

Thermo Scientific CONNECTS at GPSG Brazil Delivers Enterprise-Level Productivity Linking Laboratories to ERP

The Global Pharmaceutical Supply Group (GPSG) Brazil is an APILA unit of Janssen-Cilag Farmacêutica Ltda., (www.janssen-cilag.com.br) located in São Paulo, Brazil. Janssen-Cilag is one of the world's leading research-based pharmaceutical companies specializing in pain management and fungal disease. Janssen-Cilag is a member of the Johnson & Johnson family of companies; the world's largest personal care and health products manufacturer with worldwide annual sales totaling \$63.7 billion.

GPSG Brazil has adopted a comprehensive enterprise integration solution to streamline business processes. The adoption of Thermo Scientific CONNECTS at GPSG consists of laboratory instrumentation and informatics software, enterprise systems and document management tools to provide a fully integrated pharmaceutical manufacturing environment. Standardization on Thermo Scientific LIMS and Atlas CDS has allowed GPSG to focus on product quality in its Brazil facility.

Profile

The Johnson & Johnson family of companies comprises more than 250 operating companies throughout the world. It employs approximately 120,000 people in 57 countries, 6,000 of whom are based in the UK. Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of healthcare products and related services. It is based in three distinct healthcare sectors: consumer healthcare; medical devices and diagnostics; and pharmaceuticals. The company's consumer products, prescription medicines and medical devices and diagnostics impact the state of healthcare for patients, doctors, and nurses around the world. Since the 1950s, researchers within the Johnson & Johnson group have synthesised more than 260,000 new substances, 80 of which have been developed into marketed medicines.

Global Pharmaceutical Supply Group (GPSG) Brazil is an APILA unit of Janssen-Cilag Farmacêutica Ltda., a member of the Johnson & Johnson family of companies. Janssen-Cilag companies have a long track record in developing and marketing treatments for central nervous system disorders, pain management, infectious diseases, gastrointestinal disorders and oncology. The company is committed to delivering great



medicines and has introduced a range of innovative treatments that can make an important difference to the lives of patients with serious health conditions such as schizophrenia, epilepsy, multiple myeloma and HIV/AIDS. Medicines developed by Janssen-Cilag are used to treat around 1.5 million patients every year.

Janssen-Cilag Farmacêutica was established in Brazil in 1937, where the company's first factory was installed in MÓoca in São Paulo. Today, the company is located in the city of São Paulo and has a factory in São José dos Campos. Every month, GPSG Brazil's manufacturing plant in São José dos Campos, São Paulo, processes more than 10,000 analyses to ensure the quality of nearly 2,000 samples of raw materials, packaging materials, semi-finished and finished products, water and stability. The site is fully equipped with an incoming laboratory plus microbiological, chemical,



analytical development and research and development laboratories. The manufacturing plant handles both solids and liquids, including Tylenol 750 mg tablets, Tylenol tablets, Nizoral tablets, Tylenol drops, Nizoral cream and shampoo, and imported products such as Eprex, Risperdal tablets. 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.

GPSG Brazil has taken advantage of the latest technological advancements in its São José dos Campos laboratory complex in São Paulo as part of its quest for a state-of-the-art IT implementation. GPSG Brazil adopted a laboratory information management system (LIMS) as part of its continuous focus on product quality. The company selected Thermo Scientific LIMS to improve efficiencies and product integrity and Thermo Fisher Scientific's Atlas chromatography data system (CDS) to improve productivity in the laboratory.

Business challenge

Pharmaceutical manufacturing companies such as GPSG Brazil are required to control the quality of their analyses according to specific US 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 GPSG Brazil was the need to use validated CDS and LIMS systems that enable compliance with standards and procedures enforced in this highly regulated environment. For GPSG Brazil, a coherent strategy that integrated data between the LIMS, CDS, ERP (enterprise resource planning), and Documentation system across the enterprise was a key business driver.

GPSG Brazil wanted to deploy state-of-the-art technology which delivered significant flexibility to meet the specific needs of the pharmaceutical industry, such as stability, supplier certification and

microbiological analysis. The company has been using the Thermo Scientific LIMS solution since 1999 to store and control laboratory quality data and the Thermo Scientific CDS solution since 2001 to collect, process and ensure safety of the chromatographic data generated within its laboratories.

Vendor selection

Given the high sample throughput and the high degree of reliability that is required of a pharmaceutical company, proven systems and equipment are vital to ensure maximum productivity and retain a competitive advantage. GPSG Brazil selected Thermo Scientific LIMS to deploy in its laboratories to ensure integration with corporate enterprise resource planning package, SAP R/3. For GPSG Brazil, the incorporation of product quality information from the laboratory within ERP systems was a clear priority. Between the production plant and the laboratory that analyzes data from production, there is a need for regular exchange of information 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.

Ronaldo Galvao, Quality Operations Director – GPSG Brazil, clarifies, “At the time we selected Thermo Fisher as our vendor of choice, we made the decision to standardize on a company with proven expertise in the pharmaceutical industry. We needed a validated product that provides us with 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.”

The LIMS delivered immediate improvements to the laboratory; Galvao continues, “When we originally implemented the LIMS it was a culture change. The LIMS allowed automated control of testing. It optimized



the procedures including the skip lot functionality which determine the frequency of microbiological testing. The stability functionality generated metrics both for performance and for productivity.”

The Thermo Scientific CDS was needed because GPSG needs a validated system that controls quality of the analysis in line with Johnson & Johnson guidelines. Galvao clarifies, “The main reason that we looked for a CDS is for compliance with 21 CFR part 11 regulations. We need to use a validated system that demonstrates conformance with internal guidelines that ‘applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations.’ Using a CDS we can track and keep records, even if not used in submissions, such as training records and SOPs.”

Implementation

The LIMS has been implemented in all of the São José dos Campos laboratories, including incoming laboratory, microbiology, R&D, Analytical Development and the chemical laboratory and is used by around 118 employees. The CDS solution integrates seventeen HPLC instruments in the chemical laboratory, enabling all the chromatographic data in the lab to be accessed via one central server and is used by approximately 37 employees. Thermo Scientific Atlas offers GPSG Brazil a high degree of security and data integrity and is capable of storing the data archives and methods database for the workstations plus it takes care of the GLP requirements. Atlas allows security accesses to be managed in line with 21 CFR part 11, the approvals and rejections function follows the rules for electronic signatures and the raw data integrity is taken care of. Atlas also contains modules for traceability and auditing that are used for management accesses.

The combined implementation of the two systems generated considerably high data reliability, which led the company to upgrade to the latest versions of the systems and ensure their tight integration. The LIMS implementation was divided into cycles reflecting the production

flow starting with raw materials through the packaging cycle, the semi-finished and finished products and stability. The CDS implementation was divided into four areas, namely solids, liquids, validation and residue analysis, because of the different types of inputs and reports specific to each one of these areas.

Post-implementation benefits

Seamless integration of laboratory instruments to the LIMS and the LIMS to the existing ERP system at GPSG Brazil ensures full regulatory compliance; for example, with the US FDA 21 CFR Part 11 standard that covers storage and integrity of computer systems data. Controlled and traceable versions of the original data are created and the whole history of any modification carried out is securely stored, thus ensuring complete system validation. The CDS/LIMS integration also supports and enables the periodical auditing of the supplier certification system utilized by the company to guarantee the quality of its raw materials.

Ronaldo Galvao explains, “The LIMS/CDS solution achieves quick and accurate transfer of high volumes of data, increasing sample throughput and improving laboratory productivity.”

In the case of failed data, the company can track both the original failed result and the actual chromatograph in the system. In this way, GPSG Brazil is able 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 actions to protect consumers.

“Since the LIMS provides increased traceability, the system enables easy and quick access to background data associated with batches allowing for automated batch control,” adds Galvao.

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 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 for researchers at GPSG Brazil 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 since protection mechanisms ensure the workbooks' integrity.

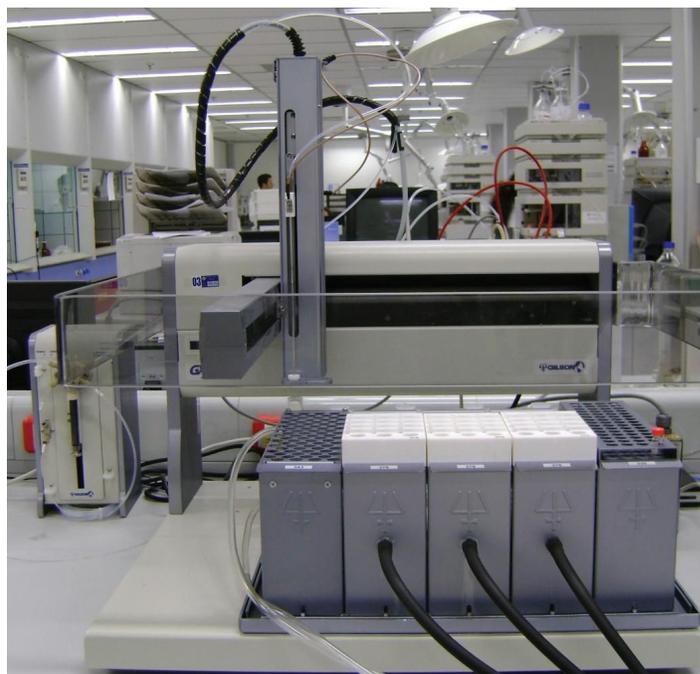
The implementation has enabled GPSG Brazil researchers to view information that was previously only available in data reports. As a result, delivery of results has been accelerated since fewer steps are required within the analysis process. Further fundamental functions are also offered such as the ability 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.

"The overall integration of our connected informatics solutions provides a seamless and secure quality environment at GPSG Brazil," concludes Galvao.

Future plans

The LIMS is integrated both with the enterprise via the SAP system and with the Janssen-Cilag proprietary documentation system. GPSG Brazil is also looking for enhanced integration of its chromatography data system, aligned with a company upgrade of Thermo Scientific Atlas CDS intending to link the CDS to SAP in addition to the existing integration with the LIMS. When the system migrates from the data servers to the 247 controller, GPSG Brazil will include the 3D spectral analysis module.

Ronaldo Galvao comments, "In addition, the LIMS has the potential for integration with other business systems. With a longstanding LIMS in place, we are confident that we can meet any future challenges. And our CDS is flexible to deal with changes in our procedures and guidelines. If the data reliability was already high with our Atlas 2000 system, whose task is to collect, process and ensure the safety of chromatographic data, then this reliability will be enhanced further with the new version."



Conclusion

GPSG Brazil needs to be able to deliver consistent product quality. The connected integration solutions deployed in its multiple laboratories help GPSG Brazil to guarantee tight quality control throughout its business processes, in compliance with strict regulatory controls – from material delivery, through production, packaging and distribution, to worldwide customer service. For GPSG Brazil, 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, GPSG Brazil is able to easily, timely and effectively access data in order to make better-informed decisions in a faster and more reliable fashion. Galvao clarifies, "With Thermo Scientific CONNECTS, GPSG Brazil is supported as processes change and business needs evolve."

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