



**For Immediate Release:**

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**VelQuest's SmartLab GMP Electronic Notebook System is Integrated with Darwin LIMS™ from Thermo Fisher Scientific**

*The integration provides a comprehensive workflow and compliance data management platform for a large multi-site pharmaceutical company.*

Hopkinton, MA, January 18, 2008 — VelQuest Corporation, the developer of the SmartLab™ GMP Electronic Notebook System, today announces the completion of its integration with Thermo Scientific Darwin LIMS™ to support a major multi-site pharmaceutical company. The pharmaceutical company is implementing a new global quality informatics platform across its worldwide manufacturing sites. The cGMP informatics platform includes the integration of VelQuest's SmartLab GMP Electronic Notebook System for QC laboratory execution, instrument integration, data capture and approvals with Thermo Fisher Scientific's purpose-built pharmaceutical QA/QC laboratory information management system (LIMS). This integration with Thermo Scientific Darwin LIMS enables a seamless workflow and protocol-driven compliance execution and documentation platform with the following key capabilities:

- Darwin LIMS to SmartLab Input – All product test requirements, sample log-in information with specifications and limits are automatically passed from Darwin LIMS to the SmartLab GMP Electronic Notebook System.
- 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 database.
- QC Lab Instrument Integration – Through the SmartLab's instrument integration library, data is captured directly from all analytical instruments and CDS along with a "compliance state check" on the instrument's cGMP calibration schedule prior to capturing data.

- Dashboard Review Process – In the SmartLab ELN, all QC data is approved by 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 speeds up the data review process by 50-75%.
- SmartLab to Darwin LIMS Input – Result values and/or “pass/fail” designations are automatically forwarded to Darwin LIMS for final batch approval including lot specification checking and final COA documentation for regulatory compliance.

“A significant goal in many large pharmaceutical companies is to harmonize the cGMP quality operations on a worldwide basis and eliminate the routine, non-value added and error-prone tasks through automation”, said Bill Buote, Chief Technology Officer at VelQuest. “In most pharmaceutical quality operations a significant amount of people are dedicated to regulatory compliance functions that use costly paper-based processes. The SmartLab software has been deployed in many cGMP facilities worldwide with users reporting at the annual International Meeting on Automated Compliance Systems (<http://www.imacs-world.com/>) their ability to eliminate the paper-based data capture and compliance reporting processes saving 20%+ on the cost of operating a quality operation and reducing the cycle times by up to 75%.

Darwin LIMS was selected because of its open architecture, flexibility and alignment with the company’s pharmaceutical business practices, allowing for easy integration in any environment with tools like those provided by Thermo Fisher Scientific. Employing these tools with SmartLab allowed the team to construct interfaces that both transformed the raw data and routed the transformed data to the correct Darwin server without the time consuming and costly effort of writing custom code. “Thermo Scientific Darwin LIMS provides integration tools that have the capability of interfacing not only to scientific equipment but also to complex systems such as SAP, thereby enabling customers to configure a single interface between their scientific equipment and LIMS - saving them significant time and effort,” says Dave Champagne, vice president and general manager at Thermo Fisher Scientific.

“The integration of Darwin LIMS with SmartLab provides a comprehensive method execution platform with an automated data capture and compliance documentation capability for 21st century cGMP quality operations,” said Bill Buote, Chief Technology Officer at VelQuest.

### **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, 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 <http://www.velquest.com/>.

### **About Thermo Fisher Scientific**

Thermo Fisher Scientific Inc. (NYSE: TMO) is the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. With an annual revenue rate of more than \$9 billion, we employ 30,000 people and serve over 350,000 customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as environmental and industrial process control settings. Serving customers through two premier brands, Thermo Scientific and Fisher Scientific, we help solve analytical challenges from routine testing to complex research and discovery. Thermo Scientific offers customers a complete range of high-end analytical instruments as well as laboratory equipment, software, services, consumables and reagents to enable integrated laboratory workflow solutions. Fisher Scientific provides a complete portfolio of laboratory equipment, chemicals, supplies and services used in healthcare, scientific research, safety and education. Together, we offer the most convenient purchasing options to customers and continuously advance our technologies to accelerate the pace of scientific discovery, enhance value for customers and fuel growth for shareholders and employees alike. Visit <http://www.thermofisher.com/>.

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