last quarter has been both a hectic and an exciting period for Freyr on multiple fronts. Our new wins, new accounts, new facility expansion and newer talent coming on board have kept the momentum going on.

And while we feel a sense of pride and accomplishment, we always have an important question facing us, "What is important now?"



Srini Sadhu











Well, let's park that question aside for some time & talk about something different. Let's talk about 'Focus'.

A simple, straight answer but with a depth that many people miss.

Recently, for the question

"What's the single most important factor for your success in life?"

Bill Gates answered in one word

"Focus"

Interestingly, most people think there is only one kind of focus. Focus, as in having an objective aligned with a goal to be achieved. Focus as a static thing. Focus as a noun.

Freyr was incorporated with a focus of creating a best-in-class global regulatory services and solutions company unrivaled in our span of expertise, in our service delivery, in our domain knowledge and in our top industry talent. Freyr chose to excel and built a comprehensive services portfolio that spans the entire regulatory value chain.

"As partners to 2 of the Global Top 5 Fortune companies, we are rapidly gaining reputation as the industry's best."

We have come a long way and each one of you stands as a testimony to the distinction our exclusive, clear and compelling focus grants us.

And that's just the first kind of focus. The second kind of Focus is not just something you have but something you have to do as an action. Focus as a dynamic and iterative process. Focus as a verb.

Taking that as a guiding light, Freyr has constantly kept a sharp eye on evolving market dynamics, emerging opportunities and unique industry demands to anticipate, pioneer, innovate and adopt at the speed of change.

From pioneering Large Centralized Regulatory Function outsourcing and De-risk Regulatory CoEs to innovating Multi-channel Regulatory Intelligence solution, end-to-end Consumer Healthcare outsourcing and a full Regulatory Cloud Suite, Freyr has been constantly redefining itself by producing clarity through a perpetual process of re-focus. And that is what truly makes us stand apart.

Now let's focus on the question, "What is important now?"

The answer lies in the ability to combine both kinds of focus into one powerful faculty - one that will allow pursuing the long term vision and also enable spotting the right market drivers to leverage success.

Social Media:

New Voice of an Enterprise Employee!



The Rise of Enterprise Social Networks

Enterprise Social Networks drive strategic business objectives. They help to improve management processes in different departments. Their benefits are translated into business KPIs that affect processes, sales, customer management, human resources,

knowledge management, and even improve productivity across the board in all members of the company. More enterprises are deploying internal social networks to encourage collaboration and improve productivity.

Employee Time Drain

Did You Know?





03.7 hours/week

Searching but not finding the information.

07.7 hours/week

Communicating & collaborating internally & externally.

02.5 hours/week

Recreating content that cant be found.

Expense of \$31,275 per employee/year

"Many employers believe the ability to communicate effectively is an essential job skill, even going so far as listing it in their job requirements. But what about providing them with the platform to communicate within the organization?"



Spent By Employees For

26.1 hours/week

Role specific tasks

07.7 hours/week

Communicationg & collaborating

06.2 hours/week

Searching for information & recreating content

"According to a study done by an enterprise collaboration software company,

74%

79%

UK employees said that Enterprise Social Networking would improve job performance

Businesses do not provide social tools for employees.

Social Media 2014 Statistics

How fast is Social Media expanding in 2014?

Do you know how many active users Facebook

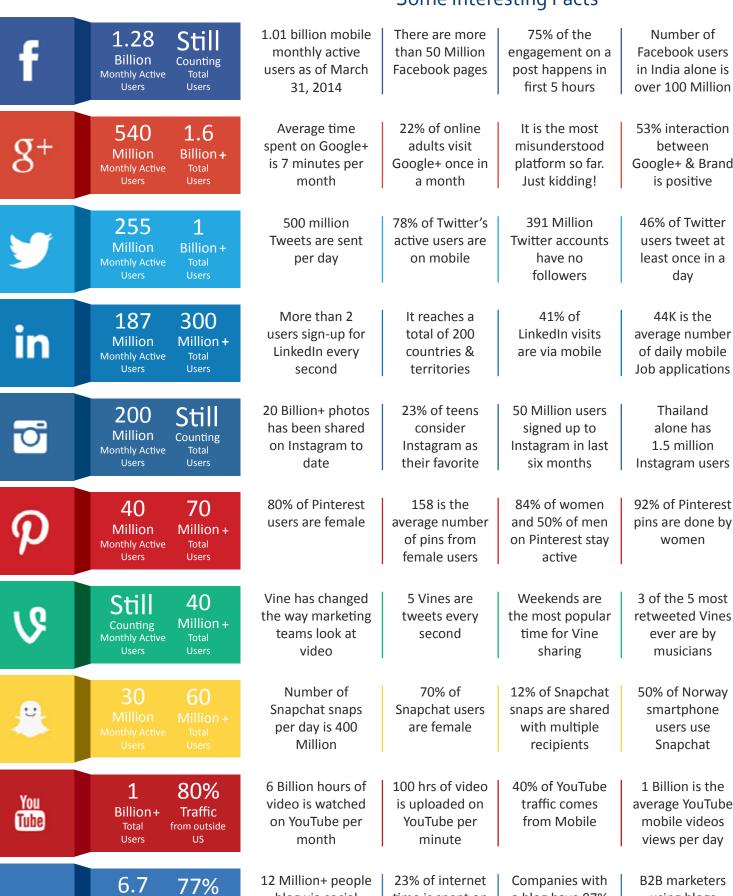
How many users have never tweeted after opening their account on Twitter?

Do you know how many hours of videos are uploaded in youtube per

Do these numbers matter to you?

How fast Googlet is evolving?

Some Interesting Facts



Blogs

Million + of Internet blogging sites blogs

blog via social networks

time is spent on blogs and social networks

a blog have 97% more inbound links than others

using blogs generate 67% more leads



Social Media Trends for 2014



KonnectCo, an enterprise level networking and employee engagement application which enhances overall productivity and operational efficiency across geographies.

Photo Courtesy: KonnectCo



A mobile app owned by Twitter that enables its users to create and post short looping video clips having a length of six seconds.

Photo Courtesy: Dan Leveille, Wikipedia

Emerging Technology

Inventions like Google Glass, Oculus Rift, the Samsung Smart Watch, and the Nod Bluetooth Ring offers us new ways to view social media.

Location, Location



Location services an important feature among many social networking apps eg; Foursquare, Facebook, **Swarmly** etc are some of the location sharing apps.

Social Searches

Facebook and Google + have increased the importance placed on social search.

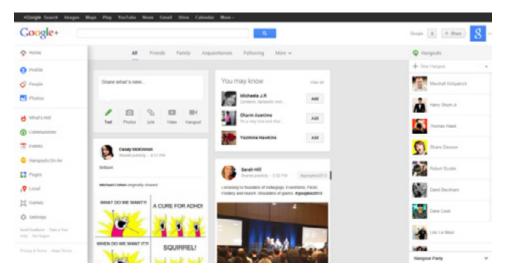


Photo Courtesy: Ariesk47; Wikipedia.

#Hashtags

With integration across Twitter, Instagram, Vine, Google Plus, and now Facebook, hashtags have become the way to express and search for content.

Lifestyle Content

Posts on social media by brands have become less about selling product and more about selling what brands stand for. Selling a lifestyle instead of individual products makes creating creative content easier.

Influencers and **Collaborations**

Collaborations with other brands and pages is the current trend which has led to many success stories for most brands on social media. Many high-end brands are branching off lifestyle content ideas and gaining celebrity endorsement.

Content Courtesy: didit.com

Native Advertising



Almost all of the social media platforms have now integrated native advertising in one form or another. Now ads come up in users' feeds, making click-through a more organic experience. Popular sites like Buzzfeed and Tumblr have integrated ads into their pages.

Photo Courtesy: BuzzFeed

Better Mobile Design

As of February 2013, 37% of time spent online was on mobile devices, brands and platforms are now trying to create cleaner website designs that translate to mobile.

> Varsha Salla Senior Content Specialist Marketing



Global Regulatory Solutions and Services

Client Appreciation

It was a tremendous accomplishment as the first pilot site has been completed and set up at the client's facility. The app and portal performed well and the team received positive feedback from all quarters.

I want to thank Freyr for putting in the extra effort to get us off to a good start and get us closer to securing the larger project that could result from a successful pilot.

Best Regards, Chief Technology Officer US-Based SMB



New Clients / Programs

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

Strategic Regulatory Submission Project for Top 20 Pharmaceutical Company

Freyr has been selected for a large regulatory submission project by a Global Top 20 Pharmaceutical company. The project will entail end-to-end services for regulatory submissions life cycle management.

Submissions Publishing Services for Top 5 Global Pharmaceutical Company

Freyrhas been engaged as a regulatory service provider of choice for a Top 5 multi-national pharmaceutical company for two consecutive regulatory service undertakings. Nine publishing associates will be deployed on-site at the client location to provide submissions publishing services including global submissions activity to FDA, EMA, LATAM and ROW in various formats (eCTD, NeeS, paper) and regulatory services for global eCTD submissions.

Artwork and Labeling Project for Top Global Manufacturer of Alternative Medical Products

Freyr has been awarded a global artwork and labeling project by a Top Global manufacturer of natural homeopathic remedies. This offshore project will see Freyr's artwork and labeling CoE function involved in creation of artwork and labels for the client's portfolio of products which will be marketed in multiple geographies.

Client Visit

Freyr management team and client partners at client headquarters



In the month of July'14, we were honored by the visit of a high profile Regulatory Affairs and Operations delegation from a Top-20, Global Pharma/Nutraceuticals Company at our office in Cranbury, NJ, USA. The visit was arranged to inaugurate the newly established near-shore Regulatory Operations Center within Freyr's office premises. The delegation team comprised of directors, managers and other staff from the customer's Regulatory Affairs and Operations vertical.

The brand new operations center inaugurated by the director, boasts of state-of-the-art facilities like dedicated and secured network connectivity set up exclusively for customer projects, VOIP connectivity, video conferencing room for meetings, secured floor access for project members etc. The delegation was also shown our current data center hosted within the same infrastructure.

Freyr's core group of program managers, delivery managers, subject matter experts and project teams along with the delegation participated in a video conference with the offshore delivery team. The director thanked and recognized Freyr's contribution towards the successful completion of a critical MDD NDA submission.

The project is significant as it is one of the largest submissions undertaken by the company, aided by Freyr. The delegation also recognized individual performers who contributed to the project's success. The director also talked about the future opportunities and valued the partnership with Freyr, thus ensuring continued support from Freyr for their Regulatory needs.

The successful visit was followed by a team lunch where the group enjoyed the time together over wine and sumptuous cuisines.



ISO 9001 & ISO 27001

Surveillance Audit

The surveillance audits of ISO 9001 (QMS) and ISO 27001 (ISMS) certifications performed by TÜV Rheinland at Freyr's facility in Lanco Hills, Hyderabad on 27-28 March 2014 ended on a pleasant note, with the recommendation for continuation of ISO certifications.

"Freyr has established and maintains an effective system to ensure compliance with its ISO/ IEC 27001:2005 policy and objectives. The audit team confirms in line with the audit targets that the organization's management system complies with, adequately maintains and implements the requirements of the standard(s)."

Audit Team
TUV Rheinland





ISO/IEC 27001:2005

"I congratulate the entire team who made this ISO/IEC 2007:2005 FU1 Surveillance audit successful with ZERO NCs...this shows strong commitment of Freyr to compliance and standards and equally demonstrates the commitment from each individual as well"

Sunitha A

Managing Director

"Security is everybody's responsibility was demonstrated by every Freyrian which resulted in the successful completion of ISO/IEC 27001:2005 FU1 Surveillance audit conducted on 27th and 28th March 2014 with ZERO NCs. I wish to congratulate everybody and of course the PMG group for the same."

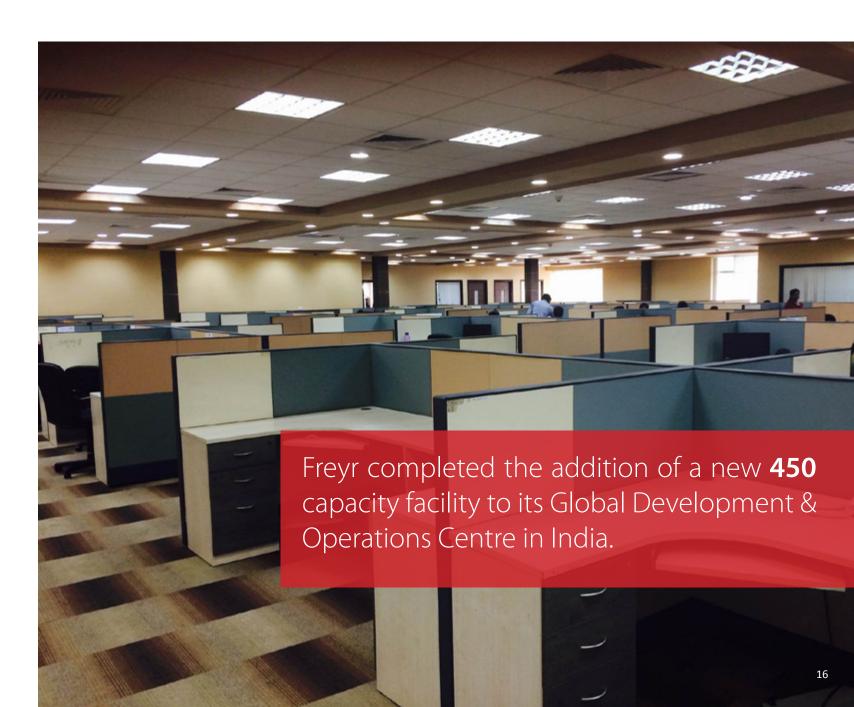
Sudheer Goparaju VP Global Operations

Facility Expansion

As part of the global expansion plan, the new facility will complement Freyr's strategic Business Acceleration Program that has recently won the company several global accounts with Top Pharma & Life Sciences companies.

Freyr is entering a new growth phase by expanding its operations base and augmenting its vision to be a global leader in the Regulatory Solutions and Services domain.

The new facility is slated to enhance and increase Freyr's delivery capabilities in key areas aligned to the future growth plans.





Give Your Company the Advantage of a Best-in-Class Regulatory Intelligence Solution

Freyr's Reg Insight is a comprehensive Regulatory Intelligence solution enabling companies and regulatory professionals to quickly and effectively meet their critical information requirements while saving on time. Freyr Reg Insight is designed to help you quickly track, analyze and present granular insights and real-time intelligence by providing instant access to an entire range of authoritative Regulatory information for informed decision making and to create superior submissions and market strategies.



Fig: Login screen

Fig: Inputs	Selected Inputs
	+ Product Category(s)
	+ Insight Category(s)
	+ Market(s)
	+ Companies Impacted(s)
	+ Active Ingredient(s)
	+ Excipient(s)
	+ Product(s)

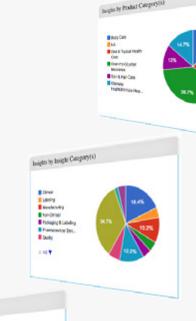
Freyr Reg Insight covers the full-spectrum of Regulatory Intelligence categories

Product Info:

Drugs, Devices, Biologicals, Veterinary / Consumer / OTC Products, Nutraceuticals.

Regulation Info:

New Guidelines & Amendment, Pharmaceutical Development, Clinical / Non Clinical, Stability & Storage, Validation, Packaging & Labeling, Pharmaceutical excipients, Impurities, Recall Alert, Safety & Pharmacovigilance, Warnings, Submission Formats, and much more.



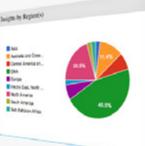


Fig. Charts



Fig. Insights Reports

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Star Achievers of the Quarter



SQA

"I want to see Freyr as a CMMI Level –III Company by the end of 2014."

What was your reaction to being named as the "Star Achiever of the Quarter"?
I was very happy when I received this news.

What has been your greatest challenge at Freyr?

I would say quality implementation at all levels.

What do you like most about your job? My job is all about to guide and facilitate all the teams about the implementation of Quality Management System. I like involvement of all the teams into Quality implementation.

What is the one thing people would be surprised to know about you? Qu"ALI"ty.

Your hobbies and/or interests. Listening to music and playing cricket.

Favorite sports or pastimes. Cricket.



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

I was very elated when I received this news update.

What has been your greatest challenge at Freyr?

Great challenges can be great achievements. I would consider all my projects as achievements instead of challenges. In addition, validation was a new aspect, however I took it as an additional task learned the nuances and finally implemented it.

What do you like most about your job? I would say learning about new things.

What is the one thing people would be surprised to know about you? Nothing.

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

I would not change a single thing, I appreciate the gifts I have received and thank the maker for giving me enough strength to carry on nevertheless whatever may be the obstacle.

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

I'm definitely not telling this piece of information, it better be a surprise for now.

Your hobbies and/or interests.

Spending time with family and friends.

Favorite sports or pastimes.

Cricket and Badminton.



Senior Manager – Regulatory Operations Life Sciences

"I would like to see Freyr as one of the listed companies on "NYSE" in the near future."

What was your reaction to being named as the "Star Achiever of the Quarter"? I was pleasantly surprised with a big smile on my face.

What has been your greatest challenge at Freyr?

Establishing an efficient team which churns out high quality deliverables thus demonstrating Freyr's expertise in the regulatory space.

What do you like most about your job? Choosing the right set of people and provide them with relevant training. This in turn helps me motivate them in their career progression and take care of their long term aspirations and goals. By doing this, I am able to contribute towards associate delight.

What is the one thing people would be surprised to know about you? I love trance, house and electronic music.

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

Create a platform where I could generate lots of opportunities for talented individuals.

Your hobbies and/or interests. Hobbies: exploring places and trying new cuisines. Interest: Keeping up with new regulations and advancements in the regulatory space.

Favorite sports or pastimes. Sports: Badminton, pastimes: spending time with my family and teaching my son new things.



What was your reaction to being named as the "Star Achiever of the Quarter"? Excited and honored.

What has been your greatest challenge at Freyr?

To know every person at Freyr!

What do you like most about your job? Freedom to experiment.

What is the one thing people would be surprised to know about you? I can be serious.

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

Buy a different house.

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

Connecting with people, travelling and driving.

Your hobbies and/or interests.

Playing cricket, hanging out with my old friends.

Favorite sports or pastimes.

Cricket and badminton.



"I would like to add few points on motivation - work force motivation can directly impact the productivity of an organization. Lack of motivation will mean that the job may not be done that effectively. As a manager, I believe in motivating each and every team member which will in turn help them to give their best in their respective job sphere."

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

My sincere thanks to the management for having chosen me as the Star Achiever of the Quarter. Freyr is an amazing place to work for all employees. Freyr believes in strengthening each and every individual with respect to their ability, roles and responsibilities.

What has been your greatest challenge at Freyr?

The initial phase had been slightly challenging in order to understand the people and work culture. However, I am really thankful to my manager Vikas Bhardwaj for making me comfortable on this journey.

What do you like most about your job?

I believe in "taking responsibility of my actions" as it gives me a sense of accountability.

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

Although by profession, I am Pharmacist you will be surprised to know that I am a certified software programmer having completed software programing courses -C, C++, Java, Perl and Oracle platform conducted by DOEACC.

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

I would give everything to do it all over again with more zeal & enthusiasm.

Your hobbies and/or interests.

Reading newspaper and swimming.

Favorite sports or pastimes.

Cricket and playing chess.



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

It was a wow moment for me. I was very excited but nonetheless I'm happy to see my efforts paying off.

What has been your greatest challenge at Freyr?

To be frank every task is a challenge for me. Regardless of the requirement, big or small, I pay utmost diligence to make the assigned task successful.

What do you like most about your job?

As a part of the HR department, the best thing I like about my job is that I get to interact with people. Above everything, I love the freedom and coordination that I have from my manager, who I respect a lot.

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

I still don't have a twitter account...lol.

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

If I could do it all over again, I would still pick my career in Human Resources and avoid the errors that have occurred.

Your hobbies and/or interests.

Shopping, movies, yoga, hanging out with my friends.

Favorite sports or pastimes.

Although I'm not very sporty, I sometimes watch cricket.



What was your reaction to being named as the "Star Achiever of the Quarter"? A definite surprise! But very much humbled by the recognition. Indeed motivated.

What has been your greatest challenge at Freyr?

People management is one area where I faced a stiff challenge Also I am glad that we at Freyr have taken good measures to set up processes for proper functioning of various projects.

What do you like most about your job? The opportunity its presents in terms visibility into entire regulatory land scape not to forget my boss and team who are always supportive and collaborative at work.

What is the one thing people would be surprised to know about you? I'd be surprised if they are surprised hearing about me.

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

I would want to improve my utility by not micromanaging a few projects which took extra time and additional effort that could have been well managed instead.

Your hobbies and/or interests.
I like to read books on Philosophy and
Autobiographies. I extensively use internet for news
and entertainment.

Favorite sports or pastimes. Cricket & tennis.



"Life is strength and weakness is death."

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

I should admit I was a bit stunned when I heard about my nomination. I want to express my gratitude to my manager and I am sincerely grateful for the recognition.

What has been your greatest challenge at Freyr?

As I am in the R&D team, I take up every task as a challenge.

What do you like most about your job?

Good response from client and the managers in all the aspects.

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

I am married.

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

Success has a lot to do with hard work, time and effort, but sometimes luck plays a part in it too. If given a chance, I would tweak few aspects and not do the same mistakes again.

Your hobbies and/or interests.

Reading books, enthusiastic to learn new things and I like to collect excerpts by Swami Vivekananda- a Hindu monk.

Favorite sports or pastimes. Kabaddi.



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

I was elated on learning the news and I would like to thank my manager for the recognition.

What has been your greatest challenge at Freyr?

My greatest challenge would be the time; I was assigned to work on the Regulatory Intelligence System (RIS), project which helped me in gaining a strong foothold.

What do you like most about your job?

The intense brain storming sessions and hard work while developing an application.

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

I was an intentional learner, who concentrated on self improvement and encouraged it in others.

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

I would not change a single thing; I would like the same life.

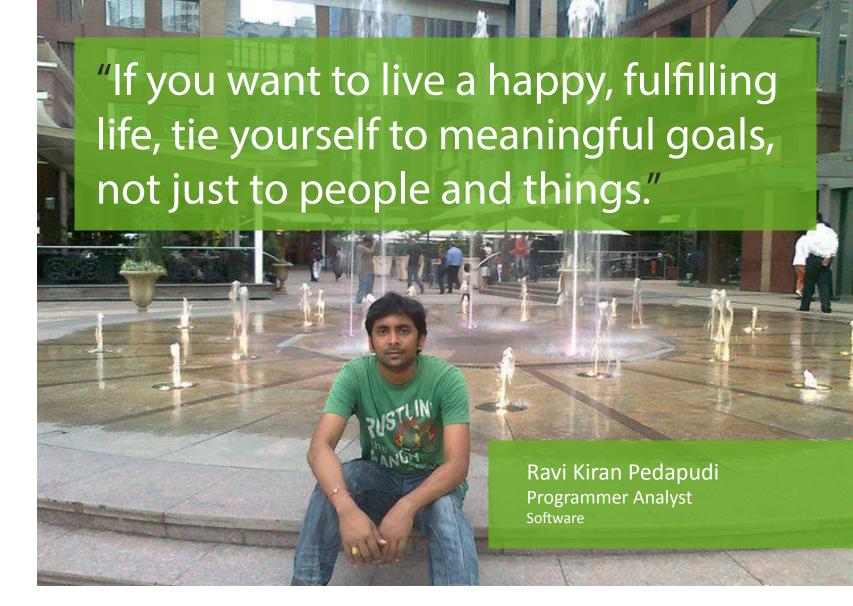
Your hobbies and/or interests.

Playing cricket and reading books.

Favorite sports or pastimes.

Cricket

"I stand by the idiom try and try until you succeed."



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

I was very happy and energized by the honor.

What has been your greatest challenge at Freyr?

Working for the social network module in KonnectCo has been my greatest challenge.

What do you like most about your job?

My favorite part is the ability to work independently and trust from the management and the people I work with.

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

I love pretty much ANY vegetable!! Okay, any food at that.

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

Never change anything. Remember, personal growth in all walks of life is a slow, steady process. It can't be rushed. You need to work on it gradually every day.

Your hobbies and/or interests.

I like listening to music and reading and learning about new technologies, gadgets.

Favorite sports or pastimes.

Playing cricket- the gentleman's game.

EMPLOYEEAPPRECIATION



Balarao M Sr. Programmer AnalystSWD

"Bala is working on one of the complicated projects with direct interaction with client and has been doing wonders. I have received excellent feedback from the client. Keep it up Bala."

Prasanna N G
Practice Lead – Delivery
Services



T. Hari Babu Programmer AnalystSoftware Department

"Hari Babu is a strong-willed and self-motivated professional who takes deep care in adhering to quality norms within projects. He is capable of managing challenging projects with remarkable deadline sensitivity without compromising quality."

D.Sai Charan Web Analyst Software Department



"Sai Charan is a dedicated professional who believes in giving his best to complete his work meticulously. He enjoys working in a team and believes that knowledge is something that should be shared openly and on a large scale. He is a quick learner and a self-motivated person."

Azam Baig

Technical LeadSoftware Department



Vishnu Teja Regulatory Associate Regulatory Affairs - CMC

Prateek Kulshrestha Regulatory Associate Regulatory Affairs - CMC



"Vishnu and Prateek have streamlined the operation process for Annual Product Review / Product Quality Review and Change Control Co-ordination. With this new streamlined process, the assigned projects can be completed with less turnaround time and desired quality. This approach demonstrates their commitment and dedications towards the assigned task. I really appreciate the hard work done by Vishnu and Prateek and hope to hear more such success stories in future as well."

Vikas Bhardwai

Senior Manager Regulatory Affairs - CMC



Ravi Kiran Pedapudi Programmer Analyst Software

"My experience working with Ravi Kiran is always a satisfying one. His professionalism and work ethic is unlike anyone I've ever worked with. He has met, and continues to meet, all the deadlines I have ever set. In fact, he usually delivers early! He is dedicated, motivated, honest and friendly."

> Mahesh Gorle Technical Lead Software



SQA

SWETHA RAVULA
QA Analyst
SQA

"I have had the pleasure to work with Swetha who is among the most delightful, kind people I know. A team player, she is hardworking, a fast learner, flexible and dependable. She is extremely thorough, organized and efficient at what she does which make her an indispensable part of my team."

SHAIK MAHAMUD ALI QA Manager



Vinod Chelmeda
Web Designer
Software

"Vinod is a fast learner and I appreciate his willingness to learn new things and deliver quality work on time. His humility and dedication is praiseworthy."

Srinivas Alagandula
UI Lead

UI Lead Software



Srikanth Reddy Sokkula Assistant Manager Regulatory Affairs

"Srikanth is a great asset and one of the strongest pillars of Dossier management team. A driven and determined individual, he excels at work related tasks and accomplishes them with perfection under tight deadlines."

Vinod Kumar Pola

Manager Regulatory Affairs



Sampath Baddipudi Jr Programmer Analyst Software Development

"Sampath is a quick learner and a self-motivated person and loves to accept challenges. I am very proud to have him on my team."

> Nareen Bellamkonda Technical Lead Software Analyst

> > 30

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Freyr Connect

Caption Contest

We are extremely thrilled with the overwhelming response the "Caption Contest" for Freyr Connect has received from all of you. All the entries were very creative with very well thought ideation and it was a huge challenge to select the winning entries.

As a first of its kind contest, the editorial team would like to thank every one of you for your enthusiastic participation and contributions.

We take this opportunity to proudly announce the top 2 winning entries.

Smriti Jha – Inspiring Innovative Thoughts



Fig: Smriti Jha collecting her prize from the Managing Director Sunita A

Luv Bagga – Learn. Share. Connect



Fig: Luv Bagga collecting his prize from the Managing Director Sunita A



Latest Regulatory Updates



U.S. Food and Drug Administration

Protecting and Promoting Your Health

US-FDA Answers Queries Relating to Generic Drug Stability Testing

US-FDA has released a new guidance "ANDAs: Stability Testing of Drug Substances and Products: Questions and Answers", on May 14, 2014, which answers some common questions regarding stability testing used to support Generic Drug applications. This guidance provides answers to questions from the public comments received by FDA on the guidance "ANDAs: Stability Testing of Drug Substances and Products" released in June 2013.

US-FDA Adopts ICH Document on Dose Uniformity

On 13th June 2014, FDA has adopted and released a new guidance on ICH document, Q4BEvaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 6: Uniformity of Dosage Units General Chapter. It provides clarity on use of pharmacopoeial texts on the uniformity of dosage units for different regions, and the conditions applied to their use in certain regions.

How to Use Pharmacology Data to Prove Biosimilarity?

US-FDA has released a new draft guidance document "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product," explaining how to use clinical pharmacology data to show similarity to a reference product. This guidance intends to assist sponsors to overcome the barriers faced during 351 (K) biosimilar submissions.

Changes to the eCTD Application

Through a notice in Federal register on 15th May 2014, US-FDA has announced the availability of revised final versions of the following four documents that support making regulatory submissions in electronic Common Technical Document (eCTD) format. The updated documents will be available on **FDA's eCTD webpage.**

- The eCTD Backbone Files Specification for Module 1, version 2.3 (which includes the U.S. regional document type definition (DTD), version 3.3)
- The Comprehensive Table of Contents Headings and Hierarchy, version 2.3
- Specifications for eCTD Validation Criteria, version 3.1
- Example Submissions using eCTD Backbone Files Specification for Module 1, version 1.3

FDAs Meeting to Explore Regulation & Medical Uses of 3D Printing Technology

In a 16th May 2014 **Federal Register announcement**, US-FDA said it will hold a meeting in October 2014 on the "technical considerations of 3D printing" to discuss the future of regulating medical products made using 3D printing techniques. FDA also plans to bring out the guidance on 3-D printing soon. But the notice also indicates that existing guidance documents, such as those specific to medical device types, will still be in effect regardless of the 3D printing guidance.



Changes to EU-Application forms for Variations and Renewals

In June 2014, the EU-Application Forms for **Variations** and **Renewals** have been updated. Updates include several minor formatting/ editorial changes across the documents.

Update to CMDh Question & Answers on Variations

This Q/A-list for the submission of variations according to commission regulation (EC) 1234/2008 **document** has been updated.

Update to CMDh Question & Answers on Active Substance Master Files (ASMF)

The CMDh questions & answers active substance master file (ASMF) **document** has also been updated.

Revised EMA Guideline on Stability Testing for Applications for Variations

EMA has adopted a revised guideline on "Stability testing for applications for variations to a marketing authorization" on 9th April 14 and will become applicable as of July 2014. It replaces the current "Guideline on stability testing for applications for variations to a marketing authorization" from 2005 and is meant as extension of the "Guideline on stability testing of existing active substances and related finished products" (CPMP/QWP/122/02, rev 1 corr). It provides general guidance on stability testing for type IA and type I B variations and addresses the data requirements for common type II variations.

Semeen Samreen Trainee Regulatory Affairs



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The scope of healthcare industry in emerging markets spanning countries in Latin America, Asia Pacific, Africa and Middle East is interesting when compared to the developed markets which include the US, Western Europe, Japan and recently included Organisation for Economic Co-operation and Development (OECD) countries. Brazil, Russia, India,

China, Mexico and Turkey (BRIC-MT countries) have witnessed an unprecedented economic growth in the last decade. This coupled with health reforms, population growth, affordability and changing disease profiles created a massive demand for healthcare and pharmaceutical products.

Road Blocks & Challenges

- Logistical, infrastructural, pricing, taxation and the regulatory landscape
- Members of Association of South East Asian Nations (ASEAN) and Latin American countries have harmonized their regulatory requirements
- Many countries have accepted ICH guidelines and CTD format however few regulatory authorities still have their own requirements and dossier formats
- Adopting new guidelines poses a challenge to the review process
- Language barrier impedes the approval process

- as guidelines are present in local language and dossiers have to be submitted to the local regulatory bodies in the required country's local language
- Separate audits are carried out by the regulatory agencies of different markets
- Regulatory bodies in emerging markets face a shortage of experts/resources which delays the review process
- Expertise level required for review for Chemistry, Manufacturing and Controls (CMC), clinical and non-clinical of the dossiers also varies partly with different regulatory bodies

Most of these countries rely upon Certificate of Pharmaceutical Product (COPP/CPPs) when they import drug products. The CPP was originally introduced by World Health Organisation (WHO) to support undersized Medicines Regulatory Authorities without a Quality Assurance (QA) facility.

"According to Accenture, BRIC nations alone may spend \$284 billion on healthcare by 2016."

Technical Challenges & Possible Solutions

Global Product Development

May be hampered owing to varying requirements of regulations for different countries. This can be minimised if various regulatory agencies initiate participation from the very beginning.

Global Stability Program

A demanding task due the fact that different countries fall into different temperature zones can be countered effectively if requirements of all markets that are targeted can be taken early on. Another suggested approach is to have batches on stability at both real time and accelerated conditions.

Global Labeling

Using same packing inventory within that particular region, pharmaceutical firms can achieve harmonization. This in turn will help companies when regulatory agencies within that particular region achieve harmonization in the labeling needs.

Pre-submission Meetings

Unlike the developed markets, the absence of presubmission meetings or meetings for scientific advice will lead to issues after submissions are completed. The agencies and experts from industry should work to address technical concerns both at product developmental level and clinical study/bio-equivalence study level.

Global Clinical Trials

Ever since the introduction of 'Kefauver-Harris' amendments to FD &C act post thalidomide tragedy

in the United States, drug development has been revolutionized compelling the manufacturers to demonstrate their drugs to be both safe and effective. The list of countries which want a clinical trial to be performed in their own populace has been on rise which made the industry to include patients from varying ethnicities and nationalities in their global clinical trial programs.

Developing a global protocol for clinical trials as a part of product development is arduous but can be beneficial in advancing towards more globalization. Until now clinical data from US/EU is widely being used to gain approval in Asian markets, this situation may soon change where agencies in developed markets would also be presented with data from emerging markets like Asia by companies to justify their findings.

"Pharma firms obtain no more than 10-30% of their total revenues from emerging markets."

> Kireeti Bheemavarapu Trainee Regulatory Affairs



XEVMPD:

How a Partner Helps Efficiently Navigate the Submissions Landscape



The EudraVigilance Medicinal Product Dictionary (EVMPD) has undergone several changes and enhancements since its inception in the year 2005 until now. EVMPD has been revised and is now known as XEVMPD with enhancements that include increase in the data to be captured, revised controlled vocabulary and submission criteria.

Most of MAH and Sponsors have earlier submitted EVMPD data; however the latest mandate requires all the stake holders to resubmit the XEVMPD submission effective from 16th June 2014 to 31st December 2014. This mandate will see a deluge of re-submissions on the EVWeb, a tool provided by the EudraVigilance.

XEVMPD: The Challenges

MAH and Sponsors,who are submitting new and existing medicinal products while managing the process internally, are required to run through the entire latest XEVMPD mandate, are required to use the EVWeb tool for their submissions and are also required to have an in-depth understanding of all the norms of EMVPD, XEVMPD and its expected transition to ISO IDMP.

Anomalies with EVWEB

Data Repository: Acknowledgement files cannot be retrieved after few days of submission and furthermore EVWEB does not feature a repository for storing these Ack files.

Product Data: EVWEB is specifically designed to handle less number of products and companies having extensive medicinal products will be unable to make use of the tool. In case if there is an error in product information (e.g.: ATC Codes) the record will be rejected. In such circumstances user must re-enter the data for submitting the same product information. It's a time

consuming process.

Audit Trials and Reports: EVWEB does not possess the reports and audits status tracking feature, making it difficult to capture the changes to metadata and user who has changed it.

XEVMPD Submissions Roadmap

The Efficient, Effective and Proven Approach

Having envisioned these hurdles, Freyr Solutions, a Global Regulatory Service and Solutions company, has developed an integrated solution and services offering that efficiently streamlines the entire process of XEVMPD submissions.

Freyr – Trusted Partner for XEVMPD Services & Solutions

Freyr XEVMPD solution is a complete automated submission system that validates the product information and creates EMA compliant EVMPD XML files. The solution is easy-to-use, hosted, on-demand web-based solution for information management with state-of-the-art navigation & user interface components.

Advanced Features that Score over FVWFB

- XEVMPD business rule validation
- Possibility of XML editing directly on Freyr XEVMPD system
- Provision of multi-level data security
- Availability of import feature in controlled vocabularies section
- Clone feature saves time in creating duplicate records if any product is available in different strengths
- Effective management of Acknowledgement files (easily retrievable)

Freyr's XEVMPD solution & services offer 100% on-time submissions while enabling significant savings of over 40% in compliance costs and helping companies reduce their submission turnaround time by up to 80%.



Have you identified your critical DI and PI Data Sources for GUDID Submissions?

The UDI compliance timelines are quickly getting shorter for companies to effectively plan their GUDID submissions to FDA.

Identifying critical DI/PI data sources from large volumes of unstructured data as well as disparate and non-authenticated sources pose as one of the biggest challenges for companies to meet their UDI compliance obligations.

Add to this an absence of version control measures, cumbersome manual submission, and inadequate data management process can further complicate the compliance initiatives.

Freyr supports global companies with end-to-end UDI compliance to ensure conformance with current Regulatory Mandates, Supply Chain Management, as well as reduction of Product's Lifecycle to enable faster Time-to-market with significant compliance cost savings of 40%.

Freyr IDENTITY

A reliable option to streamline your unstructured data

Freyr IDENTITY is an efficient, accurate, faster UDI compliance solution that helps identify and segregate specific functions and data sources from within a company to connect and collate critical device related PI and DI data.

Freyr IDENTITY ensures reliable regulatory compliance with GxP practice 21 CFR Part 11, including additional compliance capabilities like Version control, Validation, XML Conversion based on SPL and HL7 protocols, as well as Publishing and Printing to enable accurate, efficient and faster UDI compliance.

Fast-Track Your UDI Compliance

Freyr IDENTITY puts your UDI compliance on fast track with industry proven 3 Step compliance and implementation process.

It analyses and assesses your UDI obligations through effective Gap Analysis, Recommendations and Integrated Project Planning

It identifies segregates, collates and configures the source data in compliance with the regulated submission format.

Additionally, it captures, configures and manages all the critical 62 fields of Device Identifier (DI) attributes and 6 fields of Production Identifier (PI) attributes.

Efficient Lifecycle Management

Freyr IDENTITY efficiently manages a complete Lifecycle submission through its version-control system and ensures that multiple rounds of data variations are captured and organized in indexed and searchable files.

Right from deployment to regular maintenance, this comprehensive solution enables you to easily manage multiple lifecycles of the updated, modified device information whenever it occurs.

Centralized Repository

Freyr IDENTITY tracks, monitors, updates, compiles and configures your unstructured data and thoroughly checks for redundancies, duplications, errors and omissions. The final compiled data is maintained in a structured centralized database for future reference.

In-built Validator

While FDA provides an online interface for GUDID submissions, the criticality of performing a thorough data validation check before the final submission can become a major hurdle in your UDI compliance initiative.

Freyr IDENTITY eliminates any potential approval delays and rejections through its in-built validator. It uses FDA Algorithms and pre-validates the configured XML data. The accurate pre-validation ensures error-free submissions with zero-iteration cycle.

Streamlined Processes

Freyr IDENTITY deploys a robust process to streamline the GUDID submission with its advanced versioncontrol management and in-built data validation features built-on FDA Algorithms.

The validated data is submitted through an automated submission process that meets HL7 SPL protocols and can be published for accurate and error-free Label printing.

Pre-built Training

Freyr gives you choice and flexibility to deploy Freyr IDENTITY either in hosted environment or on-premise suiting your security, finance and IT requirements.

Whether in a hosted or in the on-premises deployment, Freyr IDENTITY offers a pre-built training to empower skills and enable compliance with GxP practice.

Bhargavi Soory Content Writer Marketing



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Employee Engagement



It is the art and science of engaging people in authentic and recognized connections to strategy, roles, performance, organization, community, relationship, customers, development, energy and happiness to leverage, sustain and transform work into results.

Your Employees are Engaged

Engagement is forged with different tools: trust, loyalty, open communication, clearly-articulated goals and expectations, shared values and wellunderstood reward systems. Employees engage with employers and brands when they're treated as individuals worthy of respect.

To Gauge Employee Engagement

Ask them why they feel their company is a good company to work with. If an organization has a multi-generational workforce, one must focus on the whys of working for your company before you spend a moment on the whats-what desk, what chair, what computer, what are the tasks and actions necessary to be successful. Engagement is innovative when it looks at why people behave and believe as they do rather than what might motivate them. Employee engagement certainly does not mean how the office is set up, or the toys gathered to distract restive employees, that build engagement.

Let's consider the whys of employee engagement for now.

"If you are working on something exciting that you really care about, you don't have to be pushed. The vision pulls you."

Steve Jobs

A question that all employees ask themselves Why am I here? If the employer does not communicate a shared sense of mission, vision and goals then the question remains unanswered. Employers must tell the people why they want them to work at their company.

Trust your leadership

Open communications build trust; while respect is essential to mutual trust, and also builds engagement. Business leaders must communicate clearly about goals and expectations.

Loyal(ty) to your Company

Companies which rank mutual respect and honesty above procedural activities will see a climb in engagement and productivity. Do you know why the engaged employees are loyal-because they are treated with respect and honesty.

Company Values

Organizations must make employees aware of their core values, which is intrinsic to gaining employee engagement. If the core values are not distilled across the employee ranks there is a certain implied detachment elicited from the management's side.

Recompenses

Employees must be told the rewards they would receive on working in this company. The management needs to be very clear and consistent about the rewards system which must include everything from pay to benefits, bonuses, vacation, and the path upward in the organization. Once that is settled, the employee will place their trust in the organization and work towards the goals.

Lastly, engagement is innovative when it looks at why people behave and believe as they do rather than what might motivate them.

"When people are financially invested, they want a return. When people are emotionally invested, they want to contribute." Simon Sinek, US-based author and motivational speaker



Getting work done in an efficient way which honors commitment while respecting time and allowing the body and psyche to focus and sustain the best mental state possible for emotional, professional and personal well-being and enjoyment.



Personal Productivity Apps

A good productivity app must save time or steps from a task that needs to be done frequently. It also must be multi-platform and lastly it must improve an individuals' life in some way. The mobile apps in this list could help an individual (from office workers to students) be more productive. It's by no means

a comprehensive list, but it lets you explore your options among the truly necessary productivity tools, as well as introduce you to some hidden gems that you might have missed while you were busy getting things done.

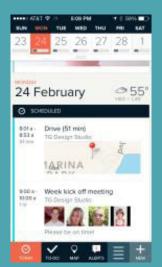


Picture Courtesy - Wikipedia



It aims to help users organize emails fast by letting them perform different swipes to archive, delete or snooze mail to be dealt with later. Mailbox syncs with iCloud and Gmail and is now available for both iOS and Android devices for free.

An app for professionals who need to write fast, iA Writer is a text editor which lets users to focus on their writing by removing all distractions. The app features written formatting commands so that a user's hands don't leave the keyboard and is available for \$4.99 at the App Store.



Picture Courtesy - Magneto Inc

Magneto Calendar, the iOS app syncs with both Microsoft Exchange and Google Calendar and is available for free in Beta, was designed for quick meeting scheduling.



Picture Courtesy - Used with permission from Microsoft

Cortana is a personal assistant built into the Windows Phone 8.1 operating system. The app can perform voice-activated search; users can allow the system to use personal data and emails to provide alerts reminders automatically. For Microsoft phone users only.



Picture Courtesy - Tempo AI, Inc

The **Tempo Smart Calendar** helps users to quickly read up on the people they're scheduled to walk into their next meeting with. The app pulls out details about the person from Twitter, Facebook and LinkedIn, reveals any mutual contacts and displays related news from sources like **Crunchbase** and **AngelList**. Tempo Smart Calendar has been created by SRI, a research institute and is available for free in the App Store.



Picture Courtesy - Lift.do

Life app is available for free for iOS and Android devices, Lift App is for those who want to apply quantified self principles to productivity. The app allows users log and track daily progress related to long habits like running, writing and learning. Users can also interact with others to cheer each other on or to provide feedback.



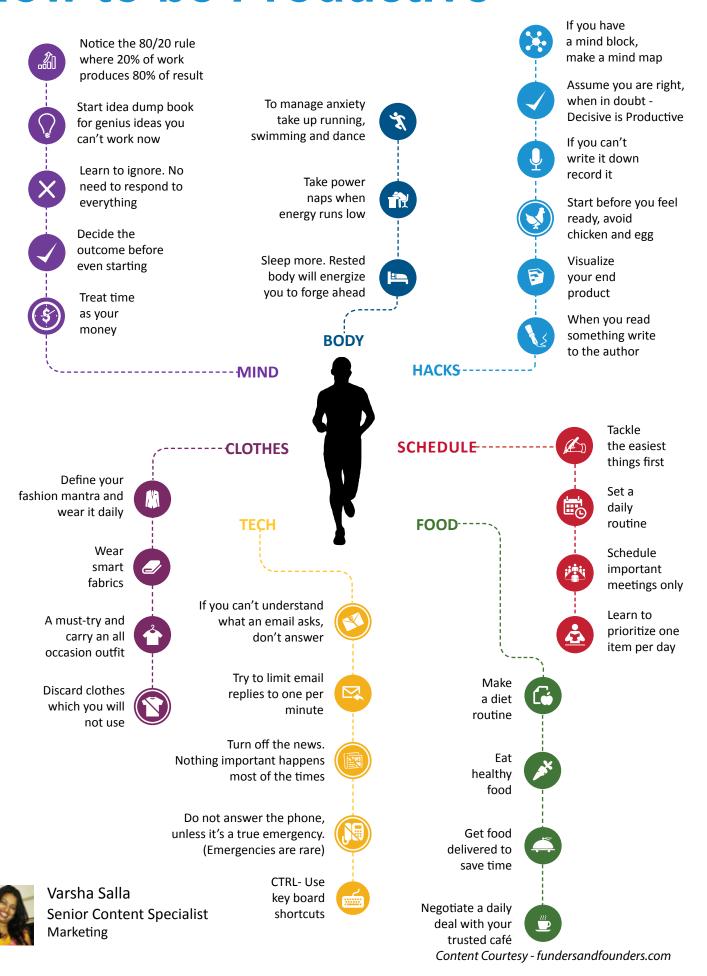
Picture Courtesy -EasilyDo Inc

EasilyDo is transforming how people get things done by finding out what they want when they need it and offering to do it for them. The app available for free on Apple and Android devices can automate up to 40 tasks. EasilyDo can call up other details like package tracking information, flight status and public transportation times.



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How to be Productive



The Communication Corner: Tips to Be a Good Influencer

Goal: Set a goal and decide on the outcome earlier on also try and motivate him/her to work towards that goal while chalking out the benefits.

Suggestion: Propose your thoughts/ideas in such a manner that he/her might carry out the work ahead of your expectation which will aid in helping you complete the task with less suggestions.

Confidence: Be certain of yourself and your suggestions as you can possibly be; a quiet, solid, clear confidence is often the best attitude.

Relationship: Consideryour long term relationship with this person or people and how your suggestions if implemented may/ may not affect the association over the course of time.

Self Goal: Be clear on what you would get if this person agreed to your request which in turn will give you more flexibility in making suggestions and/or requests from the person.

Begin at their start

point: It is best to acknowledge their point of view and allow them to begin from a point that they are comfortable from.

Bigger Picture: Think about the bigger picture and assess the problem areas the person might encounter during the task given to him/her and also think of some ideas that would minimize these difficulties.

Agreements: It goes without saying, of course, that when you are successful in influencing, you'll certainly live up to the agreements that you've made. Atmospheres in which you trust one another makes better business sense for all.

to persuade the person to be

more cooperative and take your

suggestions.

Environment: Changes you could make to the environment that would make it more likely for the person to agree to your request for instance people take suggestions broached during eating very well when compared to talking to the person over phone, mail or in person. Thinking of the environment in a slightly broader sense may help you





Employee Wellness Deskercise!

Deskercises or desk exercises are the best option one can take up to combat the perils of a sedentary work lifestyle.

How an Entrepreneur's **Brain Works?**

Cardio

Toe Tapper: This simple exercise calls for tapping of toes on the floor under your desk.

Stair Stepper: Start taking the steps two at a time and straight away accelerate to getting a real leg work out.

Spine & Neck

Neck: Tilt from front to back, tilt from side to side or rotate head from side to side.

Lower Spine: Sit with feet & hips planted solidly on the floor & turn your trunk clockwise & counter clockwise.

Legs & Butt

Air Chair: Stand with your back against the wall, bend the knees and slide your back down the wall until the thighs are parallel to the floor. Sit and hold for 30-60 seconds.

Silent Deskercise: To start toning just simply squeeze in your isometric glutes hold for 5-10 seconds and release. Try to repeat this until the glutes tire out.

Core

Perfect Posture: Adjust chair height to make sure the feet, hips, and arms are at 90-degree angles to the floor and try to keep the back straight throughout the day.

Ab Squeeze: Take a deep breath and tighten the abdominal muscles, bringing them in towards the spine as you exhale. Squeeze for 5-10 seconds and release and repeat.

Shoulders & Arms

Fist Punch: Try and make a fist and start punching in the air, repeat the exercise with alternating arms.

Shoulder Shrug: Raise both shoulders up toward the ears, and hold for 5 seconds, then relax and repeat again.

So what are you waiting for, let the Deskercises begin!!











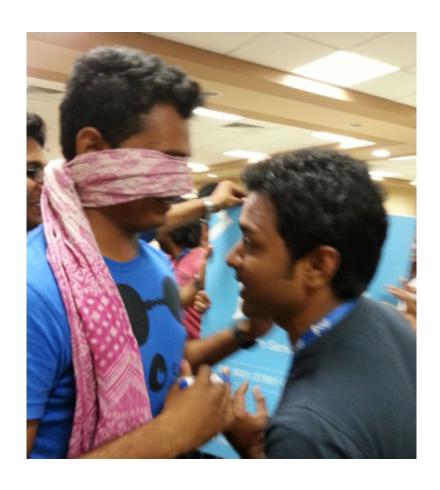




Great Place to Work

Blind Man's Bluff

A fun activity which was conducted by the GPW Fun Committee, saw participants from every team enthusiastically participating and having fun together.













Treasure Hunt

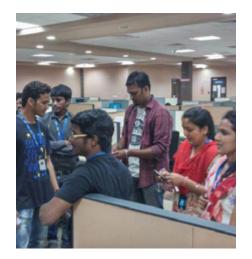
Another fun and engaging indoor game where the participants tried to find hidden articles in various locations using a series of clues.













Poems

The Bitter-Sweet Tree

The 'Neem Tree' in my garden, Tasted a bit sweet to me today.

I asked the tree of wonder,
"When I was younger,
I plucked the leaves off you
And tasted them;
You were bitter!
Then how did you turned so sweet through these years?"

The tree smiled, and replied, "I did enjoy you plucking leaves off me with your friends,

And how you shared your repulsion Towards my bitterness Indeed I was bitter, And so I am today; It might be that through these years, You turned bitter than me"

I was speechless,

The 'Neem Tree' in my garden, Tasted a bit sweet to me today.

Circled Thoughts

Every day I oscillate between being everything and nothing,
Both being and non-being.
Every act of becoming is a step towards unbecoming,

Learning and unlearning and then learning again.

Painting on papers I once erased, and smearing them again,

Drawing circles, one after another, Counts of which I never remember.

I reach somewhere every time, Yet lose sight of the shore, I find it again, just somewhere behind the door.

Half closed, half open they stare Ushering in dreams and nightmares calling out my despair.

Yet to prove myself right, I wrong my sudden fright, I stir my soul and walk on hot coals.

Every day, I oscillate between being everything and nothing,
Both being and non-being.

Steadfast I go to know the unknown, I return instead unknowing the known.

Yogi Raj Business Development Manager



Newsletter Disclaimer



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