Medical Device Manufacturer Cogmedix Successfully Earns Recertification to ISO 13485:2016

Company's robust and efficient quality management system leads to recertification in virtual audit

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WEST BOYLSTON, MASS. AUGUST 11, 2020 – Cogmedix, a wholly-owned subsidiary of Coghlin Companies, Inc. and provider of world-class medical device engineering, manufacturing and global fulfillment services to a wide range of medical and dental innovators, has successfully earned recertification to ISO 13485:2016. Cogmedix was one of the first medical device manufacturing facilities to become fully ISO 13485:2016 certified nationally when the standard was updated, and are now also one of the first to successfully complete a virtual recertification audit with Total Quality Assurance provider, Intertek, due to the COVID-19 pandemic.

ISO 13485 specifies requirements for a Quality Management System where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Successfully earning recertification to ISO 13485:2016 is a great display of the Cogmedix team's commitment to quality, compliance and continuous improvement.

"This was a new experience for us. The primary keys to our success were leadership to provide insight, flexibility to overcome technology challenges, and our firm commitment to compliance," said Scott Cook, Senior VP of Quality and Compliance at Cogmedix. "The ability to communicate, make resources available, and share the documentation of our quality system in a timely manner during a pandemic was challenging, however with some innovative solutions deployed by our TEAM, and the robust documentation practices already in place, we achieved significant success in all key areas."

"I am proud, impressed and humbled by the dedication of our Cogmedix Team and their engrained focus...always placing quality and compliance first," said Chris Coghlin, President and CEO of Coghlin

Companies. “Our team is unconditionally dedicated to a friendly client experience and delivering the safest and most compliant devices imaginable for our treasured customers.”

Through the in-depth auditing process, Intertek has certified that Cogmedix is fully compliant with ISO 13485:2016. The auditor made positive remarks about the strength of the Cogmedix quality system, design controls and electronic processes, and was pleased with how smoothly the audit was conducted, given the new circumstances.

“Now more than ever having a robust and efficient management system is critical to ensuring operations can continue with minimal interruption in the face of unprecedented external disruption” says Calin Moldovean, President, Intertek Business Assurance and Food Services. “By committing to maintaining their ISO 13485 certification, the Cogmedix team has demonstrated to their customers and the medical device industry that they are prepared for whatever comes next and that they are taking the proactive steps to ensuring quality and compliance in an ever changing and critical field. We at Intertek are pleased to be their chosen partner on this journey forward and congratulate them on this achievement.”

ABOUT COGMEDIX

Cogmedix is an FDA registered, ISO 13485 certified company that provides turnkey medical device engineering and manufacturing services to medical and dental OEMs through its Medical Technology Brought to Life™ mission. Cogmedix delivers high-quality finished devices to market with compliance, competence and commitment. Cogmedix is a subsidiary of Coghlin Companies, Inc., a privately held Time to Market Services™ Company headquartered in Westborough, MA. Visit cogmedix.com to learn more.

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