



CIMTEK's Enhanced Magellon Software Eases FDA Compliance

Medical Electronics Manufacturers Gain Speed to Market and Control in Meeting Quality Regulations

BOSTON (Nov. 19, 2008) — [CIMTEK](#), the market innovator's first choice for managing product quality, has announced an upgrade to its [Magellon](#) Quality Lifecycle Management (QLM) software – giving medical device-makers a streamlined way to rapidly deliver quality products and maintain compliance with the Food and Drug Administration's (FDA's) Title 21 Code of Federal Regulations (CFR) Part 11.

The solution brings together the data, analysis and processes required to bring high-quality products to market, quickly and efficiently. Magellon now includes electronic device history record data capture and storage to trace key product test, quality and manufacturing process records electronically, from design through manufacturing and post-sales support.

Magellon answers medical electronic manufacturers' 100 percent quality imperative: Ensure safe and efficient patient care while eliminating the potential for devastating product flaws or failures. Its browser-based interface fronts a powerful database engine that overcomes the challenging, highly fragmented approach to collecting, analyzing and storing data, often in a wide variety of formats. Providing real-time access to the manufacturing floor, the software remotely monitors quality, testing and production performance around the world.

"Manufacturers today are living under scrutiny from federal regulators and the public at-large, while their brand is measured on bringing innovative products to market," said Stan Smith, CEO of CIMTEK. "The new product introduction cycle can no longer be hindered by manually chasing down compliance information."

The FDA's 21 CFR Part 11 requires that electronic records and signatures be created, maintained and archived throughout medical product development cycles. Until now, collecting and organizing this information has been a resource-intensive, fragmented process for most medical manufacturers.

Magellon generates full audit trails proving that authorized users are involved in key development phases, test devices are operating correctly, manufacturing teams are adequately trained from design through market delivery, and the integrity of manufacturing

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2-2-2 CIMTEK Launches Enhanced Magellon Solution for FDA Compliance

operations remain constant. These capabilities also support the FDA Sentinel System which will enable the FDA to securely query multiple, existing data sources in remote locations, such as electronic health record systems and medical claims databases, for information about medical products.

The software is part of CIMTEK's award-winning quality lifecycle management (QLM) solutions, the only holistic set of test software, systems and services for electronics manufacturers. Dozens of leading medical, consumer, aerospace and automotive electronics manufacturers rely on CIMTEK's offerings as the foundation of their product development strategies – to strike the elusive balance of improving quality, decreasing production costs and accelerating time to market.

The solution is available via a hosted model on a subscription basis. Pricing is contingent on modules, locations and product volume. Additionally, test systems manufactured by CIMTEK are shipped with Magellon capabilities to provide quick implementations and rapid results. For more information, visit www.cimtek.com.

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CIMTEK solves electronics manufacturing's biggest challenge: how to bring high-quality products to market quickly and cost-effectively while driving exceptional product quality. With CIMTEK's Quality Lifecycle Management solutions, manufacturers leverage critical information on performance, functionality and reliability captured in the design, manufacturing and post-sales repair phases to drive higher quality designs, smarter sourcing and consistently profitable products. Since 1986, CIMTEK has been the partner of choice for innovative test solution by leaders in aerospace, automotive, high-tech and industrial manufacturing. Its customer include Microsoft®, Motorola®, Honeywell®, Siemens®, Visteon®, Delphi® and DuPont®. For more information visit www.cimtek.com

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