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Houston-Based Galen Data Reaches Key Certification Milestone
Certification position company's cloud-based connected medical platform solution for growth

HOUSTON, Texas (January 8, 2019) - Houston-based Galen Data announced today that it has reached a key certification milestone for its cloud-based platform solution for connected medical devices.

The two-year-old company was awarded the ISO 13485:2016 certification following the successful completion of its quality management system audit by global certification firm ECM in late November 2018. The audit ensures compliance with the latest version of the internationally recognized ISO standard.

"The ISO 13485:2016 certification is a critical milestone in Galen Data's mission to provide cloud-based medical device connectivity," said Chris Dupont, CEO of Galen Data. "Medical device manufacturers are turning to us for a cost-effective alternative to building their own connectivity platform. Now they have the added confidence that our cloud-based solution adheres to the highest industry standard for connected medical devices."

ISO 13485:2016 is a stand-alone Quality Management System (QMS) standard that includes formal processes for design and change controls, traceability, risk management, verification and validation testing, and regulatory actions, which are relevant to the medical device industry.

It supports medical device manufacturers and helps ensure consistent design, development, production, installation, and delivery of medical devices and software that are safe for their intended purpose.

"This milestone helps to further strengthen Galen Data's position in the connected medical device market and demonstrates our commitment to regulatory compliance, said Abbas Dhilawala, CTO of Galen Data. "Manufacturers can benefit from a third-party partner like Galen Data who have built their platform under industry standards and are compliant to FDA, HIPAA, and CE Mark requirements."

Building the connectivity infrastructure and meeting regulations can potentially increase costs and add unnecessary risks for companies who lack the required FDA knowledge, technical

expertise, and internal resources. Galen Data's managed solution handles all operational aspects including security, privacy, monitoring, and backups.

About Galen Data:

Galen Data provides a turn-key compliant software platform for device-to-cloud connectivity and data analysis that is compliant to FDA, HIPAA, and CE Mark standards. Their managed platform collects and securely stores data, as well as provides tools to visualize and analyze that data. For companies using the system, the time to market reduces from months to days, at a fraction of the cost.

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