[BUSINESS SOLUTION]

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# Streamlining Method Validation in Pharmaceutical Product Development with Empower Chromatography Data System

## Client: A Global Pharmaceutical Company
## Technology: Empower Software Method Validation Manager

### BACKGROUND

A global pharmaceutical company develops, manufactures, and markets dozens of prescription and over-the-counter drugs; the therapeutics are used to treat disease conditions, including allergies, arthritis, cancer, diabetes, depression, heart disease, and HIV.

As part of its drug development and approval process, the company uses numerous analytical techniques for compound quantification, purification, and characterization, including high performance liquid chromatography (HPLC ). Chromatographic method validation, the process of establishing that the HPLC method is suitable for determining identity, quality, strength, purity, and potency of drug substances and products, is a regulatory requirement.

Proper execution of method validation can facilitate compliance and pave the way for commercialization. Unfortunately, the current process of validating chromatographic methods is time-consuming and prone to errors, which not only negatively impacts productivity, but can also ultimately delay the introduction of products.

### BUSINESS BENEFITS

- Eliminated the need to transfer data to third-party software packages for statistical calculations and reporting.
- Reduced transcription errors and the time spent identifyingthose errors.
- Provided inexperienced analysts with SOP templates, eliminating the need to continually refer to complex and lengthy written protocols.

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## CHALLENGE

The company's multiple research and development businesses performed method validation using a variety of tools with different capabilities that created process inefficiencies. In an effort to synchronize method validation within the R&D units and manufacturing sites, the company sought to implement an automated method validation solution that would incorporate corporate-driven, template-based standard operating procedures (SOPs) for managing validation procedures, as well as providing a secure database to store results and enhance their ability to adhere to 21 CFR Part 11 requirements.

Even more important than the SOP templates that would guide the method validation documentation process was the need to ensure the accuracy and traceability of data. The company wanted to enable analysts to perform all method validation calculations using the same software they used to capture results. This would eliminate the need to export data to a spreadsheet for calculations, and the potential for error in data transfer, and simplify their validation efforts. The company also sought to include data review and approval functionality.

## THE SOLUTION

The company selected Waters™ Empower™ Software Method Validation Manager (MVM) as the single, comprehensive solution to satisfy all of its method validation requirements. Empower MVM is an enterprise option for the market-leading Chromatography Data System (CDS) platform that addresses the limitations and bottlenecks faced in chromatographic method validation.

With Empower MVM, analysts at the company now have the ability to:

- Incorporate established SOP parameters within the CDS software.
- Display the status of ongoing validation studies to guide the user through the workflow.
- Preemptively associate injection data to validation characteristics.
- Automatically check data to confirm that each validation parameter adheres to SOP requirements.
- Approve data at various steps in the workflow.
- Perform all validation results and statistical calculations in Empower.
- Perform multi-component analyses and batch processing of results.
- Alert users to results that are out of specification.
- Generate reports with standardized templates.

Empower MVM also assists the company in regulatory compliance by providing audit trails, tracking injections for each validation test, designating privileges to control user activity, and securing traceable data within the Empower database.

## BUSINESS BENEFIT

By implementing Empower MVM, the company has automated and significantly streamlined the method validation process.

A number of factors have contributed to an increase in overall productivity, including:

- Eliminating the need to transfer data to third-party software packages for statistical calculations and reporting.
- Reducing transcription errors and the time spent identifyingthose errors.
- Providing inexperienced analysts with SOP templates, eliminating the need to continually refer to complex and lengthy written protocols.
- The ability to manage a validation study is now cooperative effort since each individual involved in the process can determine what activity has completed at any time in the workflow.

A scientist with the company's global R&D division indicated that non-sample prep activities account for approximately 60% of the time consumed in a method validation study. With Empower MVM, he estimates this could be reduced to as little as 10%, representing a 50% overall time savings, as shown in Table 1. Just as importantly, the scientist said that with Empower MVM, he is "more confident that his method validation data is accurate and traceable."

| Validation task | % Total validation time | Time savings with Empower MVM |
|---|---|---|
| Administrative | 20 | 75 |
| Sample prep | 40 | 0 |
| Processing data | 20 | 95 |
| Report Generation | 20 | 80 |
| Total | 100 | 50 |

*Table 1. Method validation time savings with Empower Method Validation Manager.*

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