Case Study: Empower CDS Validation and Wider Validation Improvements

Introduction

Pharmaceutical laboratory operations are becoming increasingly reliant on technology as new platforms are implemented, systems are integrated, and processes are automated. This digitalisation drive is delivering a range of benefits, from quality and patient safety improvements to cost savings and error reductions. It also means there is an ever-increasing focus on, and requirement for, validation.

This case study describes a validation project that started with a requirement to validate a specific software platform – Empower CDS. The project then evolved to include the validation of other systems as well as enhancing CSV (computer system validation) policies and procedures.

The Problem

Our customer is a pharmaceutical company in Ireland. They came to us with an immediate requirement to validate their upgrade of Empower, the industry-leading chromatography data system (CDS), from Empower 3 (FR2) to Empower 3.7.0. Westbourne is ideally positioned to provide this type of support as we have extensive validation expertise combined with detailed knowledge of the Empower platform and decades of experience in IT.

We typically take a structured and phased approach to projects like this, with the first phase focusing on assessment and planning. As a result, we started this project by conducting an assessment of the company's existing systems and processes.

This assessment identified a number of areas that could be improved with a focus on ensuring compliance, improving efficiency, and enhancing operational excellence. Our team presented these findings to the client and the scope of the project was extended to include:

- Validation of the Empower CDS upgrade.
- Creation of a new Validation Master Plan according to regulatory requirements and industry best practice standards.
- Creation of templates for common validation processes.
- Review, refinement, and validation of system backup procedures.
- Validation of the company's IT infrastructure.
- Implementation of laboratory system controls to ensure compliance with GMP regulations.

A detailed project plan that included key milestones and deliverables was then developed to deliver on these objectives.

What We Did

As it would be central to all other aspects of the project, we started the implementation of deliverables by creating the new Validation Master Plan. The Validation Master Plan was carefully tailored to meet the company's requirements and was developed in accordance with regulatory requirements, GAMP guidelines, and industry standards.

We also created validation templates, again tailoring the templates to the workflows and needs of the company. Templates for a range of processes were developed, including:

- User Requirement Specification
- Initial Risk Assessment
- Validation Plan
- Functional/Design Specification
- Functional Risk Assessment
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Requirement Traceability Matrix
- Validation Summary Report
- System Retirement
- Periodic Review

Our team also went through a structured process to validate the backup application with the aim of ensuring consistent, reliable, and effective backup processes. We also established relevant procedures including disaster recovery and business continuity processes. The entire IT infrastructure of the facility, including network devices (firewalls, switches, routers, servers, client workstations, etc) were also validated.

In addition, we implemented laboratory systems control measures to ensure compliance with GMP regulations, streamline operations, and improve efficiency, data integrity, and security. Examples include:

- Stringent password policies
- Desktop controls
- Regulated Windows patch management
- Antivirus
- Internet restrictions

Training was then provided on the new CSV policy and procedures. Empower administration and Empower operation procedures were developed, along with user access management procedures for laboratory applications.

With all these elements in place, our team provided comprehensive validation support for the Empower CDS upgrade.

The Results

The project was completed successfully with all milestones and objectives achieved. The benefits to our customer include:

- Compliance – ensured the upgrade of Empower CDS complied with regulatory requirements. Compliance risks were also reduced through the validation of the backup system and IT infrastructure, and the creation of the Validation Master Plan and validation templates. The newly created policies and procedures also made compliance processes more efficient.
- Increased confidence – the process and data integrity improvements that we made as part of this project enhanced confidence in the reliability and accuracy of the Empower system, supporting better decision-making and operational excellence.
- System security – IT infrastructure security risks were reduced through our work on the backup process as well as enhancements to user access control.

Westbourne's Mayank Sharma said: "CSV requires robust policies, procedures, and templates. In this project, we were able to deliver a solution to the customer's immediate problem – the validation of its upgrade from Empower CDS version 3 to version 3.7.0.

“The main advantage for the customer, however, is the reduction in compliance and security risks, as well as the process and efficiency improvements that we delivered. We continue to provide IT and validation support to this customer and look forward to strengthening the relationship in the future.”