Lab Systems Audit of Waters Empower 2 and Upgrade Plan for Empower 3 FR5

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Contract Laboratory

Informatics Systems
- Empower 2 CDS

Service Offering
- Lab Systems Audit
- Strategic Planning
- Upgrade Roadmap

Elements:
- 1 Site
- 1 Lab
- 1 Month
- 1 CSols Team Member

A contract pharmaceutical testing lab had received citations from Health Canada regarding the data integrity of their Waters Empower™ 2 CDS. While conducting a site visit, Health Canada found individual Empower 2 workstations operating with limited control over roles and their system access, which raised data integrity concerns around the data that they were generating. The client tried to initiate their own short-term solutions for the data integrity issues, but they learned that their solutions may become unmanageable as the data grows in volume – creating more problems down the road. Health Canada gave them 90 days to resolve their noncompliance.

CSols Inc. was selected to assess the Waters Empower™ CDS workstations due to our extensive experience with Empower CDS and the success we've had with other similar projects. The client recognized CSols as a leader in the laboratory informatics space with proven best practices.

Objectives and Challenges

The objective of this project was to get the client's Empower 2 systems back in compliance with Health Canada so their laboratory testing could continue.

There were many shortcomings that needed to be identified and then paired with a solution. Unfortunately, the client's resources did not have the Empower 2 expertise to address these issues in a way to create scalable and sustainable solutions.

CSols's Role in the Solution

To meet the objectives, the CSols Empower CDS expert performed

750 Prides Crossing, Suite 305 | Newark, DE 19713
(302) 731-5290 | www.csolsinc.com

a Lab Systems Audit to evaluate all the gaps present in the Empower 2 systems, including the integrity of the data and the security of their systems that were flagged by Health Canada. During the evaluation, an upgrade to Empower 3 was recommended to help the client become more sustainable and scalable moving forward. The following are the key tasks and deliverables.

- *Evaluation of the current footprint* – Performed a detailed dive into the hardware, software, and current business process to determine the best areas for improvement that follow overall compliance and best practices. Used the current regulatory situation to help determine an action plan.

- *Proposed short-term solutions* – Performed a detailed dive into the hardware, software, and current business process to determine the best areas for improvement that follow overall compliance and best practices. Used the current regulatory situation to help determine an action plan.

- *Short-term report* – Performed a detailed dive into the hardware, software, and current business process to determine the best areas for improvement that follow overall compliance and best practices. Used the current regulatory situation to help determine an action plan.

- Once the roadmap is implemented, the data integrity issues will be remedied, thereby lifting the citations and allowing work to resume.

- An upgrade path was detailed in the roadmap to assure the client to compliance, and remove the worry of receiving future citations.

- With the CSols consultant's thorough knowledge of Empower CDS, the client may not have been able to address the issues identified by Health Canada in a comprehensive way that also provided a path to future upgrades.

Benefits

The expertise provided by the CSols Empower consultant delivered the following benefits for the client:

- The client received a roadmap report, identifying all gaps found in their Empower 2 CDS along with recommended steps to address the Health Canada citations and ensure their data integrity.