Business Outlook
USA-9 TECH ENTERPRISE

Rajiv Rangan | Co-CEO
Company

Freyr

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Freyr PROVIDING END-TO-END REGULATORY SERVICES

As automation is the next big change in the healthcare industry, customers find it challenging to adapt to new technologies, and innovations are a big challenge for the pharma industry, which frames a significant portion of the healthcare and life sciences industry. The pharma industry is going through a transformation of digitalization and is driven by global regulations. The diverse and fast-changing international Regulatory requirements demand a robust technology infrastructure to adapt to those changes and achieve 100% compliance. The cost of innovation and automation is relatively higher.

To address these challenges, Freyr offers a complete suite of Regulatory tools and software services that match client requirements: publishing and submissions, labeling, Regulatory Intelligence, Regulatory document management, trial master files, IDMP, and end-to-end Unique Device Identification (UDI) compliance solution. Freyr's proprietary Regulatory tools are flexible, intuitive, user-friendly, ready-to-use, efficient, secured, and cloud-hosted, enabling organizations to streamline all their Regulatory activities.

From developing their first EVMPD application in 2011 to being the pioneer in enabling organizations to automate their Regulatory processes in 2021, Freyr's journey is always rooted in technological transformation in the life sciences Regulatory

landscape. Over the years, Freyr has become a leading, niche, full-service global Regulatory Solutions and Services company supporting, Large, Medium and Small size global Life sciences companies (Pharmaceutical, Generics, Medical Device, 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.

Kranthi Reddy | VP Freyr Regulatory software services

Today, Freyr is headquartered in New Jersey, USA, and has regional offices across UK, Germany, Canada, Mexico, Singapore, Malaysia, South Africa, Slovenia, Sri Lanka, Australia, Poland, and has Global Delivery Centre in Hyderabad, India. The brainchild behind the company is Kranthi Reddy, VP of Freyr Regulatory software services, who is armed with more than twenty (20) years of experience in different domains of the life sciences industry and has built a solid vision for the RSS division to solve complex global Regulatory challenges, customers. Kranthi participates as a primary driving force in sizeable transformational Technology programs for Freyr's key customers and other critical industry initiatives in a consulting capacity catered to achieve long-term compliance and innovation goals with a detailed implementation blueprint.

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Freyr is a specialized end-to-end regulatory services company, unlike CROs in the industry where regulatory is only a part of the services offered. Freyr offers a full spectrum of end-to-end Regulatory services that enable life sciences organizations to meet their Regulatory goals across the globe for Pharma, Generics, Biosimilars, Vaccines, Cosmetics, OTC, Nutraceuticals/Food and Dietary Supplements, and Medical Devices. These can range from Regulatory Strategy, Market Intelligence, Dossier Compilation, Audit-ready Submissions, etc., to Post- Approval / Legacy Product Maintenance, Labeling, Artwork Change Management, and other related functions. Freyr believes that there is no “one-size-fits-all” approach and stresses need-based strategic services to be deployed for the client’s sureshot market entry. Freyr iREADY is a Technologydriven Cosmetic Ingredient Database Platform. Freyr iREADY supports proactive Regulatory compliance observance of ingredients and management of product formulae in different markets. Freyr iREADY is an ingredient database platform that enables manufacturers and brand owners to understand the Regulatory requirements for elements across global markets. It supports proactive Regulatory compliance observance and management of product formulae in different needs. Freyr iREADY can be used for new product development and life cycle management of existing products to ensure continued compliance.

Freyr assisted a UAE-based pharmaceutical company focused on providing value-added healthcare solutions with the Regulatory submission management software - Freyr SUBMIT PRO to ease the eCTD submission process. The client benefited from the streamlined submission management with the single-stop platform, which offered predefined and region-specific submission templates and enabled end-to-end submission tracking, joint submissions, preparation, and review. To make the project successful, Freyr had to validate the dossiers as per the concerned Regulatory standards and run against the tight deadlines. “The other example we could give showcase here is the generation of Annex-H reports using RIMS for a top EU-based Pharma Company. The client approached Freyr for assistance in streamlining their existing manual process of filing the Annex H report,” says Kranthi. “As the existing process was manual in nature, the client was facing multiple challenges such as lack of information on current updates, time consuming, error-prone and inaccurate data,

etc.” With minimal human intervention and zero errors, Freyr integrated the in-house Regulatory software (RIMS) to reduce the time in generating the Annex H report.

Presently, the company is working on a couple of technologies for managing end-to-end Regulatory processes integrated with Regulatory intelligence. These technologies are being used in some programs, and the latest versions will be available soon. Their regulatory services are entirely clients’ needs-driven and are highly customizable. Their clients can pick from a variety of service models, including hourly consulting, project-based delivery, FTE-based model, unit-based delivery, and on-demand services as they need. It is a unique requirement of clients and the team’s passion for coming up with a better solution every time that keeps them excited every day.

Kranthi believes in addressing the organization’s end goal, i.e., taking their product to global markets compliant within the timelines. “Stressing more on that, we think the additional value we could create for our client’s is through the extended support by offering them something, which others may fail to,” he says. “Most of the times, the unconventional side of the Regulatory requirement is the time taking and 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.”