



Coghlin Companies' Cogmedix Achieves Recommendation for Continuation of ISO 13485:2003 Certification

Domestic medical device contract manufacturer receives accolades for quality management

WORCESTER, MA. – August 11, 2009 – [Cogmedix](#), a US-based, FDA compliant contract manufacturer for medical and clinical devices, announced today that TUV SUD America, registrar for Cogmedix, recommended the company for continuation of its ISO13485:2003 certification from the International Organization for Standardization (ISO). ISO 13485:2003 certification – a quality management system that requires organizations to provide medical devices and related services that consistently meet customer and regulatory requirements – exemplifies the Cogmedix commitment to delivering the highest quality manufacturing processes and medical device products.

“ISO 13485:2003 reinforces our uncompromising commitment to manufacturing the highest quality medical devices on the market,” said Lianne Coppinger, Director of Compliance and Regulatory for Cogmedix. “Cogmedix received exceptional feedback throughout the audit, and on the final report, for the company’s consistent dedication to quality.”

Established in 2003, the ISO 13485:2003 standard encompasses quality management system requirements harmonized with the FDA’s Quality System regulations, as well as those mandated by the ISO 9001:2000 standard.

“Our goal is to deliver the very best contract manufacturing support to our customers,” said Chris Coghlin, President and CEO of Cogmedix. “Obtaining this recommendation for continuance of certification, along with our 21 CFR Part 820 compliance gives our customers the confidence that their products are provided with unparalleled quality.”