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VelQuest's SmartLab GMP Electronic Notebook is Interfaced With LabWare LIMS at a Large Multi-National Pharmaceutical Company in Support of cGMP Quality Operations

The integration provides a seamless transfer of data between a global enterprise LIMS that centrally manages and tracks all laboratory operations and a GMP electronic lab notebook system which assures the proper execution of the testing methods and all relevant instrument operations at the local site level.

Hopkinton, MA and Wilmington, DE, February 28, 2008 — VelQuest Corporation, the developer of the SmartLab™ GMP Electronic Notebook System and LabWare, Inc. the recognized worldwide leader of enterprise Laboratory Information Management Systems, announced today the integration of LabWare LIMS and the SmartLab GMP ELN at a major multi-national pharmaceutical company for its worldwide quality operations. The customer conducted extensive evaluations of both LIMS and ELN technologies and chose VelQuest and LabWare because each vendor provides "Best in Class" solutions that can be implemented rapidly and cost effectively. Furthermore, LabWare and VelQuest have demonstrated a history of working together in collaboration with the customer to provide a superior level of integration between the LIMS and ELN platforms. This global quality informatics vision will be implemented across many manufacturing sites around the world and will replace numerous installations of legacy LIMS and paper-based processes within the current manufacturing facilities.

As envisioned by the customer, the combined solution involves a multi-tiered application infrastructure that includes the VelQuest SmartLab GMP Electronic Notebook System implemented at the local manufacturing sites and handling all test method execution and instrument data capture operations within the QC and Analytical Development departments. The ELN is seamlessly interfaced with a centralized LabWare LIMS system that manages all material testing requests coming from SAP and other sources, tracking the overall sample workflow, as well as managing all stability studies and key reporting activities across the enterprise.

"This division of responsibilities between the systems makes a lot of sense for global deployments in multi-national Pharmaceutical companies", said Keith Wipprecht, Director of Pharmaceutical Business Development for LabWare. "In large global systems that are deployed to many sites throughout the world, there are key challenges presented by the wide area network when trying to achieve high levels of instrument automation and integration at all of the manufacturing sites. The VelQuest SmartLab GMP ELN, that is installed locally, allows it to more effectively communicate with all of the

local laboratory instruments and the chromatography data systems. This minimizes the amount of information and traffic that needs to be transmitted over the WAN to and from the enterprise LIMS.”

The focused integration affords the following key capabilities:

- LabWare LIMS to SmartLab Input – All product testing requirements and pertinent sample information are directly passed from LabWare LIMS to the SmartLab GMP Electronic Notebook System for execution of the method.
- QC Lab Procedure Execution – Test methods are delivered to approved analysts via hand held tablet PC’s in a wireless lab environment. Each method step is captured with full metadata documentation direct to the SmartLab database. Test method calculations are integrated into the SmartLab validated procedure manager system.
- QC Lab Instrument Integration – Through the SmartLab instrument integration library, data is captured directly from all analytical instruments and chromatography data system (CDS) along with a “compliance state check” on the instrument’s calibration status prior to capturing data.
- QA Dashboard Review Process – In the SmartLab ELN, all QC data is approved within a compliance dashboard that electronically reviews the stepwise method and observation QC test data and flags data that does not meet the desired range. The QA review group needs only to work on data elements with a compliance flag. All data can be reviewed at the click of a mouse button including chromatograms, spectra etc. This capability speeds up the data review process by 50-75%.
- Transfer of Reviewed Results to LabWare LIMS for Specification Checking, Final Sign Off, and Reporting – Once the first level of review has taken place in the SmartLab ELN, all relevant QC test result data is transferred to LabWare LIMS where the results are compared against the product specifications and final sign-off of the results occur by the QA review group. LabWare LIMS provides extensive reporting and trending capabilities to produce Certificates of Analysis, Stability Summaries, and Product Review reports and trend charts.

“Many large pharmaceutical companies are harmonizing their cGMP quality operations on a worldwide basis, eliminating routine, non-value added and often error-prone tasks associated with traditional paper-based QC test processes”, said John Helfrich, Vice President, GMP Automation Programs at VelQuest. “The implementation of SmartLab with LabWare LIMS has been adopted by several of the leading multi-national pharmaceutical companies resulting in significant cost reduction, cycle time and compliance benefits. At the annual International Meeting on Automated Compliance Systems (IMACS – www.imacs-world.com) these companies reported their ability to automate the traditional paper-based data capture and compliance documentation processes saving 20%+ on the cost of operating a quality operation and reducing the cycle times by up to 75%”.

About VelQuest Corporation

Founded in January, 1999, VelQuest Corporation provides a suite of configurable off-the-shelf software products to help transition regulated industries from labor-intensive, paper-based operations to automated, efficient systems with greater confidence in compliance than ever before possible.

The SmartLab™ solution uses VelQuest’s electronic Process Management & Compliance (ePMC™) Core Operating System that is an innovative “method-centric” software automation platform designed to provide the foundation for compliance-based activities in the life science markets. The software embraces the FDA’s “cGMPs for the 21st Century: A Risk Based Approach” and “Quality by Design” initiatives as well as ICH-Q10 (Pharmaceutical Quality Systems), and supports the company’s SmartLab™ applications for a fully compliant electronic laboratory, SmartShell™ 21 CFR Part 11 instrument and application remediation software, and SmartBatch™ electronic batch record system.

For more information, visit the Web site at <http://www.velquest.com/>.

About LabWare, Inc.

LabWare is recognized as the global leader of Laboratory Information Management Systems (LIMS) and instrument integration software products. The company's flagship product, LabWare LIMS, is used by many of the world's leading companies in support of their product development and quality assurance operations. LabWare LIMS offers a very modern and highly configurable LIMS architecture that allows companies to spend less time installing and configuring the system, and more time applying it to their specific information management needs. To facilitate rapid implementations of the LabWare LIMS product, LabWare offers a series of industry specific pre-configured solutions for the Pharmaceutical, Public Health, Forensic, Contract Lab Testing, Environmental Water Testing, and Process industries that significantly reduce the amount of time to implement and validate the product.

Founded in 1988, the company is headquartered in Wilmington, Delaware with more than 15 offices throughout the world to support its customers.

For more information, visit the LabWare website at: <http://www.labware.com/>.

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