



Demonstrating Safety and Performance

MethodSense delivers life science and medical device regulatory compliance consulting designed for clients to get compliant, and stay compliant. We invited CEO of the company, Rita King and President, Russ King, who are both the Founders of MethodSense to tell us more about the Best Life Science Consulting Firm 2017 in South Eastern United States.

MethodSense is a leading global life science consulting firm, providing services and solutions in regulatory strategy, quality assurance, technology and operations. The company helps clients maintain compliance throughout the lifecycle of their products, from ideation and design through FDA clearance or CE marking and post-market regulatory and quality activities. Rita goes into more detail about what the team does in order to help clients, as well as outlining the typical clientele the firm works with.

“Here at MethodSense, the team has industry expertise across the life sciences, but focuses in the areas of medical devices and combination products where the medical device sector converges with the pharmaceutical and biotechnology sectors.

“Typically, our clients do not have a straightforward path to market or would benefit from more support when bringing a device to market, which is why they seek our expertise. Clients we most enjoy working with have challenging, long-term needs that require strategic thinking and ongoing support. These projects often include complex medical devices, that incorporate both software and pharmaceutical products.”

Differentiating itself from its competitors, MethodSense’s

compliant collaboration solutions are of great benefit to the companies it works with, as Rita alludes to, as well as the experience that the team has built over their years of success in the industry.

“When a company works with MethodSense, they benefit from the additional support of InfoStrength Smart Enterprise Suite. InfoStrength is a transformative quality and regulatory information management solution we designed to solve real world problems for life science and regulated companies. InfoStrength provides a platform for managing the submission process, implementing document controls, maintaining critical business information, and enabling cross functional team collaboration. Combining our industry-specific experience and the power of technology, MethodSense works at the intersection of engineering and regulatory compliance in close client collaboration to create commercial success.”

When undertaking a new project, it is important the firm knows what the client expects from the project. Doing thorough research, the team at MethodSense combines their experience with previous success strategies to work out the best solution going forward, as Russ explains.

“MethodSense appreciates that all projects serve an important

business purpose for the client, and that we must focus on and target those business goals in our work. When addressing our clients’ needs, MethodSense combines deep business insight with successful industry strategies, delivering regulatory strategy, quality system regulation compliance solutions, experienced engineering support for risk management file development and safety standard documentation, product validation and usability services that expedite successful FDA and international regulatory submissions.”

Regarding the internal culture within MethodSense, Russ explains how MethodSense ensures all staff are well equipped to answer queries clients may have, resulting in great customer service.

“Importantly, MethodSense is not a staffing firm assigning workers to projects. We are a knowledge company delivering solutions to address business challenges in the arena of regulatory affairs and quality assurance. Also, we strive to create a culture that fosters learning, mentorship and independence. Most projects we work on require a collaborative approach that pools the expertise of many resources to achieve project success, and we have structured our environment to support that type of effort.”

Ultimately, Russ and Rita are clearly excited about what the

future holds for the company, as it continues to achieve its goal of helping its clients to be successful, while also preparing for a wealth of new projects and products which will see MethodSense catapult itself to the top of the industry,

“Looking to the future, our goal is to ensure more industry professionals see us as best in class in what we do,” Russ explained. “We will accomplish this by continuing to guide our clients to success. Currently, we are preparing for complex submission projects that require strategic thinking to bring products to market, such as advanced cancer treatments, radiological devices, combination products that include medical devices and pharmaceuticals, mobile medical devices that deliver more personalized healthcare solutions and many more devices that are comprised of complex systems, and we foresee more of these projects coming our way.”



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