**astrix**
TECHNOLOGY GROUP

## CASE STUDY:

# Empower Custom Fields Development and Validation

**OVERVIEW:** This project involved one of the world's fastest-growing pharmaceutical companies with an established commercial presence in over 100 different countries and annual revenue of around 15 billion dollars. The company has a wide-ranging portfolio of both name brand and generic therapeutic products that treat many different disease conditions, and also produces medical aesthetics.

In order to support its growing product line, the company was interested in engaging a qualified organization to assist with the development and validation of Waters Empower Chromatography Data System (CDS) custom fields. Over 160 custom fields and 200 reports needed to be developed and validated.

**BUSINESS CHALLENGE:** The company was experiencing a number of issues in their laboratories that they hoped to remedy with this project:

- **Data Integrity** – The customer could not fulfill their CDS data needs with Empower default calculations alone. As a result, they had created a variety of customized calculations. Unfortunately, these custom calculations were generic and depended a lot on user intervention, which left the calculation process prone to errors.

- **Custom Fields Not Validated** – The customer had validated the Empower software functionalities, including the function of creating custom calculations, but they had not run any tests that actually demonstrated that the newly created formulas worked as intended.

- **Too Many Calculations** – Many of the customized calculations that had been created were almost identical to each other, but each one only functioned for a specific method.

- **Lack of Standardized Workflows** – There were no standard procedures on how to operate these customized calculations, so two users could operate a same method with the same formulas in different ways.

- **Too Many Reports** – For each method they had, the customer had created a series of small reports for each specific step (i.e. instrument method report, sample set report, system suitability results, sample results, etc.). Similar to the situation with custom calculations, none of these reports could be used in other methods.

- **Inefficient Workflows** – All of the above issues created significant operational inefficiencies in the laboratory. Users were spending too much time creating custom calculations, entering information manually for the calculations, and generating, reviewing and managing reports.

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## SERVICES PROVIDED:

Astrix's approach on this project was to develop a framework for the development and validation of custom fields that the customer could utilize effectively and efficiently for future development and validation efforts. Towards this end, the Astrix Team provided the following services to the customer during this project:

- Created a process that facilitated proper documentation of custom fields and reports creation.

- Created 23 custom fields that would require minimum user inputs and in a generic format that could be re-used in different products/ projects.

- Created 10 "all in one" reports for the customer. These reports hold all the information required by the test method (i.e. Standard Summary, Recovery, System Suitability, Sample Results, etc.).

- Created a validation strategy for the remaining custom fields/reports, including how to maintain and track where custom fields are being used.

- Created validation SOPs, test scripts, templates, traceability matrix etc. to properly create, document and test new custom calculation formulas to assure they generate the expected results.

- Executed the validation test scripts.

- Developed a traceability matrix that allowed users to locate and reuse validation documentation for custom calculations that had previously been validated.

- Attachments to the method SOPs were created to standardize the way an analyst must operate in Empower while using the new custom fields and reports, improving the overall operation uniformity.

- Trained the customer team on new protocols for using Empower, and all aspects of development, validation and use of custom fields and reports.

**RESULTS DELIVERED:** The customer was very happy with the results of this project. A total of 23 new customized calculations were created, in a way that the new formulas could easily be reused on other methods with minor adjustments, reducing the development and validation effort for future methods.

These formulas were created to be the least user-dependent as possible, reducing user error (i.e. formulas that are less dependent on a specific peak name, reducing problems with eventual peak naming typos), and also the time consumed in entering data manually in the system (i.e. letting Empower calculate the % Recovery alone, with no user input needed).

As the formulas created could be reused on multiple methods, the validation execution effort was reduced. Each formula created was tested once, and this executed validation protocol was used as a cross-reference each time this formula was reused on a new method. For example, on a method using 10 custom calculations, in which 8 have been previously tested on other validation protocols, the validation effort would only need to test the 2 formulas that were not tested yet.

*With this "one report per method" approach, the number of reports that the customer needs to generate has been reduced by over 90%.*

Prior to this project, one method would require on average 6 reports to gather all necessary information from the multiple sample injections. With the newly developed reports, these numbers were reduced to only 1 report per method. The report has all the information needed to evaluate a chromatographic analysis, is flexible to be used on runs from one to several samples, and can be used as a template for future report developments. With this "one report per method" approach, the number of reports that the customer needs to generate has been reduced by over 90%.

This "one report" approach also brings benefits in terms of time consumption. The user does not need to select the right injections for the right report (which could also be prone to human error). Now, they just select all injections from their run, and then let Empower separate each injection for its proper reportable field. Report review and sign-off is also expedited dramatically, as the all-in-one report approach requires only one electronic signature for the entire set of data selected.

In the end, the customer was left with a custom calculation and validation process that was much less time-consuming, more accurate and less prone to errors, easily traceable and more user-friendly.