



DTx Awarded ISO 13485 Medical Device Industry Certification

15 June 2007 Melbourne, Florida

DTx is pleased to announce the receipt of EN ISO13485:2003 certification. TÜV Rheinland of Product Safety GmbH, a global Notified Body for medical products, awarded this stringent ISO standard. EN ISO13485:2003 is the internationally recognized standard focused on and designed to assure that certified OEMs adhere to the rigorous requirements necessary in the regulated medical device industry.

Tight process and product controls and resistance to change characterize the medical device industry. The EN ISO13485:2003 reinforces for our Customers that DTx takes the same care in manufacturing our products that medical device OEMs take in theirs. ***"DTx understands this industry and provides services to solve the unique challenges that medical device manufacturers face. Registration to EN ISO13485:2003 demonstrates our commitment to and support of our medical device Customers."*** said Chris Colebaugh, DTx Quality Engineer. ***"Medical OEMs making outsourcing decisions can continue to have the confidence that DTx can assemble computing solutions into manufacturing ready sub-assemblies or in other cases, build the entire medical device."***

As a global solutions provider, designing and manufacturing quality products and providing services tailored exclusively to medical device manufacturers have always been the focal points of the DTx philosophy. As far back as 1994 when ISO 9001:2000 certification was awarded, DTx pledged to provide consistent quality product. In 2003, DTx's Executive Management team initiated the streamlining of processes, focusing on DTx's position as the leading independent provider of microprocessor-based subassemblies for medical OEMs. DTx furthered its goal towards excellence introducing a scalable, lean manufacturing program (2004). The development of proprietary software automating Production, Device History Records, Product Life Cycle Management, Product Revision Control, and Product Testing (2005) are just a few enhancements to the DTx system. EN ISO13485:2003 was acknowledged as the next vital step towards the goal of quality, and the DTx team spent 2006 perfecting operating and quality processes and procedures in preparation for certification.

Having obtained this certification enhances DTx's ability to evolve strategic partnerships and engage new customers who would benefit from a supplier that provides the highest quality product, identically each time they order for the life of the product. That is the DTx promise.

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