

## Sunitha Anumula: Driving Strategic Business Opportunities with Advanced Regulatory Solutions



[Freyr](#) is a leading, niche, full-service global regulatory solutions, and services company supporting large, medium and small-sized global life sciences companies. It provides services in industries such as pharmaceutical, biotechnology, biosimilar, consumer healthcare, cosmetics, chemicals; in their entire regulatory value-chain; ranging from regulatory strategy, intelligence, dossiers, submissions etc. to post-approval / legacy product maintenance, labeling, artwork change management and other related functions.

With 19+ years of experience in Pharma services, consulting, IT and ITES industry, at various leadership positions, Sunitha Anumula, Managing Director at Freyr, has successfully managed organizations from both strategic and tactical perspectives. She is deeply rooted in technology, sales & marketing, operations, human resources and administrative functions of Freyr and has successfully led the same in other companies as well.

## **Moving Ahead Through Self-Motivation**

Every woman is a leader in her own way and this belief has played a key role in shaping Sunitha's career. She recalls, "I have always believed to be on my own and taken calculated risks." In her career, Sunitha deems that leading the most conservative side of the business itself is an achievement, especially in the regulatory domain. Today, not only she is piloting this business but also driving the innovations and processes in the sector.

## **Rising Above Challenges to Create a Difference**

Speaking about initial struggles in her career, Sunitha insists that she viewed them as steppingstones to her professional success. While the early phases of the transition have been challenging, Sunitha is proud of how far she has come today. The challenges she faced in her professional life were instrumental in helping her become a better version of herself, every time. Be it switching from the law background to an entrepreneurial role of technology and consulting organization specific, to the regulatory arena of life sciences or innovating and developing hi-end next-generation regulatory solutions and services, to enable accelerated performance, operations excellence and high cost of compliance to clients, she never deterred herself from self-progression. At present, Sunitha is spearheading the initiative of core procedural automation across the Regulatory value-chain with customized, secured, cloud-hosted, on-demand & on-site Regulatory solutions.

She is familiar with the hesitation and paranoia people tend to counter when initiating to develop and sustain a business. However, Sunitha affirms that she thoroughly enjoyed them all through to make Freyr an end-to-end Regulatory software and solutioning partner.

## **Decisiveness and Persistence: Essential Leadership Hallmarks**

Sunitha emphasizes that decisiveness and persistence are two vital attributes that every transformational leader must possess. As time goes on, success will not be a discussion point even if one is successful consecutively. But how decisive one finds herself in the tough and challenging times matters the most. And that one decision has the power to transform the whole organization, if not the functioning of the entire industry. Beyond that, it is the leader's persistence that brings the value for the

decision. Sunitha adds that if a decision is made, the leader must be resolved to live with it till the end.

## **Building Solid Client Relationship**

Freyr is focused on the customers' end goal, i.e., taking their product to global markets in a compliant way, within the timelines. Stressing more on that, the company asserts that the additional value it creates for its clients is through extended support which others fail to. Most of the time, the unconventional side of the regulatory requirement is time consuming and an expensive affair. In such scenarios, for unique device/medicinal product classification and for unconventional market-tailored business strategies, Freyr has successfully offered end-to-end Regulatory support right from strategy to submissions and lifecycle maintenance.

Sunitha explains that the company continues to solve regional regulatory problems for its clientele using its experts' on-ground knowledge, coupled with utmost attention to their needs and responsiveness. Freyr's work environment is entrepreneurial with the necessary empowerment of teams to ensure appropriate solutions for clients in a timely manner. Its patrons enjoy the attention they get and the proactive approach that its teams follow in solving complex regulatory problems. Sunitha emphasizes that Regulatory is very natural to Freyr's teams, unlike its industry peers. The combination of Regulatory expertise, process experience, global perspective and constant effort for innovation has enabled significant value addition to all Freyr's programs.

## **Disruption to Emerge as Central Business Factor**

The Regulatory function in the Life Sciences sector is held up with many manual processes impacting the organization-wide man efforts, quality standards and compliance best practices. Sunitha believes disruptive technologies like Deep Learning, Machine Learning, and Artificial Intelligence automate many of the life sciences' manual processes to spearhead rapid drug development and quick to market. She reveals that with a complete know-how on end-to-end processes of Regulatory, safety and clinical domains and respective traditional manual approaches, Freyr has developed dedicated CoEs for such disruptive technologies focusing mainly on the life sciences industry.

She assures that apart from the need to concentrate more on the simplification of things, disruptive technologies have not brought any principal changes in the role of business leaders.

## **Delivering Outstanding Services**

According to Sunitha, Freyr is working on couple of technologies to simplify its clients' compliance journey. Some of the technologies are being used in few programs and latest versions will be available soon. Freyr's Regulatory services are entirely driven by customers and clientele needs and are highly customizable. She concedes that the combination of the unique requirements of the company's clients and team's passion to come up with a better solution every time, keeps the workforce excited every day.

Sunitha informs that the clients have the option to select from variety of service models, including hourly consulting, project-based delivery, FTE based model, unit-based delivery and on-demand services as per their requirements. Freyr offers great flexibility by enabling early intelligence activities performed before the project so its team could identify bundling opportunities for multi-country projects, and thus promote efficiency, harmonization and cost savings for clients.

## **Practice What You Preach!**

Advising young talents, Sunitha suggests them to lead by example. She is a strong advocate of the adage – “Do what you Preach”! She reiterates that doing so will ensure complete trust in one's company or business, from employees to stakeholders. She acknowledges that it takes a toll while a person faces new challenges every day. However, she recommends remaining persistent and accepting that failure is a part of the journey. She also encourages to put continuous efforts and strive till one achieves its desired goals as these challenges turn into opportunities.

Further, Sunitha persuades emerging women leaders to take smart chances and embrace new ideas, drive and lead the change from the frontline, as there is power in innovation and technology that can change the way things happen.