

# From Product Manufacturing to Lot Release: The Complete Electronic QA/QC Environment

Today, technology can be adapted to totally eliminate paper-based systems and replace them with a fully all electronic method execution and data capture and review system. An example of such a system is SmartLab. The platform can stand alone as the QC information management system or interoperate with any higher-order IT infrastructure used today.

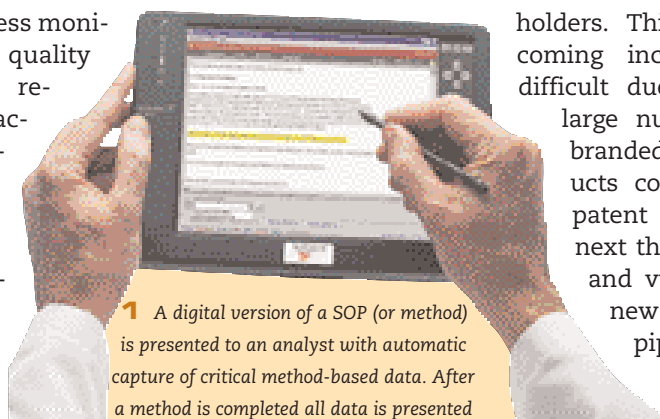
John P. Helfrich\*

**T**he worldwide pharmaceutical industry spends several hundred billion dollars on manufacturing. By improving manufacturing efficiency by only 5%, the industry could yield over \$10 billion annually. Leading pharmaceutical companies, generics and contract research organizations have prioritized programs designed to eliminate the routine, non-value added tasks through automation. Research conducted at VelQuest Corporation confirms that in most regulated companies ~70% of laboratory-based resources are focused on compliance-related functions [1]. Within the quality operations the initiative to “go paperless” is expected to create operational cost benefits yielding millions of dollars in efficiency gains. This “electronic manufacturing” environment enables immediate communication between the disparate data sources from product and process development, pilot operations, incoming raw materials inspec-

tion, in process monitoring and quality control lab results. Interfacing these data sources and higher-order information management technologies provides a platform for enterprise-wide decision making to significantly improve batch release cycle times. Going paperless allows one to manage the data across the entire enterprise – within the plant, plant to plant or across the entire global operation.

## Industry Operational Challenges

The pharmaceutical and biotech industries are challenged to improve product quality, productivity, return on investments and compliance, while, at the same time, generating an annual 10-15% growth for their stake-



1 A digital version of a SOP (or method) is presented to an analyst with automatic capture of critical method-based data. After a method is completed all data is presented to reviewers with visual “flags” for all specifications and materials expiration requirements along with instrument calibration dates, audit trails, annotations, e-signatures and direct “drill-down” links to the raw data sources at the click of a mouse button.

holders. This is becoming increasingly difficult due to the large number of branded products coming off patent over the next three years and vulnerable new product pipelines.

This means that research-based companies must roughly double the number of new lead candidates entering the clinical trial phases of the drug approval process, shorten overall time to market and decrease overall costs. The entire “product life cycle” (research, development and manufacturing) must be streamlined. Within this environment large amounts of data are being generated across the entire enterprise. Today most laboratory operations rely on the use of paper-based “systems” that are often subject to potential human generated errors and require constant “checking” and man-

\* J. P. Helfrich, Director Laboratory Automation Programs, VelQuest Corporation, 25 South Street, Hopkinton, MA 01748, USA



erators. All of these issues contribute to costs and product release cycle times, and if minimized, will significantly affect an operations bottom line.

In 1999, VelQuest Corporation developed a unique, and now patented, process to embed an automated data capture software application within a company's existing SOP's or test methods. In doing this, the software presents only the approved method to the analyst and captures all the critical data and metadata created during the process of implementing a method on the lab or process floor. Data elements include method preparation data (reagent info, weighing operations, metrology etc.), analytical instrument data (chromatography and spectroscopy), and analyst or operator observations (color, texture, shape etc.).

The SmartLab software takes existing written protocols (test methods or SOP's) and presents them as an electronic version with embedded data and metadata capture technology. Analysts and operators interact with the digitized SOP through PC's or handheld tablet PC's that, step by step, force data entry and capture either manually or automatically (direct from instruments). At the end of the method execution process, all data is aggregated in a single review screen (figure 1) with critical data flagged for specifications and a direct link to the original data source. This all electronic system provides review times that are typically reduced by a factor of 50% or more. The raw data files from analytical instruments along with their printed reports are automatically captured and organized in a secure repository for future needs.

Access to the SmartLab platform is controlled via a secure privilege grid with full audit trail and electronic signature capability providing compliance with the FDA's 21CFR Part 11 regulations. The result data is accessible to any authorized member of the QA review or management team. Data from the test methods are automatically parsed and sent to tailored reports including certificates of analysis for batch release documents. These reports can then be electronically reviewed and approved. Data and trending reports can also be created by ex-

porting the database record elements to other in-house IT infrastructure requirements such as a LIMS or ERP/MRP systems. In many respects, this technology represents the "process analytical technology" (PAT) applied to the QC laboratory processes. Just like physical manufacturing processes, the lab environment utilizes "method processes" conducted by analysts and through embedded "method-centric" software (SmartLab), the PAT philosophy can be applied to the lab with equivalent productivity improvements and significant returns on investment.

### Integration with IT Infrastructure

In the past, many organizations have generally focused on implementing a higher-order IT system such as a Laboratory Information Management System (LIMS). These solutions are focused on a limited workflow environment generally related to sample tracking and report management tools. They, in essence, provide an electronic file cabinet, but rarely deliver compelling productivity gains in optimizing laboratory processes. This limited approach is only a "piece of the puzzle" in the integration and distribution of critical-path information throughout the global QC/QA enterprise.

A key issue in any quality organization is the data and metadata produced by the execution of actual test methods and SOP's by analysts and operators. This data, such as instrument calibration data, balance metrology info and analyst observations are rarely captured during method execution, yet, represent the most critical information for investigating any failed test required for lot or batch release or a regulatory site inspection. For a comprehensive 21st Century cGMPs to be

both compliant and productive, added capabilities beyond historical information management systems are needed.

In many production environments, Enterprise Resource Planning (ERP) systems (SAP, JD Edwards, Oracle LS) are considered the integration hub for other systems and often initiate QC or process testing in support of manufacturing. This is transformed into a work order for production, which in turn simultaneously triggers the in-house LIMS to assign work and take input on samples for analysis. Typical interaction between the LIMS and ERP is to retrieve the quality data/specifications, display the work order, capture the results, check results against the specifications and redeploy additional work if needed then release certificates of analysis (CofA's) then upload summary results to ERP. Traditional systems still incorporate many paper-based processes such as the use of "forms" for data capture.

Unfortunately, these forms must be checked for accuracy and re-checked after manual transcription into the LIMS system. This process is the efficiency bottleneck and often error-prone part of the data capture and cataloging process. It is precisely here that the VelQuest SmartLab platform adds the critical-path functions in terms of eliminating the paper issues and forces analyst/operator compliance within an all electronic environment consistent with 21 CFR Part 11 at each step in the method execution. Today, the ERP/SAP-like infrastructure can link directly to the SmartLab platform and eliminate the need (and expense) of a traditional LIMS implementation (figure 2) This expedites the bi-directional data flow between the laboratory and manufacturing, while absolutely ensuring regulatory compliance and integrated data collecting and reporting on a global basis.

### References:

- [1] Laboratory IT – Enabled Solutions Research Report, VelQuest Corporation, November, 2002
- [2] Pharmaceutical and Life Sciences Industry Outlook: Growth Efficiency Enabled by Demand-Driven Supply Networks, AMR Research Report, September 17, 2004
- [3] From proceedings of IMACS 2004 (International Meeting on Automated Compliance Systems), New Brunswick, NJ, May 12-13 2004

more information

[www.new-drugs.com](http://www.new-drugs.com)



Info Click

146274

- More information about the SmartLab platform
- Productivity of Smart Lab in numbers

Fax +44 (0 19 28) 51 38 22