

IMPROVING PRODUCTIVITY AND PRODUCT QUALITY: AN INTEGRATED APPROACH

Ronaldo Galvão, Senior Manager, Quality Assurance, Global Pharmaceutical Supply Group Brazil, APILA Unit of Janssen-Cilag Farmacêutica and Kim Shah, VP Marketing and Business Development, Thermo Fisher Scientific, discuss improving productivity and enhancing product quality in the pharmaceutical industry by using an integrated approach.

The challenges facing modern pharmaceutical manufacturing laboratories and the benefits of adopting an enterprise integration approach can be achieved by implementing a coherent strategy that can integrate data from LIMS (laboratory information management systems), CDS (chromatography data systems), ERP (enterprise resource planning), MES (manufacturing enterprise systems), ELN (electronic laboratory notebooks) and other sources across the enterprise. Modern LIMS serve as common platform frameworks that other informatics solutions, instrumentation, enterprise systems and enterprise communication tools can plug into to share common functions, without having to build them from scratch for each product. The following case study demonstrates how Global Pharmaceutical Supply Group (GPSG) Brazil, a unit of Janssen-Cilag Farmacêutica Ltda., Johnson & Johnson, has taken advantage of the latest technological advancements at its São José dos Campos laboratory complex in São Paulo.

Every month, GPSG Brazil's manufacturing plant in São José dos Campos, São Paulo, processes around 10,000 analyses to ensure the quality of raw materials, packaging materials, semifinished and finished products, water and product stability samples. The site is fully equipped with microbiologic, chemical, analytical and research and development laboratories. In addition to holding a strategic position in the production of solids, liquids, creams and shampoos, GPSG Brazil imports a wide range of products while also exporting to many Latin America countries, including Argentina, Uruguay, Paraguay, Chile, Peru and Bolivia. Given the high sample throughput and the high degree of reliability that pharmaceutical companies demand, trustworthy systems and equipment are vital to ensure maximum productivity and retain a competitive advantage.



GPSG Brazil has been using a Thermo Scientific LIMS solution since 1999 to store and control laboratory quality data.

The LIMS has been implemented in all of the laboratories and, in 2001, the company decided to deploy a Thermo Scientific CDS solution to collect, process and ensure the safety of the chromatographic data generated. The CDS integrates 17 HPLC instruments in the chemical laboratory, enabling all the chromatographic data in the lab to be accessed via one central server. The LIMS implementation was divided into cycles reflecting the production flow, starting with raw materials through to the packaging cycle, the semifinished and finished products and product stability. The CDS implementation was divided into four areas, namely solids, liquids, validation and residue analysis. GPSG selected Thermo Scientific LIMS for its laboratories to ensure integration with the corporate enterprise resource planning package, SAP R/3. It wanted to deploy technology that delivered sufficient flexibility to meet the specific needs of the pharmaceutical industry, such as product stability, supplier certification and microbiological analysis. The

Thermo Scientific CDS was required because GPSG needs a validated system that controls the quality of the analysis in line with Johnson & Johnson guidelines.

Integration Benefits

The seamless integration of laboratory instruments with the LIMS — and the LIMS to the existing ERP systems — ensures full regulatory compliance (with the FDA's CFR Part 11 standard that covers the storage and integrity of computer systems data, for example) at a lower cost. Controlled and traceable versions of the original data are created and the whole history of any modification done is securely stored, thus ensuring complete system validation. 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 is integrated with both the enterprise via the SAP system and with the proprietary Janssen-Cilag documentation system. GPSG Brazil is also looking for enhanced integration of its chromatography system; a Thermo Scientific Atlas CDS upgrade will, hopefully, link the CDS

to SAP, in addition to the existing integration with the LIMS. The LIMS/CDS solution enables the quick and accurate transfer of high volumes of data, increasing sample throughput and improving laboratory productivity. As 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. In this way, users are able to find out if any operator error occurred, or a serious issue that would impact the quality of the product, and take appropriate action to protect the end-consumers.

The integrated system detects changes in the production line, determining which new analyses are to be made. Chromatograms can be viewed during the analysis and the workbook can be customized to view the analytical results. All required modifications can be performed in advance, preventing unnecessary and time-consuming rework. The configuration of a list of user profiles enables controlled access to the system as well as to certain functions, efficiently protecting data. The use of this resource allows data to be available as a function of the user's responsibility and his/her role in the laboratory. In addition, the system may incorporate a sequence and/or levels to allow access to the workbooks. The configuration of auditing actions for each user category makes it possible to trace the modifications performed in the workbooks, record the names of the individuals who performed a given action, when it was performed and what was modified. Even if the network fails, data are safe; protection mechanisms ensure the workbooks' integrity.

The implementation has enabled GPSG Brazil researchers to view information that was previously only available in data reports. As a result, the delivery of results has been accelerated, as fewer steps are required within the analytical process. Further fundamental functions are also offered, such as the ability to withhold and return acquisition queues, full-screen chromatogram expansion and baseline editing defects correction. Additionally, acquisition date is displayed on the chromatogram's screen. This precludes an analysis sequence from being saved over another one, thus ensuring the integrity of the original data.

Informatics for the Pharmaceutical Industry

Pharmaceutical manufacturing companies are required to control the quality of their analyses

Thermo Scientific CONNECTS

Kim Shah, VP Marketing and Business Development, Thermo Fisher Scientific

In response to market growth indicators, Thermo Fisher Scientific has introduced a new Informatics initiative aimed at bridging the gap between laboratory generated data and the enterprise level information that is required for mission-critical management decisions. Our company is uniquely positioned to offer this enterprise level solution set, which comprises a combination of Thermo Scientific products, technologies and services that will allow customers to more fully integrate the work of the laboratory into the enterprise, and capitalizes on our ongoing partnership with industry leaders such as Microsoft and Oracle, as well as newer entrants to the integration discussion, such as secure document management systems or ELN resources. CONNECTS enables customers to expand the business of science from the laboratory throughout the enterprise, providing both the integration of instruments and systems, and interoperability necessary to transform data into relevant business drivers. In facilitating this enterprise-wide integration of systems, management will have the information they need to see how pipeline drugs or compounds are progressing on a routine basis, but also have the critical data they need before, not after, any point of crisis that may affect operations, shareholder value or the safety of the consumer.

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 such as MES, PIMS and ERP, and enterprise communication tools like Sharepoint, BizTalk or Document Management Systems. In an ideal world, 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, and enabling management to have the critical data they need before, not after, any point of crisis.

according to specific FDA guidelines, which apply to electronic 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 and LIMS systems that enable compliance with standards and procedures enforced in this highly regulated environment. Additionally, pharmaceutical manufacturers face significant data security and consistency issues: they need to test a wide range of utilization conditions prior to the implementation of any LIMS or CDS solution, thus establishing

more trust in the system and in the information generated. Unless validation is done, a product's quality may be undermined because of an error that might have been overlooked while the system was being implemented. During the validation process, the whole production environment is recreated, the systems are replicated in a "preproduction environment" and they undergo strict testing.

Traditionally, batch control has been a completely manual process, increasing the occurrence of information errors in documents. In addition, the manual detection of how many, which and at what time batch analyses should be done often caused delays in the dispatch of batches to be distributed or further processed. These shortcomings can be addressed by implementing efficient CDS and LIMS solutions, which automatically track the batch. A further significant challenge is the need to transfer the entire documentation from both production and quality control, consisting of countless technical specifications, standards, limits and analysis criteria, to LIMS. This can be a long and demanding activity, requiring intense team involvement in the clear and detailed identification and description of the implementation tasks.

Conclusion

Given the high volume and the high degree of reliability that is demanded of a pharmaceutical company, from sample handling to finished product, reliable systems and equipment are vital for the business to ensure the safety of the consumer and maintain shareholder confidence. Integrated informatics solutions contribute significantly to today's pharmaceutical manufacturing laboratories requiring increased product quality and compliance with strict regulations in an environment of extreme cost containment. 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 more easily and more effectively access data to make better-informed decisions in a faster and more reliable fashion. **Pharma**

For more information about

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