

Improving enterprise-level productivity

By KIM SHAH

In an environment of extreme cost containment, integrated informatics solutions contribute significantly to today's pharmaceutical manufacturing laboratories that require increased product quality and compliance with strict regulations, as well as improved efficiencies that can lead to reduced costs.

Modern LIMS (laboratory information management systems) serve as common platform frameworks that other informatics solutions, instrumentation, enterprise systems and enterprise communications tools can plug into to share common functions, without having to build them from scratch for each product. These systems are capable of storing data and methods in a safe and consistent way, thereby ensuring ultimate data security and integrity as well as effective processing distribution.

As a consequence, scientists and researchers are able to easily access data in order to make better-informed decisions in a faster and more reliable fashion. Adopting a comprehensive enterprise-level integration approach to streamline business processes can alleviate some of the challenges facing modern pharmaceutical manufacturing laboratories.

In response to market growth indicators, Thermo Scientific CONNECTS helps bridge the gap between laboratory-generated data and the enterprise-level information that is required for mission-critical management decisions. Because our company is uniquely positioned to offer this enterprise-level so-

lution set, Thermo Scientific CONNECTS allows our customers to more fully integrate the work of the laboratory across the organization and to expand the business of science from the lab throughout the enterprise.

We are also able to capitalize on our ongoing partnership with industry leaders such as Microsoft and Oracle, as well as newer entrants to the integration discussion, like secure document management systems or ELN resources. CONNECTS provides both the integration of instruments and systems, and the interoperability necessary to transform laboratory data into relevant business drivers.

In facilitating this enterprise-wide integration of systems, management will have the information they need for early insight into how pipeline drugs or compounds are progressing on a routine basis, as well as the critical data they need before, not after, any point of crisis that may affect operations, shareholder value or the safety of the consumer.

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We are engaging with our customers in dialogue that will facilitate management-level discussion about the necessity of integrating all of the sources of potential data, including the laboratory and all related instrumentation, enterprise systems like MES (manufacturing enterprise systems), PIMS and ERP (enterprise resource planning), and enterprise communications tools like Sharepoint, BizTalk or document management systems.

In the ideal situation, this end-to-end integration of the entire enterprise will facilitate better data correlation and collaboration, end-to-end report generation, and more secure data exchanges, with the goal of providing management with a dashboard view of the key business metrics essential to running the business.

Pharmaceutical manufacturing operations, contract manufacturing organizations (CMOs) and active pharmaceutical ingredient manufacturers (APIs) are highly regulated and required to control the quality of their analyses according to specific FDA guidelines, which apply to electronic format records that are created, modified, maintained, archived, retrieved or transmitted in their laboratories.

These regulations are valid even for records that are not used in a submission, such as training records and SOPs. As a consequence, one of the major challenges facing the industry is the need to use validated CDS (chromatography data systems) and LIMS that enable compliance with standards and procedures enforced in this highly regulated environment.

For pharmaceutical manufacturing companies today, a key business driver is the availability of a coherent strategy that can integrate data from LIMS, CDS, ERP, MES, ELN (electronic laboratory notebooks) and other sources across the enterprise.

Solutions

Global Pharmaceutical Supply Group (GPSG) Brazil, a unit of Janssen-Cilag Farmacêutica Ltda., Johnson & Johnson, has taken advantage of the latest connectivity opportunities in its São José dos Campos laboratory complex in São Paulo. GPSG Brazil has adopted Thermo Scientific CONNECTS, an integration solution that provides the connectivity for laboratory instrumentation and informatics software, enterprise systems and document management tools, enabling a fully integrated pharmaceutical manufacturing environment.

Every month, GPSG Brazil's manufacturing plant processes more than 10,000 analyses to assure the quality of nearly 2000 samples of raw materials, packaging materials, semi-finished and finished products, water and stability. The site is fully equipped with an incoming laboratory plus microbiologic, chemical, analytical development and research and development laboratories. The manufacturing plant handles both solids and liquids, including Tylenol 750 mg tablets, Tylex tablets, Nizoral tablets, Tylenol drops, Nizoral cream and shampoo, and imported products such as Eprex, Risperdal tablets.

GPSG Brazil selected a Thermo Scientific LIMS solution to deploy in its laboratories to ensure integration with corporate enterprise resource planning package, SAP R/3. Between the production plant and the laboratory that analyzes data from production, there is a need for regular exchange of infor-

mation about quality and analysis values. In order to leverage the full benefits of modern ERP solutions, GPSG Brazil needed a solution to interface the LIMS with SAP so that the LIMS feeds data into the ERP.

By interfacing the LIMS with its ERP, GPSG Brazil can expedite the data flow between the lab and the manufacturing functions, streamline data handling, and integrate data collection and reports. GPSG Brazil needed a validated product that provided sufficient flexibility to deliver all the requirements that a pharmaceutical plant has, such as data security and consistent quality data; a centralized repository for the quality management data; fast and accurate data storage and recovery, and all the industry functionality.

Seamless integration of laboratory instruments to the LIMS and of the LIMS to the existing ERP systems at GPSG Brazil ensures full regulatory compliance at a lower cost. CDS/LIMS integration

also supports and enables the periodic auditing of the supplier certification system utilized by the company to guarantee the quality of its raw materials.

The LIMS/CDS solution achieves quick and accurate transfer of high volumes of data, increasing sample throughput and improving laboratory productivity. Since the LIMS provides increased traceability, the system enables easy and quick access to background data associated with batches, allowing for automated batch control. In the case of failed data, CDS/LIMS integration allows scientists to track both the original failed result and the actual chromatograph in the system. This enables users to find out if there was an operator error or a serious issue that would impact the quality of the product, so as to take all of the appropriate action to protect consumers.

The integrated system detects changes in the production line, determining new analyses to be made. Chromatograms can be viewed during the analysis and the workbook can be customized, in order to view the analytical results. All required modifications may be performed in advance,

preventing unnecessary and time-consuming rework.

The integration of laboratory and enterprise systems has enabled GPSG Brazil researchers to view information that was previously only available in data reports. As a result, delivery of results has been accelerated since fewer steps are required within the analysis process.

Enterprise-level integration is crucial in today's business climate, where near instantaneous response is required by pharmaceutical companies to protect the public and the environment. With CONNECTS, our goal is to bring key business knowledge originating in the laboratory to management at all levels of the organization. The integration of the entire enterprise will facilitate better data correlation and collaboration, end-to-end report generation and more secure data exchanges, with the ultimate goal being to provide management with a dashboard view of the key business metrics essential to running the business. ■



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