

Eliminating Chromatography Data Transfer to Spreadsheets

Client: A Global Generic Pharmaceutical Company

Technology: Empower Chromatography Data System

BACKGROUND

The Analytical Development group of a global generic pharmaceutical company is responsible for late-stage analytical development. The group transfers a number of product characterization methods required for batch release to the Quality Control group, including those tests required for content uniformity. The laboratory is equipped with approximately 100 HPLC systems.

Scientists employ Microsoft® Excel® spreadsheets to perform a variety of calculations with the data generated from their chromatography software. The results generated from these methods are critical, as they ultimately determine whether or not commercialized product is released and how quickly the corresponding revenue can be realized.

CHALLENGE

The Analytical Development group must process large sample volumes as efficiently as possible, while generating highly accurate results. In performing the requisite chromatographic data calculations, the group faces a number of challenges, including:

- Data transfer and data transfer verification.
- Transcription and calculation errors.
- Each scientist spends one to two hours per analysis performing calculations.
- Time and cost associated with software training.
- Costs to develop and maintain macros to perform calculations.
- Software and macro verification and validation.
- A large number of very tedious calculations.

BUSINESS BENEFITS

- Improved productivity by significantly reducing the time required for data transfer to Excel spreadsheets and its verification.
- Using predefined tolerance levels, the software can detect out of spec values and immediately halts problematic runs.
- Mitigating risk by reducing transcription errors.
- Reducing the time and effort required for analysts to confirm data traceability.
- Improved data integrity.
- Reduced time and cost required for validation.
- Improved overall laboratory workflow.
- Testing is performed more rapidly, facilitating batch release.



THE SOLUTION

To address the time, cost, and risk factors associated with developing testing methods for batch release, the company employed Waters™ Empower™ Chromatography Data System (CDS) for data acquisition, management, processing, reporting, and distribution. Utilizing Empower's custom calculation functionality, the company was able to automatically process data and integrate the information within Empower for easy review.

BUSINESS BENEFIT

With Empower CDS, the company is able to perform data acquisition and analysis simultaneously in one integrated software package, thereby realizing a number of high-value benefits, including:

- Improved productivity by significantly reducing the time required for data transfer to Excel spreadsheets and its verification.
- Using predefined tolerance levels, the software can detect out of spec values and immediately halts problematic runs, saving the analysts' time and reducing the cost of solvent that would be wasted if the run were to proceed to completion.
- Mitigating risk by reducing transcription errors.
- Reducing the time and effort required for analysts to confirm data traceability.
- Improved data integrity.
- Reduced time and cost required for validation.
- Improved overall laboratory workflow – the one to two hours required per analysis to perform calculations was eliminated, allowing scientists to focus efforts in other areas of the laboratory.
- With streamlined methods implemented in the Quality Control group, testing is performed more rapidly, facilitating batch release.

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