Inside QA/QC Data Management for the Chem and Pharma Industries

By John P. Helfrich

In an effort to improve their financial, technical, and compliance positions, leading chemical and pharmaceutical companies have priority initiatives to eliminate the routine, non-value-added tasks in research and manufacturing through automation. Industry research confirms that in most regulated companies, about 70 percent of laboratory-based resources are focused on compliance-related functions. In addition, most of the QC data capture and documentation is still accomplished within a paper-based process containing multiple layers of review and transcription into other computer-based systems, causing time, manpower, and potential error inefficiencies. Within the quality operations, the drive to go paperless is expected to produce operational benefits yielding millions of dollars per year in efficiency gains. This “e-manufacturing” environment will enable immediate communication between the data sources ranging from product and process development, pilot operations, incoming inspection of raw materials, in process monitoring, and final quality control lab results. Interfacing those disparate data sources with information management technologies provides enterprise-wide intelligence that can work together to improve batch release cycle times significantly and reduce operational costs. Another significant benefit of “going paperless” is that systematic, automated compliance tasks can be “built in” to ensure that only authorized analysts using approved and up-to-date methods, running on validated instruments and using approved and non-expired reagents, actually perform the work. This “right first time” capability is similar to the Process Analytical Technology (PAT) initiatives used in the chemical manufacturing process.

Industry Challenges

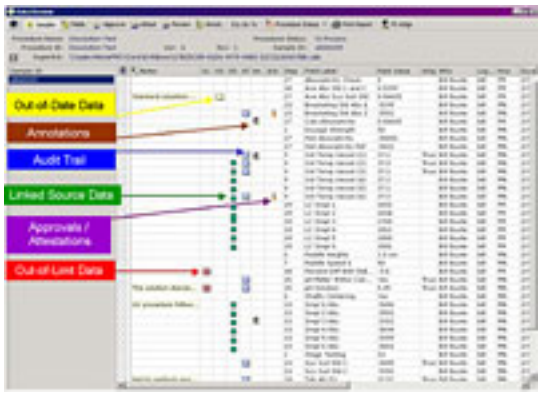
The chemical and pharmaceutical industries are challenged to produce a 10-15 percent growth for their stakeholders in the face of demanding global competition and increasing regulatory constraints. This effectively means that innovator companies must increase the number of new products entering the market and shorten overall time-to-market while decreasing 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 in support of operations. Today most laboratory operations rely on the ubiquitous use of paper-based “systems” that are often subject to potential human-generated errors and require constant checking and manual verification tasks that add no value to the operations and significantly contribute to the costs.

Paperless Labs

The automation initiatives in manufacturing over the last decade where driven by the need to control production processes precisely and to cut costs. That environment is now being further adjusted by reviewing the costs associated with

non-value-added tasks. An identified area is the large amount of paper processes used in manufacturing, particularly quality control and quality assurance functions. This e-QA/QC initiative has received attention as one of a small number of critical-path issues that, if solved, will yield significant cost savings for decades. Some key insights obtained from a research survey conducted in 2002, titled “Laboratory IT &#151 Enabled Solutions Research Report,” are revealing:
&#149 Our company has a priority initiative to delegate decision-making, enrich jobs, and create accountability for delegated decisions. We see paperless labs as a tool to empower analysts to fulfill this charter. We also want to reduce the time lab supervision spends on review and investigations so that they can work on process improvement.
&#149 We believe that, through paperless labs, real-time feedback makes it possible for analysts to reduce errors, minimize rework loops, and correct ambiguous results immediately.
The key issues mentioned here are reduced review times, reduced operator errors, minimizing rework and investigations, and ultimately enhancing the work experience for well-trained analysts and operators. All these issues contribute to costs and product release cycle times and, if eliminated or minimized, will significantly affect the QA/QC operational productivity. QA/QC management often refers to these issues as “right first time” initiatives designed to improve productivity and eliminate the time and resource-intensive investigation processes should a questionable data element be detected late in the method or release process.

Patented Software Platform



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Data is presented with visual flags for all specifications and material expiration requirements along with instrument calibration verification, audit trails, annotations, e-signatures, and direct "drill-down" links to raw data sources.

A patented software platform was developed in 1999 to automate the test method execution by analysts and to capture electronically the data and metadata during each step in the method. The software links directly with existing SOPs and test methods. In doing this, the software presents only the approved method to the analyst/operator and captures all the critical data created during the process of implementing a test method in the lab or on the process floor. Data elements include method preparation data (reagent info, weighing operations, etc.), analytical instrument data (chromatography and spectroscopy), and analyst or operator observations (color, texture, etc.). Called SmartLab, the software takes

existing written protocols (methods or SOPs) and presents an electronic version with embedded data capture technology. Analysts and operators interact with the digitized SOP through PCs or hand-held tablet PCs that force data entry/capture automatically &#151 direct from instruments.
At the end of the process, all the data is aggregated in a reviewer screen with all data flagged for specifications with a direct link to the original data source. Raw data and printed instrument reports are automatically captured and organized in a secure repository for future reference. Access to the SmartLab platform is controlled via a secure and granular privilege grid with audit trails and electronic signature and annotation functions, providing compliance with electronic data regulations.
The result data is accessible to any authorized member of the lab management team. Customized reports, including certificates of analysis for batch release documents, can be automatically and electronically created and approved. The release data elements are parsed directly into the report template without transcription by staff, completely eliminating the time and human costs of this process in a traditional paper-based environment. Data and trending reports can be exported to other in-house IT infrastructure requirements, such as LIMS or ERP systems.
In many respects, this technology represents PAT for laboratory processes. Just like physical manufacturing processes, the lab environment utilizes “method processes” conducted by analysts, and through SmartLab, the PAT philosophy can be applied to the QC lab with productivity improvements and significant operational cost reductions.

Conclusions

The chemical and pharmaceutical industries are seeking to improve the financial viability of their manufacturing operations as a result of questionable new product pipelines and the erosion of business due to global competition and the large number of products coming off patent over the next 10 years. For decades, most of the data management processes in QA/QC have been “paper-based” requiring numerous non-value-added checks to ensure that data integrity and product quality standards have been realized. Today’s technology can eliminate these paper systems and replace them with an all-electronic capture and review system.
An example of such a system is SmartLab, a platform designed to present existing, approved test methods in a digital form and embed software to prompt analysts and operators automatically to follow the procedure as written and automatically capture all the method data and outcomes. Should the method step have data outside an expected threshold, the analyst is immediately notified and an appropriate action initiated. This process eliminates the operator error or transcription problems that occur when working with a typical paper-based notebook. For the review process, the data is automatically grouped and presented to the reviewer with color-coded flags for specification verification, e-signatures, and full audit trails of activity. Final lot or batch release documentation is automatically created and presented for final review and sign-off.
This lab automation technology provides a compliant platform to maintain operational excellence in the QC/QA lab to ensure product safety and consistency while meeting stringent regulatory requirements. In addition, significant productivity improvements and reduced overall cycle times greatly reduce operational costs.

John P. Helfrich is the director of lab automation programs at VelQuest Corp. Additional information is available at www.velquest.com.

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