SARACA reduces CER development time by up to 40% with best practices tracker tool

Growing experience producing Clinical Evaluation Report updates leads to highly-effective and cost-efficient methods that benefits clients

FAIR PLAY, SOUTH CAROLINA, UNITED STATES, August 25, 2020 /EINPresswire.com/ -- Growing experience producing Clinical Evaluation Report updates leads to highly-effective and cost-efficient methods that benefits clients

After producing more than 100 Clinical Evaluation Reports for medical device companies during the last three years, SARACA Solutions has developed a tracking tool that supports reducing the time it takes to create an update using new standards by up to 40% -- while remaining highly effective and cost efficient for clients.

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>
> *Kuldeep Tyagi, CEO and managing director*

"Our team's deep experience in international medical device regulatory issues has led to creating these best practices for the benefit of our clients who depend upon us for this reporting compliance," said Kuldeep Tyagi, CEO and managing director of SARACA Solutions. "A number of companies we work with invested time and money into this process but turned to us to help complete them as they were challenged by interpretation of the standards. These companies found us much more effective and cost-efficient which lead to repeat business."

SARACA Solutions, he said, developed a method of grouping specific experts to collaborate. This led to the development of a unique AI-based tool that automates some of the research and collection work, particularly for relevant article searches, which reduces tasks that typically take nearly 15 hours down to about one hour.

A CER documents conclusions for a medical device's clinical evaluation and consists of analyzed clinical data collected from either investigation of a company's device or studies of substantially equivalent devices. Required for all medical devices marketed in Europe, the CER demonstrates that the device achieves its intended purposes without additional risk.

The new European Medical Device Regulation (MDR 2017/745) originally required all medical devices to adopt the new standard this past May. Tyagi noted that many companies held back complying with this regulation with the possibility that regulations would be adjusted, or the deadline extended due to the complex completion challenges. However, early this year regulators pushed this deadline to May 2021 due to the COVID-19 pandemic. In addition, after filing the new standards, he said, companies will need to make annual updates.

Tyagi said their business for producing CERs greatly increase in the last few years due to the approaching deadline. “Everybody waited for the last minute,” he said. “Developing or revising a CER can be complex and the regulations don’t necessarily provide a clear path to its final structure while the resulting report or data, analysis and conclusions for device safety needs to be understood by the notified body.”

ABOUT SARACA SOLUTIONS
SARACA Solutions, founded in 2014, is a leading international engineering services company providing solutions and services in quality, regulatory, mechanical engineering, and open source software development for the medical device industry. The company is based in New Delhi, India, with a location in Fair Play, SC. Our technical and service capabilities range from complete end to end solutions to special requirements for medical OEMs and service providers. SARACA mechanical and embedded engineers have strong technical backgrounds in Design, Engineering, and global regulatory standards – US FDA, EU MDR, EU IVDR, MDD, ISO 13485, TGA, 21 CFR Part820, ISO 62304 and ISO 14971.

Our service-oriented team of regulatory and clinical experts, engineers and designers possess extensive medical industry experience and has a keen understanding of the challenges faced by modern medical device companies. This understanding helps SARACA provide cost-effective customized solutions for market segments including Orthopedic, Cardiology, Medical Software, Neuromodulation, Radiology, Surgical, Imaging Systems, Remote Patient Monitoring, and Laboratory Equipment. SARACA Solutions also has expertise in the Aerospace, Defense, Rail and Transportation industries. Learn more by visiting saracasolutions.com or email contact@saracasolutions.com.
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