[BUSINESS SOLUTION]

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Becoming Paperless with an Integrated Laboratory Informatics Landscape

Client: Pharmaceutical Division of a Global Healthcare Organization
Technology: Empower Chromatography Data System and NuGenesis Laboratory Management System

BACKGROUND

The pharmaceutical division of a global healthcare organization has a comprehensive distribution network along with major production facilities in Europe, North America, Latin America, and Asia-Pacific.

The QC laboratories at one of the company's large active pharmaceutical ingredients (API) production sites in Europe utilize more than 100 chromatographic instruments manufactured by multiple vendors. Most of the chromatographic operation was controlled by Empower™ Chromatography Data Sytem (CDS), but a second CDS solution was used for some of the instruments. Their sample workflow was managed by Waters™ legacy Q-DIS/QM,™ a classical Laboratory Information Management System (LIMS), and the weighing process was supported by Balance View, a third independent system.

CHALLENGE

Although the existing system architecture managed daily chromatographic activities adequately, integration of these platforms was lacking. As a result, laboratory operations were still dominated by paper processes. Utilizing paper for information exchange was identified as a significant source of waste and variability, e.g., handling paper documentation was very time-consuming and the related manual steps were prone to errors. Additionally, archiving the analytical raw data on paper added significant cost overhead to their laboratory services. For example, a chromatographic sequence that consisted of 20 samples would equate to the storage of a 50 to 60 page report.

BUSINESS BENEFITS

- Increased compliance.
- Reduced errors.
- Increased data security.
- Improved data sharing.
- Streamlined workflow.
- Increased efficiency.
- Significant cost savings (time, storage space, paper).

Empower™

Since their laboratory operations adhere to GxP regulations, customer and regulatory agency audits are a routine part of business. However, retrieving results and data stored on paper was a very laborious process. For example, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) or FDA regulatory audits, required significant preparation time for structuring paper data, photocopying the relevant documents and cross-checking. Additionally, customers throughout the company's distribution channels would occasionally request information during root cause investigations, which would necessitate expending significant effort to locate and retrieve paper records.

To establish a more automated data flow along with enhanced data management integrity, the client sought to achieve a fully integrated laboratory informatics landscape.

THE SOLUTION

STANDARDIZING ON A SINGLE CDS

The first step towards comprehensive integration was to standardize on a CDS – Empower Software was chosen for this purpose. The advantages of Empower identified by the client include:

- Continuous product improvements.
- Ability to run under technologies like Citrix.
- Comprehensive Application Programming Interface (API) for information exchange between external systems.
- Full scalability so it can be extended as needed.

Previous experience with Empower Software in the client's corporate headquarters laboratories further solidified its selection as the single CDS solution. Empower now controls all chromatographic instruments (over 100) and supports 80 to 90 users at the production site.

A SINGLE DATA REPOSITORY

Although Empower provides comprehensive management of chromatographic data, the client desired an additional solution capable of managing information from a wide variety of analytical techniques. NuGenesis™ Laboratory Management System (LMS) was introduced into the laboratory to meet these needs. NuGenesis LMS was implemented to capture all printed reports for both chromatographic and non-chromatographic results so that all reports would reside in a single compliance-ready and searchable data repository. The benefits of a single repository for reports include a common place for review and approval; easier retrieval of during an audit; and the ability to summarize and send reports to other systems such as LIMS by making using of the API.

A PAPERLESS INFORMATION WORKFLOW

After the adoption of a single CDS for chromatography workflows and an LMS for all testing reports, it was possible to integrate the laboratory information workflow together electronically. Work lists are created within the LIMS and transferred into an internally developed database. The weighing system transfers the weights from the balances into the same database where the weights are included into the work lists. The relevant data is consolidated into the work lists and then transferred into the sample sets of Empower Software. After performing the tests and calculations within Empower, the reports are generated by Empower and printed into NuGenesis LMS where they can easily be accessed. The electronic signature workflow includes two checks by different individuals and is fully supported by NuGenesis LMS. The results are displayed again before eventually being transferred to the LIMS. This entire process, which includes an audit trail, is done without paper or manual steps, thereby reducing time and errors. Hence, NuGenesis LMS works as a central data repository where all chromatographic and related data are securely stored and can easily be retrieved and accessed. Result reports captured by NuGenesis LMS also appear exactly as they had in paper, facilitating a high level of acceptance.

ELECTRONIC DATA RETRIEVAL

When customers request information about certain batches they can now retrieve it themselves within the system based on the ID number. Granting customers access to data within NuGenesis LMS can be done confidently – access levels allow them to see only what they have permission to use. An additional benefit of electronic searching within the LMS data repository is that the time required to prepare documentation for audits is almost zero. Data can be retrieved on short notice independently of record age. Data can be accessed by relevant search terms (i.e. metadata), and printed out for the auditor. In total, this takes only ten minutes (instead of days), which demonstrates to auditors that data management is effective and compliant.

BUSINESS BENEFITS

Adoption of Empower CDS and NuGenesis LMS as the standard CDS and LMS solutions (and integration with the LIMS and sample weighing system) have allowed the company to transition to a greater than 90% paperless process in the chromatographic portion of laboratory operations for API batch release. This has led to a number of significant business benefits, including:

- Increased compliance.
- Reduced errors.
- Increased data security.
- Improved data sharing.
- Streamlined workflow.
- Increased efficiency.
- Significant cost savings (time, storage space, paper).

Measurements performed after project completion have demonstrated that costs for the entire solution were recouped in less than 12 months and analysis processes are more than 50% faster than before. The new paperless lab is an important step towards meeting the company's first time-right culture.

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