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**freyr**  
**CONNECT**

Vol. 2 Issue 1

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# From the Editor's Desk

Dear Freyrans,

First of all, here's wishing you all a **Very Happy New Year** and a **Happy Sankranti!**

It gives us immense pleasure to celebrate a new beginning by bringing to you the annual edition of your very own, Freyr Connect!

Our cover story for this issue takes a look back and bids a final adieu to 2013 - The Year Gone By! A beautiful collage of pictures takes you down the memory lane to reminisce the moments of joy, pride, and accomplishments we all celebrated at Freyr.

And while we are taking a look back, it's even more exciting to take a look forward to envision what 2014 has in store for all of us.

We all took a seemingly impossible journey and made it a living, thriving and real organization. We all performed, contributed and have grown at a speed that is considered impossible in the prevailing economic scenario. Yet, it was our combined grit and determination to tread the path to becoming fast-growing Global Regulatory Solutions & Services Company that successfully delivers to global fortune giants!

But, this is just the beginning of the journey!

2014 is the year where we have set bigger targets, faster growth plans and a strategic business vision to create accelerated successes and wins. We have acquired large accounts, aggressively competing for other larger deals, and are steadfast in our commitment to grow the count exponentially. We have set in motion the expansion plans for augmenting sales and marketing functions to ensure wider market and social brand proliferation for increased opportunities. We have new services and products in the offing that will further expand our portfolio footprint for a competitive advantage in our domain.

The opportunities are plenty, the vision is defined, and the success is ours for the taking. All we need is to keep up the momentum through our performance and a relentless will to achieve greater success in 2014.

With that we invite you to dive in and enjoy this annual issue.

Once again, have a great year full of successes ahead!!

A big thank you to all the contributors, who helped make this annual issue truly memorable. Looking forward to hearing from you all, and don't forget to send feedback, contributions and suggestions to [ranvijay.singh@freyrsolutions.com](mailto:ranvijay.singh@freyrsolutions.com)

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## *The Team behind*

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# Management **Speaks**

The last one year has been a heck of a journey for all of us in Freyr from old timers to new people who have joined in various stages or phases of this journey .

Transforming from a boutique small and midsize customer focused company to a company that can deliver to large pharmaceuticals in a short one year period of time is not trivial. It needs a different kind of work force (not ordinary extra ordinary) people who can be constantly on their toes to bring that kind of acceleration towards stable state. Mind you this looks like a dream to me. Yes few people here in US had something to do with this dream. But you know, people can always dream, the success story is not about dreaming. It has to be made reality. It's you all who made this a reality.

As cliché it sounds, no organization is perfect. The combined individuals' attitude forms the organization's attitude. If something is not right, it may not be just because of one person or few people. We all have something to do with it. If you feel something is not right, fix it. Every person in the organization has the responsibility and the right to contribute towards fixing it. We have to constantly keep trying. It does not matter if it got fixed immediately or several months later or never got fixed. But how consistent we were in trying to fix it shows our attitude and our organization's attitude.

When a year comes to an end, we start thinking about what is in store for the next year. What should we be doing? What should be our dream come true for our organization?

This time, let's do differently. Why don't you make your list? Three things that we should do as an organization and three things that you as an individual would like to contribute. It can be small, big, and unachievable, anything under the sun. Let's compile all the responses and see what we come up with as a team. It will be an interesting exercise provided significant of you contribute.

Good luck to one and all for 2014!



*Srini Sadhu*



*Sunitha A*



*Rajiv Rangan*



*Suren D*



*Vasu R*



*Sudheer G*



# Flashback 2013

The year gone by

*“2013 the world was doomed to end. But we had an awesome start. A start to success, to new highs and to exploring new borders geographically. Of course, we have never imagined that we would have such a successful year.”*

We have acquired new clients, new projects, faced audits and a lot more. The ever enthusiastic team at Freyr has shown tremendous verve when it came to late nights, ad hoc requests, working on weekends and holidays. All of us had a common goal: to excel in our job and take Freyr to a new level altogether. Our founders had a dream of sculpting their regulatory vision on the global market. We made that dream our mission.

We have had tough times when we were given some projects which seemed like a hurdle. But we overcame the problems and made timely, error-free deliveries which further strengthened our position.



At Freyr we believe in balancing work and fun. We have our share of Friday fun. We had events like Musical chairs,







passing the parcel, potluck. The Great Place to Work Committee was launched in mid-September. We have never had a dull moment since then. The GPW members



have taken the extra effort to make Freyr a great place to work indeed. From celebrating birthdays, to organizing fun events they have done every bit to live up to their



name.

The annual day celebrations commenced with the sports week. Games like cricket, badminton, chess, caroms, Chinese checkers, tenniquoit were organized and we had active participations from the floor. Never have we seen such smiling faces and childlike enthusiasm.

We celebrated our annual day with full fervour at a resort in the outskirts of the city. It was a day we let go of ourselves completely. The day started with the cricket finale and



ended with the prize distribution for the sports events. We had a cultural program where we had an assortment of songs, plays, dance and ramp walk all organized by GPW.



This saw the active participation of one and all starting from the employees to the management.

We cannot rest on our laurels; the mission of our founders is still our vision. We ushered in the New Year on an ecstatic



note and look forward to yet another year of meaningful work and more fun filled days.



# Striking the Perfect Balance: Work and Life

*I am so privileged to write on work life balance for my beloved Freyr employees. It gives me immense pleasure to share anything and everything which could help an individual to flourish and keep motivated. It is actually an essential concept and idea which I believe all the employees should know.*

I am so privileged to write on work life balance for my beloved Freyr employees. It gives me immense pleasure to share anything and everything which could help an individual to flourish and keep motivated. It is actually an essential concept and idea which I believe all the employees should know. Today we all have become like a machine, a machine which is running 24/7 without a break.

Now answer me? You eat too much, drink too much and work too much. How fair is it when you do all of these too much and neglect your family too much. We step out of our home every day for a living but actually forget to live.

## What is work life balance?

Balancing and prioritizing between our work (career and ambition) on one part and on the other your family health and spiritual life.

## I would like to share four core observations:

### 1. Solve your problem:

Certain jobs and career issues are essentially mismatched, which is being significantly engaged on the day to day basis with a young family. 1st step to move forward and solving any problem, is acknowledging the reality and

situation you are in. and the reality of the society is there are 1000's of people out there, living life of screaming desperation.

“Well you put in your efforts to work on something long hours, especially job you hate to do, just to impress some kind of individuals you don't like” think about this?

### 2. Face the Truth:

Look at yourself; you need to take a stand for yourself. Take the control and responsibility for the types of life you would like to lead. “If you don't design your life, someone else would design it for you and there is a possibility that you may just not like their idea of balance. It is particularly important that you don't put your quality of life in somebody's hand.

### 3. Learn to balance, how to balance:

You have to be realistic; you can't do all good things in one day. Have a time frame by choosing a middle way of organizing things and making a way for your conflicting demand.

### 4. Approach balance in a balanced way:

Do you have to allow your work to dominate your work. Small things matter a lot. Smallest investment in the right places radically transforms the quality of your relationship and life

### **Poor Life Balance will lead to?**

- o You don't feel like coming to office, no interest in work.
- o Attrition rate of an organization will increase.
- o Productivity will come down.
- o You don't feel like coming to office, no interest in work.
- o Satisfaction on job will be low.
- o Health will be in a bad shape and will cost you more.
- o Low commitment and loyalty= Poor customer service

## **Poor Life Balance will lead to?**

### **Set your goal and prioritize your work accordingly:**

Have clarity on what you want to do and where you want to be five years down the line. If you are not clear on your vision and mission, how will you conclude on setting your priorities? Ultimately what would happen? You will remain confused throughout.

### **Have a proper structure and learn to say "NO":**

Is it necessary to yes to every single thing coming in the way? Why one has to start the day with a note that he/she needs to impress such amount of people at the end of the day. If your bucket is full, you can say NO politely there is no harm in it.

### **Take regular holidays and break:**

Add spice in your family relationships by taking them out. Ultimately why do you spend so much time in earning? Is that not for your family? Take that extra stride just to bring a cute little smile on your daughter's face when they end up telling you that dad/mom today was the best day of my life to spend time with you.

### **Manage your time:**

Life is not to be enjoyed after you are done with your retirement, everything has to be moved parallel don't you think so? You cannot think of giving happiness to your family when you are exhausted completely. Or may be at a point when you have nothing more to do at office. We need to manage our time in such a way that we pull out some amount of time for our family, friends, social gathering, self-learning, health, diet etc. to grow and progress

### **Undertake continuous training, "but remember that it will not be real perfect all the time":**

Relax and chill so what if you could not make this time? There will be so many opportunities where you can make your future bright with the past learnings. Never allow your tears to come before your eyes, so that you cannot see the next coming opportunity.

### **Treat special to self:**

Spend time to groom yourself; may be a massage center or a beauty parlor or may be spending time in some shopping. When you look and feel good about yourself it is certain that you spread positive energy where ever you are going and with whatever you are doing.

### **Stay healthy and feel extremely great:**

staying healthy is so important if at all you want to step up and achieve the mile stone. Eat healthy, have a planned balanced diet for you and your family. Drink more water, science has proved that 95% of sickness will stay away from you if you drink 8 glasses of water each day. Go for a doctor's checkup at regular intervals.

### **Love your job:**

it is very essential that we love what we do, because if you don't love what you are doing, there is maximum chance that you will not be there in the same job for long. Keep your eyes wide open before you pick any job. Enjoy your work have a passion for what you are doing and let your creative mind explore more with wonder working ideas.

### **Stay positive, passionate and enthusiastic:**

these are the three mantras for anyone under the sky to keep going. No matter what is hindering you or pulling you down. Tell yourself that you are specially designed and you are here on this earth with the purpose. I bet you that no negativity will even dare to come near you.

### **Love your life:**

Life is so beautiful; we all have been created so beautifully. Just to take tensions of all hustles and bustles of life or to balance it well and enjoy every single moment. If you have a bad moment remember there is a good moment waiting to embrace you.





# QbD Paradigms: Regulatory Stimulant for Manufacturers

**Dr. Prabhat Shrivastava**  
Manager- Regulatory Affairs

Quality by design (QbD) is based on sound science and quality risk management through which quality is built into products. Although the benefits of QbD are obvious, the industry has been relatively slow in adopting the concept because QbD often falls low on the list of immediate priorities and understanding. The pharmaceutical industry and regulators understand the need to move from end-product testing to a more enhanced quality model. The ideal model would utilize the concepts of quality by design, risk management and quality systems for identification, prioritization, design and product quality control.

The focus should now be on how to overcome the hurdles to implementing these key concepts. The establishment

of Q8, 9 and 10 provides guidance on the concepts of Pharmaceutical Development, Risk Management and Quality Systems, but are not “how to” documents. Firms

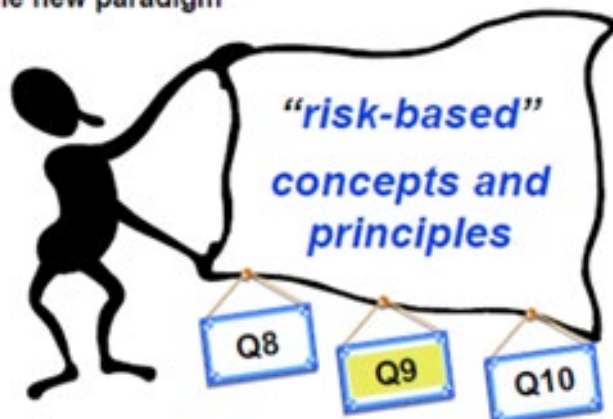
must determine how to best integrate these concepts into their company specific programmes and processes. There are a number of key questions and concerns that industry and regulators are working on to evolve the maturity of these concepts into more practical guidance:

\* First and foremost, quantifying the benefits of a QbD approach today and at some future point where “regulatory flexibility”

may be achieved.

\* What amount of regulatory oversight is needed to take advantage of a QbD approach? For instance, how much information and knowledge should a firm provide in a

The new paradigm



regulatory submission to describe the design space and control strategy?

\* Questions remain regarding the regulatory inspection approach to review risk assessments that firms may perform as a part of a QbD Risk Management program.

Although the Q8, 9 and 10 concepts are not strictly required by global regulations, they are becoming expectations, and many firms have begun implementing these concepts because of their business benefits. The implementation of QbD brings with it a host of questions that a firm will ask itself to determine whether or not to implement and, if so, to what extent.

\* First and foremost, quantifying the benefits of a QbD approach today and at some future point where “regulatory flexibility” may be achieved.

\* What are the costs and what is the likely return on that investment (fewer rejected batches, less scrap, less rework, etc.)?

\* Will there be some type of **“regulatory flexibility”** for those firms that adopt QbD and adequately identify their critical quality attributes, understand their process and develop a robust control strategy that ensures proper quality of the drug product?

\* What will be the mechanisms for a post approval adoption of a QbD approach?

When fully considered and implemented, Quality by Design translates to better-developed critical quality attributes for drug product, drug substance and raw materials. In addition, all critical sources of process variability have been identified in a control strategy, measures have been taken and controls have been put in place to mitigate unacceptable risks. The benefits of this include the following:

\* **Product waste is minimal**

\* **Fewer process controls are required or the existing controls are more meaningful**

\* **Batch cycle times are minimize**

\* **The impact of process changes are fully understood**

\* **Costly equipment and processing changes are limited**

\* **Faster/more successful regulatory approval**



\* **Project deadlines are on target**

\* **Marketing dates and subsequent revenue streams are hit**

\* Utilization of enhanced manufacturing approaches that allows manufacturers to vary the process based on variable inputs to produce more consistent drug product.

The QbD guidelines identify and define different elements of the QbD-based approach to pharmaceutical development. These elements have been proposed in order to inspire and guide pharmaceutical companies towards a practical implementation of QbD. Table-1 lists the main regulatory documents introducing and defining the QbD paradigms, along with the main contributions these documents provide.



**Table 1 Main regulatory documents introducing and defining the QbD paradigms.**

Document	Main contribution
ICH (1999)	Defines the concept of quality and assists in the establishment of global specifications for new drug substances or drug products.
FDA (2004a)	Outlines the QbD concept and summarizes initiatives to encourage science-based policies and innovation in pharmaceutical development and manufacturing. Proposes risk assessment as a tool to evaluate the impact of variations in process inputs on product quality.
FDA (2004b)	Introduces the Process Analytical Technology (PAT) framework. Defines process understanding, critical quality attributes and critical process parameters, and identifies PAT tools. Introduces the real time release concept.
FDA (2004c)	Defines the industrialization process as the set of activities related to product design, process design and technology transfer. Acknowledges that problems in these steps routinely derail or delay development programs.
ICH (2005)	Defines the concept of risk for pharmaceutical quality and provides principles and examples of tools for risk assessment and management.
ICH (2008)	Describes a model for an effective quality management system throughout the lifecycle of the product. Outlines the control strategy and continual improvement concepts.
ICH (2009)	Provides an overview of QbD in pharmaceutical development. Defines most of the QbD paradigms (quality target product profile, critical quality attributes, risk assessment, design space, control strategy), providing guidelines for their implementation and submission in technical documents.
ICH (2010)	Proposes questions and answers sessions in order to facilitate the implementation of the Q8/Q9/Q10 guidelines. Provides several clarifications and the regulatory perspective mainly focused on QbD topics as design space, real time release testing and control strategy.
ICH (2011)	Provides a guide for ICH Q8/Q9/Q10/Q11 guideline implementation, with emphasis on criticality identification, control strategy, design space and process validation. Introduces the use of modeling as a tool to implement QbD at every stage of development. Categorizes models and provides an outline for their implementation, validation and verification.

## Conclusion:

We are embarking on a journey to develop enhanced quality principles for pharmaceutical manufacturing. There are differences between industry and regulatory agencies around the globe regarding the interpretation of QbD principles. Work by ICH is important to define key terms and concepts, to facilitate further dialog between industry and regulatory authorities and bring both business and regulatory rewards to those that adopt QbD approach. While it should be somewhat easier to apply these principles to new drug products and processes, there

is a need to bridge the gap to include the introduction of QbD to existing systems. This is an exciting time for the pharmaceutical manufacturing industry as these principles are applied in the ongoing effort to ensure a more consistent quality product. By failing to identify and correct the root causes of problems early in the design phase of the process- and product-development cycle, organizations risk quality, yield, and supply-chain issues. QbD should be viewed as an opportunity that brings value and business benefits to the sponsor.

# Overview on DMF/CEP: Need of Regulatory Submission

Vishnu Teja  
Regulatory Associate

## Introduction

Drug Master File (DMF) is one of the important parts of the documents submitted to the regulatory authorities. DMF contains complete information on an Active Pharmaceutical Ingredient (API) or Finished Drug substance. It is known as US-Drug Master file (US-DMF) and European Drug Master File (EDMF) or Active Substance Master File (ASMF) in United States and Europe respectively. DMFs usually cover the Chemistry, Manufacturing and Controls (CMC) of a component of a drug product e.g. drug substance, excipient, packaging material. Drug product information or non-CMC information (e.g., facilities, toxicological) may be filed in a DMF. DMFs have significant importance because they support the NDAs, ANDAs, and INDs which represent multi-billion dollar potential profits for drug applicants, and several hundred thousand to several million dollars each in corresponding investment time and research.

Submission of DMFs by the manufacturers to the authority creates the quality impact on the consumers and it can increase the trust of the manufacturer in the market pertaining to organisation & quality of product.

## 1.1 Parts of DMF

Unlike US-Drug Master file, the scientific information of EDMF or ASMF is physically divided into 2 parts as per European filing procedures.

### A. Restricted part (Closed part) -

Information regarded as to be confidential and to be submitted only to the Authority.

- \* Manufacture
- \* Manufacturer(s)/site of manufacture
- \* Detailed description of the manufacturing process and process controls
- \* Control of materials (Starting material of the API, reagents, solvents, other materials used)
- \* Control of critical steps and intermediates

- \* Process validation and/or evaluation
- \* Manufacturing process development

### B. Applicant's part (Open part) -

Information regarded as to be non-confidential and to be given to the applicant. This information is also given to the authority as part of DMF.

#### These parts include:

- \* General information
- \* Characterization
- \* Control of API
- \* Reference standards or materials
- \* Container closure system
- \* Stability

## 1.2 DMFs format

DMFs may be submitted following the format recommended in the "Guidance for Industry M4Q: the CTD - Quality". The Common Technical Document (CTD) is a set of specification for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. It was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, U.S.) and the Ministry of Health, Labour and Welfare (Japan).

## TYPES OF DMFs (FDA)

**Type I** - Manufacturing Site, Facilities, Operating Procedures, and Personnel (no longer applicable)

**Type II** -Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product

**Type III** -Packaging Material

**Type IV** -Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation

**Type V** -FDA Accepted Reference Information





## Best Practices: **Sales**

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*“Focus on the prospect, not on the company or the situation. Because it is the prospect who will ultimately give you the business.”*

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Many people wonder how a top performing sales person stands out in a crowd. In most cases, it's because they apply a number of best practices in their daily routine. Here are some best practices that put you on the creamy layer:

Set **HIGH TARGETS** for yourself. Set your own goals that are usually more ambitious than the corporate targets instead of waiting for your manager to set targets.

**PLAN** for the quarter, month and week, as well as your day instead of only looking at the day or the week ahead. Look at the bigger picture.

Set **OBJECTIVES** for every sales call. It is essential to know exactly what you want to accomplish before you make your call (face-to-face or telephone).

**ASK** hard-hitting questions that prick to the heart of the issue. This sounds pretty simple but this is where most sales people stumble at and ask weak, feeble questions. Ask tough questions that make your prospects think.

**LISTEN** carefully to what prospective customers say instead of waiting for your turn to speak. You can ask all the questions in the world but if you don't hear what people tell, you won't be able to present the proper solution.

**CLARIFY** when you are not sure about what your prospect means. People often say things that are unclear and most sales people make assumptions.

**WAIT TO PRESENT** your product, service, solution or idea until you know exactly what the prospect's situation is. Wait for the right moment instead of jumping into the “sales pitch” right away.

**RECAPITULATE** your prospect's need and begin with the situation in mind. A quick summary of your customers' situation give you the opportunity to ensure that your presentation addresses their key issues.

**ADAPT** your sales presentation if their prospect's situation has changed. Making impromptu changes is challenging but it is one way to gain a point from your competition.

**POSITION** your product or service according to the customer's needs. Do not end up talking a lot and ending up with something which is of no relevance to the customer.

**FOCUS** on the prospect, not on the company or the situation. Because it is the prospect who will ultimately give you the business.

Be **PREPARED** for potential objections. Plan your questions and counter questions before the call.

Establish the **NEXT STEPS**. Decision makers are busier than ever which means they are more difficult to connect with. Avoid losing contact with a prospect by agreeing on the next steps after every sales call. Do this in face-to-face meetings and telephone calls.

**FOLLOW-UP** after the initial call or meeting. Do not expect him to call you back.

Always look for ways to **KEEP IN TOUCH** with customers. A sale is not a one-time deal. You always need to find ways to keep your name in your customer's mind to prevent a competitor from squeezing in. All the best!!

**Shahbaaz Khan Muhammad**

Manager Business Alliances and Clients Services





accessible to authorized users when required.

### ISMS and ISO standards

Information and information technology is often the key to the success of a business, and businesses decide on how to make these important assets more secure and less vulnerable to attacks and disasters. Dealing with information security in corporations calls for a systemic and complex approach. ISO norms ISO/IEC 27001 and ISO/IEC 27002 make the job of making your information more secure easier.

Both standards are closely related, but each of them plays a slightly different role. ISO 27002 provides a detailed step or a list of security measures which can be used when building an ISMS. ISO 27001 talks about how to implement, monitor, maintain, and continually improve an ISMS Information Security Management System. ISO 27001 is also the standard that governs ISMS certification.

### Why do I need to have

#### ISMS?

Implementing sound ISMS in a company is not free and can take many months; however, it can also bring many valuable benefits.

\* If information is the key asset that is needed in your business then ISMS helps to protect your business case,

- \* ISMS delivered via ISO standards is compatible with others in the market,
- \* Company management is always involved in the security and always has access to information,
- \* Your partners view you as more reliable, credible, and trustworthy,
- \* ISMS certification opens doors to new business (for example better competitive position in the EU market),
- \* Information and data sources are utilized more efficiently,



- \* ISMS makes your investments into information security more efficient,
- \* ISMS brings the importance of information security to your employees and makes them more involved in your business,
- \* ISMS changes the culture in your company (brings responsibility and accountability).

ISMS is not only a mechanism or a system to improve the security of your data and

information; it also leads to more effective utilization of your information and thus acquires a better competitive position in the market.

Pavan Popuri  
IT Manager



## Tech Check: **Looking Ahead**

“*What future beholds for us always remains uncertain. However, let’s explore what technology has in store for us in near future.*”

### **Size zero, technology minimized:**

According to Futurist Brian David Johnson, the advancements in computer technology has so limitlessly effected, that the housing for computer is almost zero. Scientists are working on an atomic model that would eventually change the way we see and use computers. The computer brains have diminished, requiring about just 1 to 5 atoms and this might take up about 10-20 years eventually atoms replacing the chips sets we use.

### **Brain hacking:**

Is it really possible to read your brain? It’s been since a decade, the studies are still been carried out by University of California. They’re working on a neurotransmitter that would translate the neural signals into digital format. It would be a huge break-through in the medical field enabling patients suffering from dementia to speak out their thoughts before they forget.

### **Big-Data:**

It is the most spoken technology in year 2013. The exceptional huge amount of data that is available through web-based storage. Beneficial to media and marketers who work round the clock to hack the interests

and strategize the end users. The algorithms, machines and data mechanisms are used to manage and help us making sensible decisions unlike being independent.

### **Level: Nano**

“Nanotechnology (sometimes shortened to "nanotech") is the manipulation of matter on an atomic, molecular, and supra molecular scale.” -Wiki. Now what is so fascinating about nanotechnology is that its application in the medical field would unlock solutions for various deadly diseases that humans are facing at various times. They are one billionth part of a meter, and here it proves that size does matter. Because illness happens at the very cellular level, and as these meds work mostly at cellular level, it makes them possible to work on most narrow and minuscule centre of control. Hence they could be used in both curative and preventative as required.

At first we look into these technologies and it mesmerizes us thinking about the future, but what’s on stake is the security. Everything that goes online stays there forever. Cyber world is still a brand new place, uncertain and constantly evolving in nature that could be more worse given the situation rather solving and posing a threat to world peace.

Tausif Ahmed Khan  
BDE

# 30 Bizarre, Eerie & Crazy Things

To Do With Your Life In Your Life

*I reckon everyone agrees that this World is an oyster and Life is inter-connectedly complicated, with many potential forces around, exerting their influences and consequences on us, the people. So be precise and concise by swearing an oath of neutrality. Here's the pronto list.*

Arjun Teja  
BDE

- 1 Make peace and maintain it always with your parents, friends and neighbours. Invariably, be the one to forgive them for being wrong even if they actually have your best interests in mind or not
- 2 Minimize your passivity
- 3 Open up a banking fixed account. Forget about it.
- 4 Meet strangers and talk random stuff, randomly and recognize the freedom, an unexpected feeling.
- 5 Survive your life without telephone and forget the internet for at least 10 days.
- 6 Try to start a relationship with your first crush by telling them that you want them. Talk direct and honest and make yourself very clear to them.
- 7 Just don't do thing you won't like. Be impulsive and arrogant sometimes. Don't complain that you can't see sun in the night times.
- 8 Revisit the places you like the most and those which makes you relaxed, where you can find peace. Because places are forever and you aren't. It can be your school, a park or a hill-station. Any recalls?
- 9 Figure out your empowering leisure activity or a passionate hobby that you always look forward to do it.
- 10 Spot the elements, circumstances and factors that intimidate you. Get dictated by people who have had already overcome them, instead of letting down every move you make.
- 11 If you have nothing to do, clean up your belongings and move the household or office-hold items to a newer place which makes you feel "There's no need to keep it forever". It can be your pair of boots, your ex or your official diary.
- 12 It is always imperative not to panic and for the sake of being different, don't choose wrong paths. Also stop hating yourself.
- 13 Go somewhere far away, get isolated, relax on a grassy hill with no presence of city lights, look at the stars and feel the earth moving.



- 14 Accumulate your favourite set of cartoons, movies, musical tracks, e-books and software.
- 15 Try to take an advantage of health insurance (if you have so).
- 16 Be Extroverted. Tell others what and how you feel.
- 17 Buy a MacBook, sit on a bridge and browse for a while.
- 18 Quit your job if it's making you miserable or inactive.
- 19 Lose friends and end relationships not only with the people who make you feel lunatic but also with whom you may perpetually on the verge of puking.
- 20 Go to a musical concert. Be it western rock or Indian classic. Just see your favourite music bands live performance. Enjoy the crowd, enjoy the environment.
- 21 Take your parents to a nice restaurant and buy them dinner with earnings. Feel the joy of pay back joy, love and kindly responsibility. Make them feel that you are the one.
- 22 Be a citizen of the World. Roam around. Go to places that fascinate you. Travel to other continent far away from wherever you're.
- 23 Learn a new foreign language. Push yourself from your comfort zone and try to blend with other culture and get terrified.
- 24 Have an extra-ordinary and eccentric conversation with someone regardless of age, appearance and IQ, who has varied beliefs and faiths.
- 25 If you are eligible to Vote. Do that. You may not get a chance to complain to express your views and perspectives.
- 26 Have your hair dyed with some totally cool and different colour.
- 27 Forgive Enemies. Let the revenge fade out. Be out of unhealthy pursuits.
- 28 Learn different cuisines. Try something new and un-pronounceable recipes and have fun.
- 29 Learn how to pragmatically say bad things in a good manner.
- 30 Be ridiculously reckless, turn yourself as a clod, wake up somewhere you are not familiar with and brainstorm how you get home on your own.

# FUN ZONE

## Jokes Apart

Yasmin Mohammed  
HR

Please be advised that there are NEW rules and regulations implemented to raise the efficiency of our firm

### Lunch Break

Skinny people get 30 minutes for lunch as they need to eat more so that they can look healthy.

Normal size people get 15 minutes for lunch to get a balanced meal to maintain their average figure.

Fat people get 5 minutes for lunch, because that's all the time needed to drink a Slim Fast and take a diet pill.

Thank you for your loyalty to our company. We are here to provide a positive employment experience. Therefore, all questions, comments, concerns, complaints, frustrations, irritations, aggravations, insinuations, allegations, accusations, contemplation, consternation and input should be directed elsewhere.

### Surgery

Operations are now banned. As long as you are an employee here, you need all your organs. You should not consider removing anything. We hired you intact. To have something removed constitutes a breach of employment.

### Personal Leave

Each employee will receive 104 days of personal leave a year. They are called Saturdays & Sundays. a breach of employment

### Company Vacation Days

We are a good company that, on top of your entitlement to 104 days of personal leave a year, allows all employees to take their vacation at the same time every year.

### Dress Code

It is advised that you come to work dressed according to your salary.

If we see you wearing Prada shoes & carrying a Gucci bag we assume you are doing well financially and therefore you do not need a pay rise.

If you dress poorly, you need to learn to manage your money better, so that you may buy nicer clothes and therefore you do not need a pay rise.

If you dress in-between, you are right where you need to be and therefore you do not need a pay rise.

### Sick Leave

We will no longer accept a doctor statement as proof of sickness. If you are able to go to the doctor, you are able to come to work.

### Internet Usage

All personal internet usage will be recorded and charges will be deducted from your bonus (if any) and if we decide not to give you any, charges will be deducted from your salary. (note: Rs.20 per minute as we have 4MB connection).

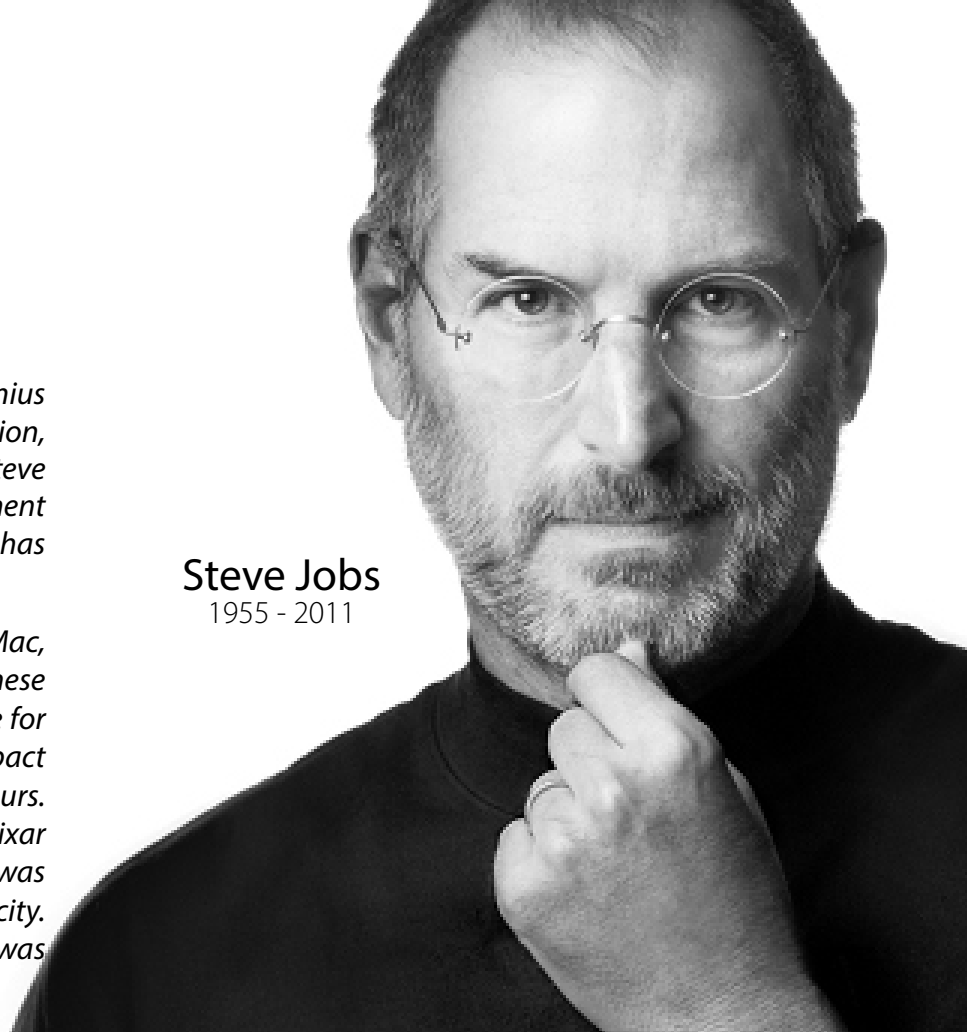
Just for the record. 73% of the staff will not be entitled to any salary for the next 3 months as their internet charges have exceeded their 3 months' salary.

# Remembering a Legend

*A global visionary and an innovative genius who believed in creativity, design, imagination, and technology, it's none other than Steve Jobs my friends. I'm glad to take this moment remembering this legendary icon who has changed our world.*

*I'm not going to say anything about Apple, Mac, iPod or iPhone...I hope everyone knows these gizmos. But I would like to make some space for the alter ego of Steve Jobs that had an impact on countless professionals and entrepreneurs. As Co-founder and CEO of Apple and Pixar Animation Studios, his persuasive power was equaled by his creativity and business sagacity. His devotion and dedication to a product was unique in his own way.*

**Steve Jobs**  
1955 - 2011



## Passion

During the development of Apple's Web Service, Steve was very ruthless and aggressive on his developers because the product was not up to his expectations, and he disbanded his whole team. His passion to make the perfect product and his approach got his team to dream and do things that they thought were impossible.

## Innovation

staying healthy is so important if at all you want to step up and achieve the mile stone. Eat healthy, have a planned balanced diet for you and your family. Drink more water, science has proved that 95% of sickness will stay away from you if you drink 8 glasses of water each day. Go for a doctor's checkup at regular intervals.

## Entrepreneurship

Applying creativity and beauty to engineering was always the focus of Steve. Rehired by Apple back in 1997 he said "let's not look back at our failures" and had his team motivated and the results are iMac, iPod, iPhone and iPad within 12 years.

## Leadership

According to Jack Welch, Steve Jobs was "the most successful CEO" of our era. Redefining his vision for a better tomorrow, relentless focus, flawless execution and motivation of people to make sure his vision becomes a reality are few leadership lessons that we could learn from Steve's career.

## Presentation

Steve was excellent communications specialist. He makes the critical point in his presentation so clear that it easily drives the intended message through people's minds. He always used visuals to make a point and sold benefits of the products. Thing is, that he knew the page before people can turn into and read it.

Dictatorial, uncompromising, pushing to the limits and atrocious personality has brought Steve Jobs fame where people would consider him as a cautionary tale. Regardless, his focus, vision, and charisma had a far greater effect. For me Steve jobs was a great visionary because he truly did change our world.

**Yasser Mohammad**  
Business Development Executive



# Employee Appreciation



## Mallikarjunan Rajendran, Sr. Project Manager says...

I wanted to appreciate **Soumma** since long for the time and efforts she spent in bringing our newsletter a success. I was very impressed to watch her so skillfully navigate between the different project/assignments; outcome was very good. Keep up the good work!!



**Shruthi** has put in outstanding efforts in the Freyr Submit product. The updates/guidance she is providing to product engineering and QA team is valuable. I am looking forward to seeing the good work.

## Prasanna NG, Project Manager says...

The success of this project could not be imagined without **Ram**. Technical expertise and the ease of handling tight situations come naturally to him. He is a great and valuable asset to the company!



**Arvind** has worked for this project with tremendous rigour. His pleasant smile and attitude towards work is commendable. It's a pleasure to work with him any day!



## Lakshmireddy, GM-International Drug Regulatory Affairs says...



**Sunil**, has prepared an excellent overview on the benefit risk assessment for a product based on which the client has taken a decision to go ahead and file/ register the dossier in Europe. They had approached Freyr for the same and we delivered the strategy within a time frame with positive outcome.



**Sheetal**, is quick learner, flexible, dedicated and hardworking professionally and very soft and gentle personally. She carries an obedient and well-mannered attitude. I wish her all the best to reach the great heights of success in his professional carrier.

## Murali Krishna, Manger - Regulatory Affairs says...

**Rayappa Reddy G**, completed a large number of RMQs in set time lines for GnR Project, there was very tight time line to complete the set target. Rayappa has shown a great positive attitude towards work and taken the task positively and also worked on weekends to meet the set targets.



**Mahesh Gorle, Technical Lead says...**



**Balakrishna,** We appreciate the endless hours of service he has dedicated to getting the previous project completed on time. Especially I like his involvement and commitment during project development. I wish him all the best in his future endeavors.



**Vinod Reddy,** I was personally impressed with the way he kept the team motivated and focused, even in the face of several obstacles. I have seen lot of improvement within short period of time.

**Azam Baig, Technical Lead says...**



**Hari Babu,** I would like to appreciate him for the amazing work on the DMS project. The endless hours he has spent working on this project, and the professionalism that he has portrayed has impressed the team. I appreciate him for delivering the work in time.



**Rathna Kumar,** It's worth mentioning that he is working as one of the team members in our DMS project. He is a good team member. I appreciate his smartness and quick quality delivery on time. I like his attitude and professionalism in helping team members in my absence. I appreciate the way he has trained himself in SharePoint and came up with good results.

**Nareen, Technical Lead says...**

**Upendar,** I really appreciate the effort he has put in the project. He has been putting in a lot of extra time, and the results are paying off. I'm so happy to see his hard work resulting in such success!



**Tirumala Rao,** his motivation and dedication towards the work is highly appreciable. It's really commendable to see how he organizes his time and inspires his team members to move forward. I am happy to have a team member like him who is enthusiastic and motivated.



**Shabaaz Khan Muhammad, BDM says...**

**Tausif** has been an excellent support throughout, I highly recommend him for his extreme dedication towards work. He is a great business development professional to work with who not only understands all the dynamics of the industry and products/services but has innate abilities to integrate it with the overall business vision for profitable outcomes. He goes up and beyond his designated job responsibilities, which is what I feel is the biggest asset in him.



# Demystifying Clouds with Services and Security

Ankur Bapna  
System Administrator

## INTRODUCTION

Cloud computing comes into focus only when we think about what IT always needs: a way to increase capacity or add capabilities on the fly without investing in new infrastructure, training new personnel, or licensing new software. Cloud computing encompasses any subscription-based or pay-per-use service that, in real time over the Internet, extends IT's existing capabilities. "Cloud computing is a general term used to describe a new class of network based computing that takes place over the Internet, basically a step on from Utility Computing. In other words, this is a collection/group of integrated and networked hardware, software and Internet infrastructure (called a platform)."

Grid computing is a technology approach to managing a cloud. In effect, all clouds are managed by a grid but not all grids manage a cloud. More specifically, a compute grid and a cloud are synonymous, while a data grid and a cloud can be different.

### Grid Computing -

Refer to resource-pooled environments for running computer jobs (like image processing) rather than long running processes (such as a Web site or e-mail server)

### Utility Computing -

Refer to resource-pooled environments for hosting long running processes, and tends to be focused on meeting service levels with the optimal amount of resources necessary to do so.

Cloud computing describes both a platform and a type of application. A cloud computing platform dynamically provisions, configures, reconfigures, and deprovisions servers as needed. Cloud applications are applications that are extended to be accessible through the Internet. These cloud applications use large data centers and powerful servers that host Web applications and Web services.

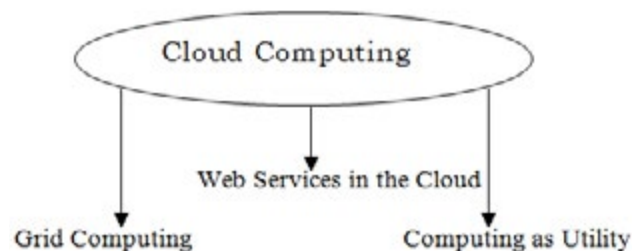
### PURPOSE OF CLOUD COMPUTING:

The term cloud is used to describe and to reflect this class of Internet centric computing infrastructure being transparent (users do not need to know what is behind the scenes!), highly scalable (scale up and down as needed), on-demand, pay as needed and as used.

By using the Cloud infrastructure on "pay as used and on demand", all of us can save in capital and operational investment.

Cloud Computing = + Software as a Service

+ Platform as a Service  
+ Infrastructure as a Service  
+ Data as a Service.



## 2.1 Cloud Computing is Transformational for IT:

- \* Adoption of the cloud is accelerating
- \* Deliver innovation and business priorities
- \* IT transformation: Org, Architecture, Ops
- \* Leverage and Advantage

## 2.2 Technology Trigger:

### ARCHITECTURE

A cloud computing system can be divided into two sections: the front end and the back end. They connect to each other through a network, usually the Internet. The front end is the side the computer user, or client, sees. The back end is the "cloud" section of the system. The front end includes the client's computer (or computer network) and the application required to access the cloud computing system. Not all cloud computing systems have the same user interface.

### CRITICAL AREAS FOR CLOUD COMPUTING (SECURITY)

This environment is a new model which cannot be well protected by traditional "perimeter" security approaches. From this exhaustive document, we have selected six specific areas of the cloud computing environment.

#### 4.1 - Securing Data at Rest

Cryptographic encryption is certainly the best practice and in many U.S. states and countries worldwide, it's the law for securing data at rest at the cloud provider. Fortunately, hard drive manufacturers are now shipping self-encrypting drives that implement the TCG's Trusted Storage standards. Self-encrypting drives build encryption hardware into the drive, providing automated encryption with minimal



cost or performance impact. Software encryption can also be used, but it is slower and less secure since the encryption key can be copied off the machine without detection.

#### 4.2 - Securing Data in Transit

Encryption techniques should also be used for data in transit. In addition, authentication and integrity protection ensure that data only goes where the customer wants it to go and is not modified in transit. Well-established protocols such as SSL/TLS should be used here.

#### 4.3 - Authentication

User authentication is often the primary basis for access control, keeping the bad guys out while allowing authorized users in with a minimum of fuss. In the cloud environment, authentication and access control are more important than ever since the cloud and all of its data are accessible to anyone over the Internet. The TPM can easily provide stronger authentication than username and passwords. If the fired user is logged into the cloud, they can be immediately disconnected. Trusted Computing enables authentication of client PCs and other devices, which also is critical to ensuring security in cloud computing.

#### 4.4- Cloud Legal and Regulatory Issues

To verify that a cloud provider has strong policies and practices that address legal and regulatory issues, each customer must have its legal and regulatory experts inspect cloud provider policies and practices to ensure their adequacy. The issues to be considered include data security and export, compliance, auditing, data retention and destruction, and legal discovery.

### OPPORTUNITIES AND CHALLENGES

#### Opportunities:

1. It enables services to be used without any understanding of their infrastructure.
2. Cloud computing works using economies of scale:
  - \* It potentially lowers the outlay expense for start-up companies, as they would no longer need to buy their own software or servers.
  - \* Cost would be by on-demand pricing.
  - \* Vendors and Service providers claim costs by establishing an on-going revenue stream.
3. Data and services are stored remotely but accessible from "anywhere".

#### 6.2 Challenges

1. Use of cloud computing means dependence on others

and that could possibly limit flexibility and innovation.

2. Security could prove to be a big issue:

3. There are also issues relating to policy and access:

#### Advantages Of Cloud Computing

- \* Lower computer costs
- \* Improved performance
- \* Reduced software costs
- \* Unlimited storage capacity
- \* Increased data reliability
- \* Universal document access
- \* Latest version availability
- \* Device independence.

#### Disadvantage Of Cloud Computing

- \* Requires a constant Internet connection:
- \* Stored data might not be secure:
- \* Stored data can be lost:

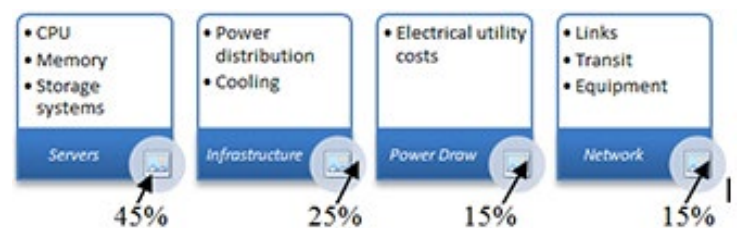
Each cloud systems use different protocols and different APIs... so it may not be possible to run applications between cloud based systems.

#### COST OF A CLOUD:

Amortized Costs (one time purchases amortized over reasonable lifetimes, assuming 5% cost of money)

#### CONCLUSION:

In today's global competitive market, companies must innovate and get the most from its resources to succeed.



This requires enabling its employees, business partners, and users with the platforms and collaboration tools that promote innovation. Cloud computing infrastructures are Next generation platforms that can provide tremendous value to companies of any size.

- \* **Remotely hosted:** Services or data are hosted on remote infrastructure.
- \* **Ubiquitous:** Services or data are available from anywhere.
- \* **Commodified:** The result is a utility computing model similar to traditional that of traditional utilities, like gas and electricity - you pay for what you would want!



# GPW 2013: The year in pics









# Upcoming Events

## January

Sun		12	Tricolour Twist
Mon		13	27
Tue		14	Email Etiquette by Raj patra for All Employees
Wed	1	15	29
Thus	2	16	Work to Orphanage 30
Fri	3	17	Wisdom Box: Clothes Donation drive 31
Sat	4	18	
Sun	5	19	
Mon	6	20	
Tue	7	21	
Wed	8	22	
Thus	9	23	
Fri	10	24	
Sat	11	25	

## February

			Valentine Week	23
				24
				25 TPS by Shrawan for All Employees Developers
				26
				27
			Secret Valentine 14	Client Presentation 28 by Raj patra for All Employees
1		15		
2		16		
3		17	Positive attitude by Anmol for All Employees	
4		18	Work Life Balance Muhurat Pooja for All Employees	
5		19		
6		20	PDR by Vinod pola Life science	
7		21	Team building by Sangeeta Choudhary for All Employees	
8		22	MY Passion Face Painting	

## March

		9		23
		10		24
		11		25
		12	Telephonic Etiquette by Yasser for All Employees	26
		13	CSS3 + HTML by Srinivas A for Software Developers	HTML5 by Nareesh for Software Developers
		14	CSR by Deepak Paturi for Life science	M4 and M5 by Sunil kishore patra for Life science
1		15		29
2		16		30
3		17	Work Life Balance by Maheshwari for All Employees	31
4		18		
5		19		
6		20		
7	My Passion Photography Competition	21	OSR/OOS by Dr Prashant for Life science	
8		22		

# Glimpses of Client Visits



Chief Safety Officer  
- One of the Top 5 Pharma Companies



Manager Audit & Compliance  
- One of the Top 5 Pharma Companies.



Freyr UK Team



Chief Medical Officer & Global Category Manager  
- One of the Top 5 Pharma Companies

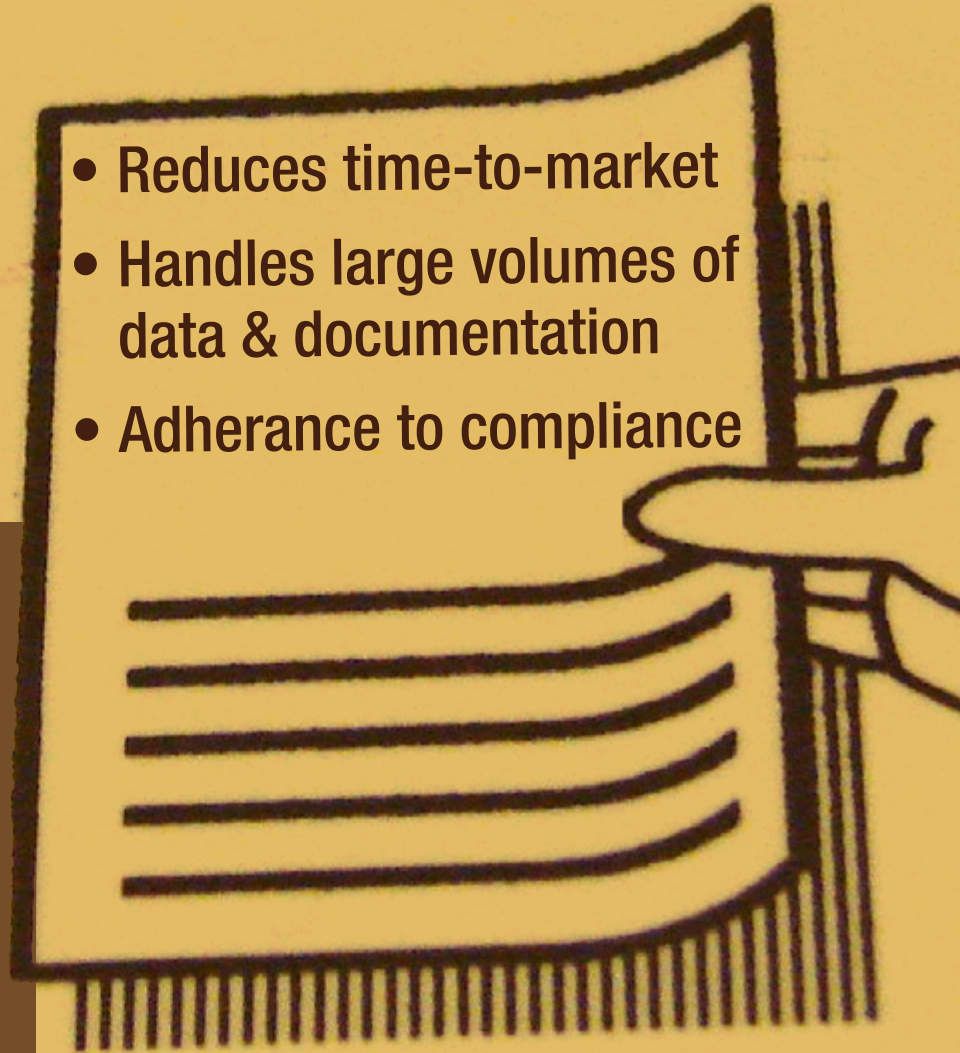
# Freyr Submit

## Reliable Partner in Global Regulatory Submission Needs



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- Handles large volumes of data & documentation
- Adherence to compliance

- 21 CFR Compliant Submission Preparation
- SFDA, FDA, EU - Regional Submissions
- eValidator feature for Submissions
- NeeS Preparation



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# Global Regulatory Responsibility Services

**Regulatory Business Consulting Services**

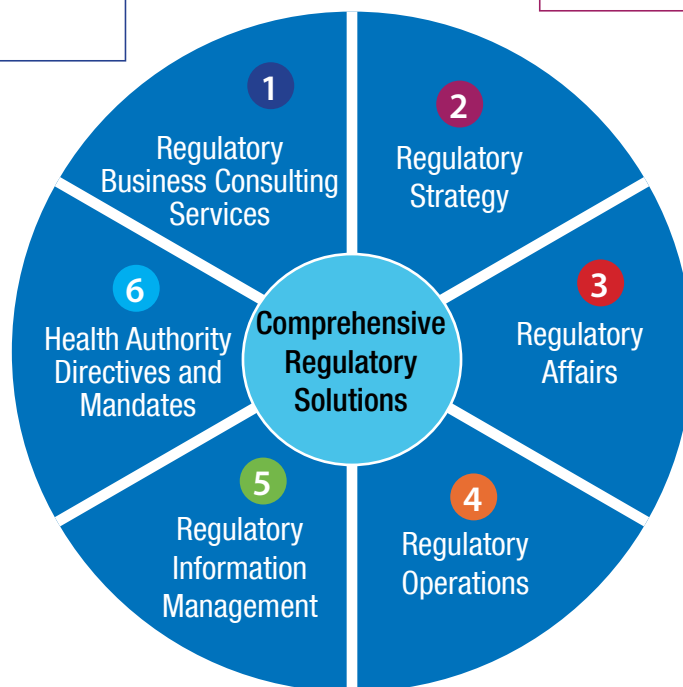
- Regulatory Centralization
- Global Regulatory Process Standardization

**Regulatory Strategy**

- Product & Market Strategy

**Health Authority Directives & Mandates**

- EVMPD/ IDMP Compliance (EU directive)
- PSMF ( EU Directive)
- Cosmetic Safety Assessment (EU directive)
- Metal residue specification Limits ( EU directive)
- Shelf Life Data ( FDA Directive)



**Regulatory Affairs**

- Dossier Preparation
- CTD Modules
- CMC and Change Control
- Labeling
- Clinical Safety and Toxicology Assessment
- Clinical Study Reports
- Cosmetic Safety Assessment

**Regulatory Information Management**

- Regulatory Data Management (Freyr PRM)
  - Products, Market Registrations, Commitments Tracking, Market Application Lifecycle Management, PSMF metrics
- Regulatory Document Management (Freyr DMS)
  - SMPC, Labeling Documents, Submission Documents, Company Core Data Sheet Management, Product Dossiers, Market Registrations/Licenses, Trial Master Files, Legal and Audit Compliance Documents
- Regulatory Submissions Management (Freyr SUBMIT)
  - Market Authorizations, Application Life Cycle submissions, Safety Variations, CMC variations, PSURs, EVMPD

**Regulatory Operations**

- Submission Management (Electronic, Paper, eCTD, Nees)
- Artwork Management
- PSMF Compliance Management
- Raw Material Management

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