Empower 3 Software Method Validation Manager

Perform chromatographic method validation, from protocol planning through final reporting, with one application

ESTABLISH AN EFFICIENT, AUTOMATED METHOD VALIDATION WORKFLOW

Chromatographic method validation is a critical step in many types of laboratories, whether your industry is pharmaceutical, food safety, chemical, or environmental. The current process of validating methods is time-consuming and prone to errors, which negatively impacts productivity.

Waters® Empower® 3 Software Method Validation Manager (MVM), an Enterprise option for the leading Chromatography Data System (CDS) platform, addresses the numerous challenges, limitations, and bottlenecks faced in chromatographic method validation.

From strict compliance requirements to transcription errors, data traceability and process inefficiencies, Method Validation Manager successfully streamlines your method validation practices.

With Empower 3 MVM you can automatically:

- Manage method validation workflow in one comprehensive and automated application
- Clearly display the status of ongoing validation studies — enabling you to see at what step each individual validation parameter is in the method validation process
- Track adherence to the validation requirements and acceptance criteria — flagging any out-specification results
- Perform all result and statistical calculations in Empower 3, eliminating time-consuming data transfer to spreadsheets and the associated problems of transcription errors and security concerns
- Perform multi-component analyses and batch processing of method validation results
- Generate reports with standardized templates
- Approve protocols and validation results using electronic signatures

BENEFITS

- Cut method validation cost and time by as much as 80%
- Eliminate manual steps in your current method validation process
- Satisfy compliance requirements more easily, while significantly improving data traceability
- Eliminate the use of separate software applications during method validation
- Automate, streamline, and simplify the method validation workflow
- Easily determine if your data adheres to your method validation requirements and results are within specification
- Store your method validation data securely in the Empower database
FLEXIBLE METHOD VALIDATION MANAGER IMPROVES PRODUCTIVITY

Empower 3 MVM provides chromatography labs with a powerful workflow-based solution. Designed to greatly improve lab productivity and regulatory compliance, Empower 3 MVM helps you manage chromatographic method validation from start to finish — using just one comprehensive, automated tool.

Empower 3 MVM allows you the flexibility to incorporate established SOP parameters and uses a typical validation workflow, regardless of the validation parameters that you’re assessing or the type of requirements you need to meet. Empower 3 MVM can effectively reduce the time needed to validate a method by at least 50%.

CREATE A SEAMLESS WORKFLOW BY VIEWING AND MANAGING DATA FROM ONE WINDOW

Chromatographic method validation is a complex, multi-step process that requires significant manual manipulation of data. From acquiring data to transferring data to various software packages for analyzing and reporting, the process can be extremely cumbersome.

By displaying the status of ongoing method validation studies, Empower 3 MVM gives you the ability to execute, control, and view your workflow — from data acquisition and processing through reporting — within Empower 3. Additionally, automated data checking is performed at every step of the workflow to ensure that all of your data adheres to your validation requirements and that the validation results are within specification. This creates a streamlined, efficient workflow, eliminating the need to rely upon written protocols.

This functionality gives multiple users the ability to manage a study as a cooperative effort. You can readily determine what colleagues have accomplished at any given time in the process. And, vitally important, is the fact that your data and results are secure in the Empower database.

ELIMINATE DATA TRANSFER AND ITS POTENTIAL FOR ERROR

Exporting or manually transferring CDS method validation data to third-party analysis software introduces the possibility of transcription errors. Minimizing those errors is critical for complying with regulatory standards; however, this is a significant burden on individuals who are responsible for checking data for inaccuracies. Empower 3 MVM eliminates the need for data transfer to spreadsheets or other applications — all method validation activities, including all statistical calculations and reporting, are performed within Empower 3.
PROCESS VALIDATION RESULTS IN JUST ONE CLICK
With Empower 3 MVM, all results and statistical calculations are automatically processed with just a click of a button. And it’s just as simple to prepare a standardized report. You save significant time throughout your entire method validation process.

EFFORTLESSLY TRACE VALIDATION RESULTS
You can effortlessly trace validation results back to the metadata, raw data, or chromatographic results since all data types are relationally associated.

EMPOWER 3 MVM
- Organized with three hierarchical levels: Compound Type, Analytical Method Type, and Development Phase
- Captures corporate method validation requirements within Empower 3
- Allows data to be approved at the required steps in the workflow
- Preemptively associates injection data to your validation characteristics so that data management is done by Empower 3, not by you
- Automatically performs all requisite, structurally validated results and statistical calculations – in just one click
- Provides automatic data-checking to confirm that the data for each validation parameter adheres to your SOP requirements
- Alerts users to results that are out of specification
- Allows fully customizable reporting

A TOTAL SOLUTION
Empower 3 MVM is your total workflow-based method validation solution and is a powerful, automated tool to help you deliver compliant methods and assist your organization with delivering new products more efficiently than ever before. Incorporating a multitude of features in just one single program, Empower 3 MVM allows your method validation workflow to move forward rapidly, eliminating bottlenecks and manual steps in the process.
IMPROVE LAB PRODUCTIVITY AND EFFICIENCY

■ Perform early stage method validation, late stage method validation, and anything in between
■ Validate methods as part of the pharmaceutical drug development or commercialization process
■ Perform a method transfer study for pharmaceutical applications or analysis
■ Validate methods used for food analysis, chemical analysis, cosmetics, or environmental testing
■ Assess the precision and accuracy of your clinical assay
■ Assess the robustness of your environmental assay
■ Assess the limit of detection or limit of quantitation for an impurity analysis
■ Assess the linearity of a content uniformity or dissolution assay

COMPLIANCE-READY

■ Track the injections that pertain to a particular validation test
■ Audit trails capture all validation activity
■ A full set of user privileges for controlling user activities
■ Corporate method validation requirements can be approved/locked, reflecting your method validation protocol
■ Secure and traceable data and results stored in the Empower database
■ All calculations are structurally validated by Waters

WATERS GLOBAL SERVICES

Delivering world renowned services and support
Waters Service and Support offerings are tailored to optimize your laboratory productivity while addressing your budget realities. Our offerings help maintain system peak performance, minimize down time, address scientific application challenges, and support stringent compliance requirements. As your services and support provider, we are committed to the success of your laboratory and business.

Waters quality support and consultative services ensure your success wherever your laboratory is located in the world.

WATERS PROFESSIONAL SERVICES

YOUR "NEXT STEPS" PARTNER
A global network of project managers, informatics engineers, and application scientists dedicated to ensuring the success of your organization — providing a comprehensive suite of tailored services to optimize efficiencies, lower costs, and maintain regulatory compliance in constantly changing markets.

Waters has consecutively earned the ACE Award since 2001 for providing best-in-class technical knowledge, issue resolution, and process support.