



VELQUEST CORPORATION
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INDUSTRY:

Life Sciences (pharmaceutical
and biotechnology)

ANNUAL REVENUE:
PRIVATE

EMPLOYEES: PRIVATE

**ORACLE PRODUCTS AND
SERVICES:**

Oracle Database and RAC 11g

KEY BENEFITS:

- 20-40% Productivity Improvements
- 50-75% Cycle Time Reductions
- Assurance of cGMP Compliance and Documentation Requirements

VelQuest Enables Laboratory Operational Excellence and Compliance

"100% of VelQuest's customers rely on the Oracle database's rich functionality and robustness to support the SmartLab™ and SmartBatch™ applications of VelQuest's electronic Process Management & Compliance ePMC™ platform system.

To thrive in the highly competitive and rigorously regulated 21st century pharmaceutical industry, companies must automate their inefficient, error prone, paper-based processes. Leveraging the Oracle database for its SmartLab and SmartBatch applications for electronic Process Management & Compliance ePMC, VelQuest has enabled its customers to realize significant operational excellence improvements in the form of 25-50% reduced product release cycle times, 20-40% improved resource productivity and costs and 50-75% reductions in cGMP QC Lab and plant batch record compliance deviations."

Ken Rapp, CEO
VelQuest Corporation

Many leading pharmaceutical and biotech companies have priority initiatives to eliminate the routine, non-value added tasks in research and manufacturing through automation. Enabling automation with enterprise-wide intelligence that results from connecting various data islands (e.g., product and process development, pilot operations, incoming inspection of raw materials, in-process monitoring, and final quality control (QC) lab results) improves batch release cycle times.

Additionally, research conducted by VelQuest Corporation confirms that the drive to "go paperless" is anticipated to create significant operational cost savings through efficiency gains. Going paperless allows one to manage the data stream across the enterprise – within the plant, plant to plant, or across global operations. Also, going paperless enables "built-in" compliance by insuring that only authorized analysts, using approved and up-to-date methods, run on validated instruments and use approved reagents to perform laboratory work. This "right first

time” capability reduces laboratory and plant deviations, thereby further cutting time and cost of operations.

SmartLab™ is VelQuest's GMP Lab Execution System and ELN that enables a fully validated and automated approach to paperless data acquisition and compliance documentation storage and retrieval. Its success has been reported by users at the annual IMACS meeting (see below) who cite reduced compliance risks, liberation of valuable resources, and addition of value to existing document management and IT resources. The system integrates with existing IT infrastructures including ERP, LIMS, CDS and Document Management platforms.

The system is deployed in global pharmaceutical companies, generics and contract organizations including AstraZeneca, Bristol-Myers Squibb, Eli Lilly & Company, Forest Laboratories, Gerard Laboratories (a Mylan Company) GlaxoSmithKline, Nycomed, McNeil Consumer Healthcare, Meda Pharmaceuticals, Mundipharma Research LLC, and many more.

Industry Validation

IMACS (International Meeting on Automated Compliance Systems Conference) was developed to provide a forum to detail IT-based compliance and productivity solutions for pharmaceutical, biotechnology and medical devices QC/QA laboratory environments. Topics include paperless lab initiatives, QC/QA e-notebooks, 21CFR Part 11 and 21st Century cGMP remediation issues, integration of PAT technologies, SOP/method-centric automation platforms and process batch record automation. In addition to many general compliance topics, the organizing committee invites industry speakers who have implemented VelQuest's solutions using the Oracle database to detail their technical, business and operational metrics after implementation. Over the last few years, dozens of presentations by leading life science companies have outlined three key benefits from implementing the VelQuest/Oracle solution:

Productivity Improvements

- “50% Elimination of Data Review Time”
- “20%+ Labor Content Liberated”
- “43% Resource Reduction”
- “We Went From 10-15 Errors/Month to ZERO”

Cycle Time Reductions

- “75% Faster Overall Process in Review and Documentation”
- “Instant Access to All Quality Lab Information”
- “When You’re Done, You’re Done – NO MORE PAPERWORK”
- “50% Reduction in Report and Documentation Time”

Reduced Compliance Risks

- “Proper Recording – Enforced Method Execution and Review”
- “Platform for Right-First-Time Initiatives”
- “60% of Labor in QC/QA IS Paperwork – Causes Increase Errors”

Why Oracle?

Both the system configuration information and analytical data are stored in Oracle tables, with extensive use of Oracle procedures supporting the business logic of the application. VelQuest built its SmartLab™ and SmartBatch™ applications using Oracle database servers because Oracle provides the rich functionality and reliability features such as RAC needed for managing data vital to the life science industries. Through continuous development of innovative features, Oracle provides partners the confidence to develop on a reliable, enterprise-grade platform that will continue to remain an industry leader well into the future. Furthermore, as the industry leader in the life science market, the powerful tools and facilities of the Oracle Database accelerated the release and adoption of the SmartLab and SmartBatch systems.

Implementation Process and Best Practices

Implementation scope for VelQuest's customers varies from a single site in one state or country to global deployments of over twenty production facilities. Through VelQuest's innovative "Rapid Implementation Technology" tools and the Oracle database, a typical deployment timeline is approximately 180 days for a fully validated system. In general, the VelQuest deployment team initiates a pilot program to assist customers in gaining real-world experience on a small set of methods and products. It then automates the high-value, high-volume production products, and in the process trains the customer's IT and laboratory resources to finalize the remaining products.

The paperless lab and paperless production plant is now a reality with VelQuest and Oracle.

VelQuest's Mission: Automating cGxP Compliant Method Execution, Data Capture, Instrument Integration and Data Review to eliminate paperwork bottlenecks.

VelQuest, a privately held company, was founded in response to an extensive research and fact-finding mission among pharmaceutical and biotechnology manufacturers. The six-month study confirmed that compliance-related activities have become a major bottleneck in the drug development and commercialization cycle, indicating that up to 70% of laboratory resources are now devoted to decades old, paper-based compliance.

VelQuest developed the industry's first and only integrated GMP Lab Execution System and Electronic Notebook, which eliminates tedious manual paperwork in both the QC lab and the production floor, while providing a common platform for data exchange.