[BUSINESS SOLUTION]

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

Increasing Lab Efficiency by Chromatography Data System Harmonization

Client: A Generic Pharmaceutical Company
Technology: Empower Chromatography Data System

BACKGROUND

The client is engaged in the research, development, and production of generic human medicines and in R&D of biotechnology-based medicines. With a vertical integration of business units, their activities span from chemical development and production of active substances, to the pharmaceutical development, manufacturing, and packaging of finished dosage forms. Products cover a large number of therapeutic areas that require complex syntheses and sophisticated dosage forms. The company manufactures and sells products in Europe, as well as in the United States, South America, Australia, and other parts of the world; hence, they must comply with regulatory requirements for the respective countries where it sells products as defined by regulatory agencies such as the FDA, EMEA, and TGA.

CHALLENGE

The analytical R&D, as well as production-related laboratories in the U.S. and Europe consisted of a diverse chromatography software landscape. Most of the LC and GC instruments utilized specific workstation software from several different vendors. This required a high-training effort in order to ensure that individuals made optimal use of the different systems. Due to the number of software packages, keeping the different software solutions current and validated was an additional challenge. Finally, data management, such as exchanging chromatographic information was very cumbersome since data was stored on different drives, DVDs, and CDs. Additional information was contained on paper, in spreadsheets, documents, etc. Furthermore, analytical services was often perceived within manufacturing as the bottleneck during the batch release.

BUSINESS BENEFITS

- Reduced data transfer and switching of applications.
- Reduced training and maintenance efforts.
- Reduced validation efforts.
- Easy exchange and availability of all chromatography-related data and information within and between the different sites.
- Saving of paper and storage space.
- Compliance-ready software.
- A reduction of bottlenecks during batch release.

Empower™

THE SOLUTION

In 2007, the client's Analytical groups began investigating ways of increasing the efficiency of U.S. and European laboratory operations in order to 'do more with the same people' and ultimately reduce bottlenecks during batch releases. This strategy centered on automating processes by introducing a laboratory information management system (LIMS) and by harmonizing the chromatographic data systems (CDS).

The client selected Waters™ Empower™ Chromatography System for their CDS, since it was viewed as the industry standard that undergoes continuous improvements of both standard and add-on capabilities, such as third-party instrument control, method validation, and method development. The software's GMP compliance technical controls and ability to control a wide variety of UPLC™, HPLC, and GC instruments from multiple vendors weighed heavily in the decision. Also of critical importance, the application programming interface (API) allowed Empower to interface with the LIMS.

An Empower client server installation was introduced as the company's standard CDS in the Analytical Research, Development, and Quality Control laboratories and was deployed as independent networks for each site. All implementations were deployed to satisfy regulatory requirements in a validated environment for development and QC. Functionalities with the largest impact from an efficiency standpoint included the integrated e-signature process and the dissolution option, which are considered necessities for a laboratory operating in a generic pharmaceutical company.

The implementations at all sites have exactly the same configuration for the regulated GxP laboratories, therefore the documentation and validation overhead is streamlined. URS, IQ, OQ, and PQ are the same at all regulated sites, which significantly reduces the overall validation time and effort. Also, the Empower Method Validation Manager (MVM) Software, which was deployed in R&D, provides additional savings in time and validation effort. Additional benefits of the Empower CDS implementation include the ability for the QA department to modify standard operating procedures (SOPs), so that paper reports are printed only at the very end of a completed testing procedure versus throughout testing, as had been the case previously, to increase analyst ease-of-use and align with business sustainability practices.

BUSINESS BENEFITS

The harmonization of the CDS application installations and introduction of Empower has significantly increased overall operational efficiency. Despite a heterogeneous mix of projects in the different laboratories, their initial goal of doing "more with the same people" was realized and the Analytical departments experience much less pressure from their production-focused customers.

Benefits include:

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- Reduced training and maintenance efforts.
- Reduced validation efforts.
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- Saving of paper and storage space.
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Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 1 508 478 2000
F: 1 508 872 1990
www.waters.com