

**NEWS RELEASE**

**For immediate publication**

***HCL Technologies launches 'CrosSView'- a Validation Methodology - for Life Sciences industry***

Enables companies to meet FDA validation requirements

**New Delhi, August 31, 2004** - HCL Technologies, one of India's leading global IT solutions providers, today announced the introduction of '**CrosSView**', a framework based Computer Systems Validation (CSV) methodology for the development of robust software applications in the Life Sciences arena. US Pharmaceutical and Medical Devices companies can now enjoy the benefits of validated software development, as per the FDA's stringent requirements.

Validation is the practice of ensuring that the software used in the process of manufacturing of pharmaceuticals and medical devices, or in hospitals for patient data, is completely error free, reproducible, and access-secured. Any pharmaceutical manufacturer who does not use validated software, risks the safety, quality and efficacy of its products. CrosSView integrates the stringent guidelines set forth by the FDA, for Validation of Software Systems, with HCL Technologies' existing Quality Management System, thus providing a powerful proposition for vendors across the Life Sciences industry.

Pointing out the salient advantages of CrosSView, Pradep Nair, Director, Global Life Sciences Practice, HCL Technologies said, "The introduction and application of CrosSView, will enable HCL Technologies to deliver systems with verifiable quality to Life Sciences customers, thus improving transparency, satisfaction, trust and over all responsiveness."

CrosSView is a template-driven end-to-end methodology that is predictable, repeatable and verifiable, ensuring that the software applications developed using this framework, consistently meet and exceed the demanding and exacting standards set for Life Science applications.

Nair added, "All Indian pharmaceutical manufacturers targeting the US market, will also have to comply with the validation requirements of the FDA and our framework will provide them the necessary cover to do so."

CrosSView is designed for use in both prospective and retrospective validation efforts for bespoke and commercial off the shelf systems. It lays special focus on

requirements as defined in 21 CFR Part 11 (Code for Federal Regulation) Electronic Records and Electronic Signatures and other relevant predicate rules (Part 58, Part 210, Part 820), as defined by FDA regulations for multiple good practice (GxP) systems. This methodology incorporates Validation Planning, Risk Analysis and Mitigation, Site preparation, System Development, Qualification (Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)) processes, which qualify, or test the optimum and accurate hardware and software performance in highly exacting environments.

The methodology ensures that the CSV-related activities automatically harmonize with the best practices employed in the usage of any Software Development Lifecycle. It marks yet another significant step supporting HCL Technologies' goal to establish itself as a premier provider of services and solutions to the Life Sciences industry.

HCL Technologies' Life Sciences practice provides composite solutions to customers in the areas of Biomedical informatics, Clinical pharmacogenomics, Clinical Trial Management solutions, 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](http://www.hcltech.com)

### **Disclaimer**

Certain statements in this release are forward-looking statements, which involve a number of risks, and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. The risks and uncertainties relating to these statements include, but are not limited to, risks and uncertainties regarding fluctuations in earnings, our ability to manage growth, intense competition in IT services including those factors which may affect our cost advantage, wage increases in India, our ability to attract and retain highly skilled professionals, time and cost overruns on fixed-price, fixed-time frame contracts, client concentration, restrictions on immigration, our ability to manage our international operations, reduced demand for technology in our key focus areas, disruptions in telecommunication networks, our ability to successfully complete and integrate potential acquisitions, liability for damages on our service contracts, the success of the companies/ entities in which we have made strategic investments, withdrawal of governmental fiscal incentives, political instability, legal restrictions on raising capital or acquiring companies outside India, and unauthorized use of our intellectual property and general economic conditions affecting our industry. The company does not undertake to update any forward-looking statement that may be made from time to time by or on behalf of the company.

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