HCL TECHNOLOGIES | HCL

NEWS RELEASE

For immediate publication

HCL Tech first in India to achieve ISO 13485:2003 certification, for design and development of medical devices

Customers gain as certification renders HCL Tech design processes FDA and CE compliant

Noida, August 4, 2004: HCL Technologies, one of India's leading global IT solutions providers, today announced that it has achieved ISO 13485:2003 certification from TUV Rheinland, for the design of medical devices. HCL Technologies has thus demonstrated that it is the ***first Indian company*** to have the requisite quality systems in place and that these systems are consistently executed in daily operations.

The ISO 13485:2003 (successor to the ISO 13486:1996) is an internationally recognized quality standard, specifically applicable to the design, development and manufacturing of medical devices. This certification will enable HCL Technologies to improve quality and customer responsiveness, besides providing wide-ranging design services to the Medical devices industry.

Speaking about this achievement, Mr G H Rao, Associate Vice President, HCL Technologies, said, "At HCL Technologies we took an early decision to pursue this quality certification so our customers could benefit. The cost of non-certification adds a significant burden in terms of additional time, effort and resource expended in convincing regulators that acceptable quality standards are being met. This cost is indirectly borne by customers. We are proud to be the first Indian company to have taken this initiative, enabling us to offer quality, cost effective solutions to our customers."

Traditionally, medical device companies have retained in-house, the entire life cycle of product development from design to manufacture. Today, some of the top medical devices companies have begun to outsource their product design and sustenance services. In this scenario, the biggest challenge faced by design service companies such as HCL Technologies, is the implementation of regimented medical device development methodologies, mandated by regulatory authorities such as the FDA, European Union and other country specific regulatory bodies.

HCL Technologies' ISO 13485:2003 compliant Medical Quality Management System (MQMS) also addresses several issues specific to the development of medical devices not covered under ISO 13485:2003. Leveraging its considerable design experience, HCL Technologies has adopted additional standards including ISO 14971 for Risk and Safety Management, AAMI's (Association for the Advancement of Medical Instrumentation) SW68 for software development and documentation standards like DHF (Design History Files) for FDA and TCF (Technical Construction Files) for MDD. Thus HCL Technologies comprehensive MQMS allows designers to exceed regulatory requirements set by the FDA or CE, providing significant time-to-market advantages to customers.

HCL Technologies has a significant Life Sciences practice which provides composite solutions to customers in the areas of Clinical data analysis, Clinical Pharmacogenomics, Medical devices & diagnostics and Hospital Management systems, in compliance with FDA regulations.

About HCL Technologies
HCL Technologies is one of India's leading global IT services companies, providing software-led IT solutions, BPO and infrastructure management services. Founded in 1991, HCL Technologies focuses on technology and R&D outsourcing, working with clients in areas at the core of their business. The company leverages an extensive offshore infrastructure and its global network of 26 offices in 14 countries, to deliver solutions across select verticals including Banking, Insurance, Retail, Aerospace, Automotives, Semi-conductors, Petrochemicals and Life Sciences. As of 31 March 2004, HCL Technologies along with its subsidiaries, had 14,783 employees. For more information, visit www.hcltech.com

For more information, contact

Sunayna Malik HCL Technologies Ltd. Tel: 95120-2520917 sunaynam@corp.hcltech.com	**Aseem Bhargava** IPAN Tel:91-11-23326200/6212 abhargava@ipan.com