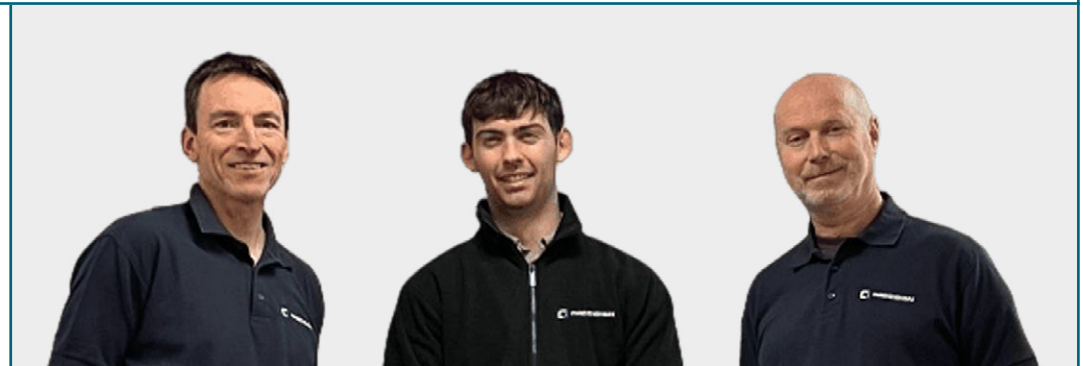# Grupo LETI Ci-DMS upgrade

Background

Grupo LETI is a major pharmaceutical manufacturer, based in Venezuela. They have used Ci-DMS to manage the weighing and dispensing of ingredients at their site in Guarenas since 2007.

Ci-DMS controls the critical dispensing activity, helping the factory adhere to current good manufacturing practice (cGMP). The system records every action and maintains full ALCOA+ compliant records, without operators having to stop and complete paperwork and without the extra cost of second checkers.

Ci-DMS is integrated with the factory's ERP system, so stock adjustments and batch information are updated in real time. It is also integrated with hardware in the booths, including weighing equipment and label printers.

CI Precision project team assigned to the Grupo Leti project

The client commented that "The CI Precision team was fundamental in finishing the project on time, on scope and on budget. The team was knowledgeable, professional and excellent team players. Overall, we are very pleased and feel very confident in having CI Precision as a strategic partner."

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Project objectives

Grupo LETI had planned a major update to their Windows servers and PCs to ensure continued support and security. This included updates to the operating systems and the replacement of existing hardware.

At the same time, they wanted to upgrade to the latest version of Ci-DMS.

Approach

Specialists at CI-Precision drafted a detailed project plan for the 18 week long upgrade. This was reviewed by the combined project team, comprising staff from Grupo LETI, their consultants Axios and CI-Precision. These discussions included assessing the risks at every step and agreeing acceptable mitigations.

The new version of Ci-DMS was installed onto the validation server environment for installation qualification (IQ) and operational qualification (OQ) testing. The hardware proving included installation of the Ci-DMS modules onto new PCs which were tested individually with equipment in the dispensing suite.

The go-live and performance qualification (PQ) were completed successfully within a short, planned shut-down of the dispensing suite.

Challenges

During the hardware proving stage, the team identified an issue with one of the balances used in a dispensing suite, which would not communicate correctly with Ci-DMS. This equipment is an integral part of Ci-DMS operations and so essential for validation. The hardware manufacturer was unable to offer a solution, so the CI Precision team carried out further investigations and discovered that a USB hub in the dispensing suite was using outdated drivers. By updating this we were able to fully resolve the issue.

A further challenge arose in the communications between Ci-DMS and the ERP system. During testing it became clear that certain weight values were being passed incorrectly between the two systems. By monitoring the network traffic the CI Precision team discovered that the problem lay with localised number formats, specifically the thousand and decimal separators (commas and periods). Because Ci-DMS has a dedicated ERP gateway module, a revised data transformation could be applied in the configuration to achieve the required outcome for successful validation.

Outcomes

The project was validated and put live on schedule, without exceeding the short, planned shut-down of the dispensing suite.

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