

Headline: Frestedt Incorporated Receives 2021 Best of Minneapolis Award!

Sub header: Frestedt is Growing!

Author: Frestedt Incorporated / Alimentix

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Just like last year, Frestedt Incorporated received the 2021 Best of Minneapolis Award in the Research Institute category Business Hall of Fame by the Minneapolis Award Program.



Best of 2021 Minneapolis

Awarded To: Frestedt Incorporated
Awarded by: Minneapolis Award Program



Best of 2020 Minneapolis

Awarded To: Frestedt Incorporated
Awarded by: Minneapolis Award Program

The Minneapolis Award Program is focused on quality, not quantity. Winners are determined based on information gathered and data provided by third parties. This annual awards program honors Minneapolis-area business achievements and accomplishments. Recognition is given to companies using best practices and implementing programs to generate competitive advantages and long-term values. This award recognizes the best of Minneapolis-area businesses contributing to the U.S. economy.

Frestedt Incorporated's mission is to continually improve clinical, regulatory, quality and engineering affair services to meet client requirements and to adhere to strong business ethics.

Frestedt is different!

Frestedt Incorporated continues to strengthen our differentiation in the marketplace. We are known for our high-quality products and services. We specialize in work across silos and translating languages from clinical to regulatory to quality to engineering. We understand when a drug can be a single molecular entity or must be considered a biologic or botanical. We know when a medical device needs to be considered a combination product and when clinical data is required for device clearance or approval. We also have experience supporting the science behind foods to prevent a food from becoming a drug in the United States. We understand the importance of marketing claims and the limitations required by the regulations. As global regulatory requirements become increasingly complex and as the integration of safety, efficacy and performance across all silos comes more into focus, Frestedt Incorporated helps with immediate project solutions and long-term training and quality system developments. Frestedt can help your team stay on the path to product launch while maintaining clinical, quality, regulatory and ethical engineering compliance.

Frestedt is growing!!



Frestedt Incorporated recently welcomed Adrienne Schroll to the Frestedt Team as VP of Quality! Adrienne is a versatile Quality leader with over fourteen (14) years of experience proving adaptability in a wide-range of areas within the pharma and medical device industries. Adrienne is skilled in development and implementation of quality management systems, establishing and driving site-wide quality objectives, and providing leadership to implement, maintain and improve quality management systems. She has expertise in identifying areas of risk to compliance via proactive monitoring, development and management of processes related to quality systems. She is a proven problem-solver, resolving issues using investigational tools and application of knowledge to effectively communicate a solution.



In addition, Amewoke Adamaley joined the Frestedt Team as a CRQE Assistant! Amewoke is a skilled medical research professional with experience in clinical trial coordination, protocol development and participant relationships. He is experienced in both medical practice and clinical research environments. Amewoke has excellent professional writing and presentation skills, strong knowledge of medical terminology, high analytical aptitude and expert problem-solving abilities.

Dr. Frestedt stated “We are very happy to have Adrienne and Amewoke on the Frestedt Team and we look forward to many more interactions with our client base!”

Frestedt works hard with you!

Recently Frestedt completed an Internal Audit against ISO 13485:2016 for a full quality management system at a novel, virtual medical device company using extensive third-party Contract Manufacturing partners.

Frestedt provided both in-house and virtual regulatory support/strategy to successfully bring generic drug and convenience kits to market for a start-up pharmaceutical company.

A midsize class II device manufacturer needed risk management quality support and recall advice. Frestedt updated SOPs, WIs and templates to ensure ISO 14971 compliance, trained team, implemented new quality system components and supported a class III recall for a device dysfunction.

Frestedt was hired by one of the largest medical device companies in the world to provide engineering support for an FDA submission to ensure technical aspects of IFU and labeling met engineering requirements.

Frestedt also delivered a global Regulatory Plan for a novel radiation protection system at another start-up medical device company.

Alimentix completed a deep analysis of the essential nutrients found in several food types commonly consumed within the United States for a large food company.

About Frestedt Inc.

Frestedt Incorporated (www.frestedt.com) is a service provider founded on February 26, 2008 as an S Corporation in Minnesota. Frestedt Incorporated provides exquisitely customized clinical, regulatory, quality and engineering system solutions for the pharmaceutical, medical device, biotechnology and food-related industries. Frestedt Incorporated clients are involved in all stages of product development from bench, preclinical, and clinical trial services to post-market research and the integration of new safety, efficacy and performance data into the developing risk management portfolios. Frestedt Incorporated provides clinical research design and development leadership to companies and research centers and regulatory submission negotiations and quality system development services in order to improve the quality and cost effectiveness of client products and services. As a result of this broad-based service approach to the industry, Frestedt Incorporated clients have included some of the largest and smallest manufacturers of drugs, devices and foods in the world, as well as academic centers, clinical research organizations (CROs) and clinical trial sites.

About Alimentix

Alimentix (www.Alimentix.com) is a comprehensive clinical investigation center (clinical trial site) dedicated to conducting clinical trials for foods, food ingredients, dietary supplements, natural products, over the counter pharmaceuticals and non-significant risk medical device products. The Alimentix team has conducted trials as diverse as weight loss and osteoarthritis, for products from seaweed calcium to meal replacement beverages and we have published and presented our work both privately and publicly at the podium and in peer-reviewed literature.

Contact

Diane Van Skike, EAA/Office Manager

(952) 426-1747

dvanskike@frestedt.com