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Top 10 CROs - 2019

The demand for clinical research organization (CRO) and conducted clinical trials have been and will keep growing in the upcoming years. This trend is being driven by pharmaceutical, biotech and medical device companies outsourcing these clinical activities to CROs as a result of the increasing size, complexity, duration and costs in clinical trials. With stringent and complex regulatory policies for drug development, the demand for CROs to develop new devices and drugs have become higher than ever. Also spearheading the CRO market is the growth in biosimilars and biologics markets, requirement for specialized testing services and the adoption of advanced technologies in the drug development industry. The growing expenditure in research and development has also been the driving force for the global market of the contract research organization (CRO) industry.

For CROs, drug discovery share is becoming one of the fastest growing segments as contract organizations are crucial in the pharmaceutical sector for drug development in various countries across the globe. As artificial intelligence and machine learning generate great momentum and interest in the pharmaceutical industry, there is a great potential seen from a drug development and clinical trial perspective. AI and ML will bring in increased efficiencies to the statistical analysis and programming of clinical data along with the increasing costs in drug development. Due to a need for experts in therapeutic areas and indications, regulatory requirements and pharmacovigilance, specialists in CRO will be in greater demand.

The current pharma R&D space is being steered by precision-based medicines and immunotherapies for smaller population, genetic led therapies for oncology and rare disease treatment with demanding, complex protocols for drug development. Keeping in mind the current expansions and requirements of the organizations in the pharmaceutical industry, a distinguished panel comprising of CEOs, CIOs, VCs and analysts along with Pharma Tech Outlook's competent editorial team have put together a list of the prominent CROs in the industry. This edition will give you an outlook on the services and capabilities that they have to offer.

We present to you, Pharma Tech Outlook Magazine's "Top 10 CROs - 2019."

Company:
Frestedt Incorporated

Description:
A full-service strategic partner providing targeted research solutions to meet clinical research, biotechnology, regulatory, quality, and biomedical engineering needs

Key Person:
Joy Frestedt
President & CEO

Website:
frestedt.com

Frestedt Incorporated

One-Stop-Shop for Clinical, Regulatory, Quality, and Engineering Affairs Expertise

Science and business don't always go hand-in-hand. But, for decades now, these opposites have been working in alignment, and the outcomes have been and continue to be impressive and path-breaking. For Dr. Joy Frestedt, an industry veteran with over 35 years of experience in regulatory affairs, clinical research, and business leadership, these concepts go even deeper: her business is science. Dr. Frestedt established Frestedt Incorporated, a Minnesota-based CRO in 2008 to offer services in the broad areas of clinical trial development and execution as well as regulatory compliance, medical writing, and the management of corporate quality systems for organizations across regulated industries. "We are a women-owned, independent company working to solve problems with a forward-thinking approach designed to provide all deliverables within tight timelines and budgets," says Dr. Frestedt, President and CEO of Frestedt.

Since its inception, the firm has been providing in-depth expertise in creating, running, and monitoring clinical trials, alongside development and negotiation of regulatory submissions within a company or with regulatory authorities around the world. "We specialize in delivering strategic consulting services and exquisitely targeted clinical, regulatory, quality, and engineering system solutions for the pharmaceutical, medical device, biotechnology, and food-related industries," adds Dr. Frestedt. The company handles highly complex projects for many companies around the world, including some of the largest manufacturers of drugs, devices, and foods, as well as academic centers, CROs, and clinical trial sites.

The decade-old organization's mission is to continuously improve to facilitate adherence to strong business ethics, and work with "good people on good projects using good processes." In alignment with this goal, Frestedt provides products and services designed to meet or exceed customer requirements in compliance with best practices, applicable standards, and specifications.

Dr. Joy Frestedt, President & CEO

Delivering Value through Holistic and Customized Approaches

From preclinical and clinical trial services to post-market research and the integration of new safety, efficacy, and performance data with the development of risk management portfolios, Frestedt supports all stages of product development. The firm offers design and development leadership to research centers conducting clinical trials and regulatory submissions for improving the quality and cost-effectiveness of the research service provided. In addition, Frestedt has a robust, user-friendly, ISO 9001 certified quality management system including a set of standard operating procedures with supporting documents. The company uses this institutional knowledge to develop quality manuals, standard operating procedures (SOPs), and forms or checklists for others.

Furthermore, Frestedt also conducts quality systems audits, to analyze gaps and guide on system improvements. With

thousands of new products—be it drugs or devices—coming to the marketplace each year, a profound need is growing to negotiate clinical trials and regulatory submissions with ease and expertise. Frestedt is poised to fulfill this demand through its comprehensive, high-quality, timely, and cost-effective services.

For example, in the clinical research space, Frestedt is often called to help with regulated medical writing. "From planning and writing a clinical trial protocol to the overall regulatory submission work, monitoring and safety reporting through post-market surveillance activities, our ability to support clients through crisp and clear medical writing is imperative to delivering consistent messaging reinforced by data," says Dr. Frestedt. The organization plans, creates, and oversees development of the critical documentation necessary for regulatory activities in compliance with company policies, notified body requirements, and international regulations and standards.

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The Frestedt Difference

"What truly differentiates us in the marketplace is our approach to tailor each client endeavor to facilitate a timely and high-quality outcome always in compliance with the regulatory requirements," asserts Dr. Frestedt. Currently, Frestedt receives projects based on a respected and valued reputation for quality through "word-of-mouth" advertising. "No project is too big or too small for us. We have an unparalleled team of over 70 knowledge experts who are dedicated to providing the right solution to meet each client's needs." The company's prowess lies in an ability to serve clients as their "first call for help," whenever they need clinical, regulatory, quality, or biomedical engineering support.

If one thing has accelerated the success of Frestedt and driven them ahead of the competition curve over the years, it is their specialized network of passionate industry experts. "Our people have gone beyond the boundaries of clinical research, regulatory negotiations, and quality management systems to address the various pain point of our clients with a holistic approach," states Dr. Frestedt. "We deliver the best value through high-caliber, integrated services based on sound practical experience while working as an extension of an organization's internal team. We strive to be flexible to meet the demands of our clients and hence, collaborate with them as a strategic partner." Another differentiator for Frestedt, greatly appreciated by Frestedt's customers, is the company's willingness to train. Frestedt offers training sessions designed to secure the release of products and claims to the market. In a nutshell, through all the services offered, Frestedt aims to bring good, well-experienced people together to find the right path forward to help accelerate the right solution for specific projects.

Breeding Innovation along the Way

Frestedt believes in the collaboration and sharing of knowledge. In light of this, the company created the Frestedt Learning Center (FLC) to provide access to specific and custom training courses for clients and the surrounding community. FLC offers training for beginner, intermediate, and advanced learners in medical writing, good documentation practices (GDP), clinical evaluation reports (CER), as well as investigational new drug (IND) and investigational device exemption (IDE) applications. In the months to come, Frestedt hopes to serve more clients while delivering the best quality in the market. The company's immediate plans include rolling out significant quality improvement initiatives. "We will continue to support our clients in clinical, regulatory, quality, and engineering affairs and we will assist them in controlling timelines and costs," concludes Dr. Frestedt. Ph