LIFE SCIENCES TECHNOLOGY SPECIAL

CIO APPLICATIONS

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Company:
MethodSense, Inc.

Key Person:
Rita King
CEO & Senior Regulatory Consultant

Description:
Provides a platform to enable clients to safely and securely share information and collaborate with suppliers and partners

Website:
methodsense.com

Top 25 Life Sciences Technology Vendors - 2017

Amidst technological innovations, regulatory changes, and increased reliance on patient-centric models, there seems to be a multitude of growth opportunities for life sciences companies. Life sciences undoubtedly remain one of the industries that see rapid technological evolution ahead of them. Even though life sciences has been considered a slow adopter of technology over the years, the future of the industry looks better—with companies adopting new age patient care technologies. Not just that, companies in the life sciences sector today are automating their routine tasks with a vision to invest their time in innovating and creating new business models that are more progressive and patient-centric. From digitizing the way they generate reports to their appointment schedules models and further, post-discharge care, everything is being transformed, which clearly indicates a better future for both—the life sciences companies and patients.

These companies are shifting their focus to technologies like artificial intelligence and automation for assisting patients with innovative services and researching new treatments. With their vision to streamline operations and support patients, the healthcare providers are clearly on their way to completely digitize their operations and reinvent healthcare. On the other hand, healthcare regulations have are also pushing the industry towards better data storage, collaboration, and data sharing in the cloud. In such a scenario, companies are looking to leverage the latest technologies to move to automate their processes and innovate.

To help these life sciences players partner with trusted technology companies, we are featuring a list of "Top 25 Life Sciences Technology Vendors - 2017". The list includes the technology providers that offer groundbreaking solutions to healthcare providers and help streamline their processes.

MethodSense, Inc.

Regulatory Compliance through Software and Services

Technological advancements in the fields of pharmaceuticals, biotechnology, and medical devices bring new compliance challenges with them. Modern and granular regulatory scrutiny for product submissions increase the time to market of products and tend to increase the cost of production. As a premier consultant in the medical sciences, MethodSense, based in Research Triangle Park, NC, helps clients tackle these compliance-related challenges. The company offers InfoStrength—a regulatory compliance information management software—to augment its consulting services and to ensure requirements are met during projects and product development cycles.

InfoStrength software was the result of the years of experience and knowledge of its founders regarding the needs of the life science industry. The software is tailored to cater and support life-science businesses in the areas of product design, development, commercialization, and operations management among others. The solution allows companies to manage critical business operations and control content from one place. Rita King, CEO and Senior Regulatory Consultant, explains, "Our platform enables our clients to safely and securely share information and collaborate with their suppliers and partners while retaining control of their IP and addressing multiple international regulations."

MethodSense's consultants adapt to varied client needs and deliver services that effectively meet global regulatory requirements. Consultants formulate astute commercialization strategies that ensure quality compliance and deal with product submissions, usability studies, quality management system development and management, software validation, risk file management, and other services. All along, they ensure regulatory compliance for the clients operating in the global markets. Also, MethodSense conducts internal compliance audits, provides leadership to support strategic direction and acts as a virtual quality department for the clients seeking clearance of their products.


Rita King, CEO & Senior Regulatory Consultant

In the life sciences industry, information management is not only about the preservation of data, but also about IP protection. InfoStrength enables its clients to meet regulatory requirements of ISO 9000, FDA 21 CFR Part 11, Part 820 Quality System Regulation, ISO 13485 and Annex 11 effectively. The company maintains data integrity throughout the development, implementation, and maintenance of design controls. Though these restrictions are mandatory and stipulated by the industry regulations, MethodSense customizes them for the specific needs of the business through a variety of product offerings. As a software product developer and regulatory consultants, MethodSense is well versed in enforcing software development life-cycle requirements and methodologies, and in implementing software risk management and validation, which have become instrumental for clients who integrate software into their products.

Abiding by its guiding principles of always seeking opportunities to learn and the core belief that a team is stronger than an individual, MethodSense employs a vibrant team that works tirelessly to help their clients become acquainted with FDA and other regulatory norms in the life-sciences industry. The team has successfully supported organizations with sophisticated medical devices with their combination of software and services. For an international medical device company, MethodSense helped identify and develop a product that, through its commercialization, strengthened a partnership with a large pharmaceutical company and created early market entry opportunities for the client and their partner. MethodSense identified the necessary deliverables that were required to bring the product to the market and managed the strategy to attain product realization. The company completed the combination project from initiation to FDA clearance within 12 months, enabling the client to generate profits within the first year of product commercialization.

Recently, MethodSense guided a team of engineers through the commercialization process of a medical device. Taking care of the development of a quality management system, product lifecycle, risk management, and human factors validation, the company helped the client to bring the product to the market in 18 months. In the near future, MethodSense aspires to be a recognized leader in the life science space while executing growth plans with an unwavering focus on client success. CA