Scitara DLX Case Study: Empower CDS Integration with LIMS

Objective

The primary goal of the global consumer health company is to enhance the efficiency of the QC workflow for high volume analyses supporting stability studies and the release of product. The company evaluated Scitara DLX for the integration of the Empower CDS with LIMS to deliver on connectivity requirements and yield value in the following areas:

☐ **Analysis workflow efficiency** ☐ **Review workflow efficiency** ☐ **Data integrity**

The value analysis considered four different chromatography analyses performed using Empower, namely assay, impurity, content uniformity, and dissolution. The company assessed the value of Empower CDS to LIMS integration for a representative site and extrapolated value calculations to 19 additional sites using the same assumptions.

Current State (As-Is)

The current process does not include any integration, thus requiring manual data entry to prepare the Empower Sample Set and enter results into Empower.

The analyst enters LIMS metadata for samples and standards into the Empower Sample Set, including the LIMS sample name or ID and weights. The analyst performs the chromatographic run and executes Sign Off 1. The Reviewer reviews the Empower data in Empower and executes Sign Off 2. The analyst manually enters the Empower results and metadata into LIMS. Result metadata may include Result ID, column ID, and notebook reference. The Reviewer reviews the Empower data in LIMS to ensure the manual data entry was correct.

***Figure 1** describes the Current State process.*

The Solution - Scitara DLX (To-Be)

Scitara DLX was deployed to automate the bidirectional exchange of data between Empower and LIMS, eliminating all manual data entry steps and enforcing workflow requirements.

DLX facilitates the workflow in two major ways:

- DLX automates creation of the Sample Set Method
- DLX automates entering Empower results into LIMS

The Analyst registers samples in LIMS and enters the metadata of samples like the LIMS ID and sample weight. The creation of the Empower Sample Set Method is initiated within LIMS. The analyst is prompted to identify the Sample Set Method to be used. DLX then combines the LIMS sample data along with the Sample Set Method data (i.e., position, injection volume, number of injections, placement of the samples/ standards) and creates a Sample Set Method in Empower with no manual interaction. There is seamless exchange of Sample data between the LIMS and Empower CDS.

The analyst proceeds to run the created Sample Set on Empower and executes Sign Off 1. The Reviewer will continue to review the Empower data in Empower and execute Sign Off 2.

The Sign Off 2 event with specific Sign Off Reason triggers the DLX Orchestration that retrieves the result data from Empower, reshapes it and writes the results and associated metadata into LIMS. Since the result entry is automated and validated, the Reviewer will no longer need to review the Empower data in LIMS to ensure the manual data entry was correct.

The total time savings per sample set run is 56 minutes/run from analysis to approval of results on Empower data in LIMS.

***Figure 1** describes the To-Be process.*

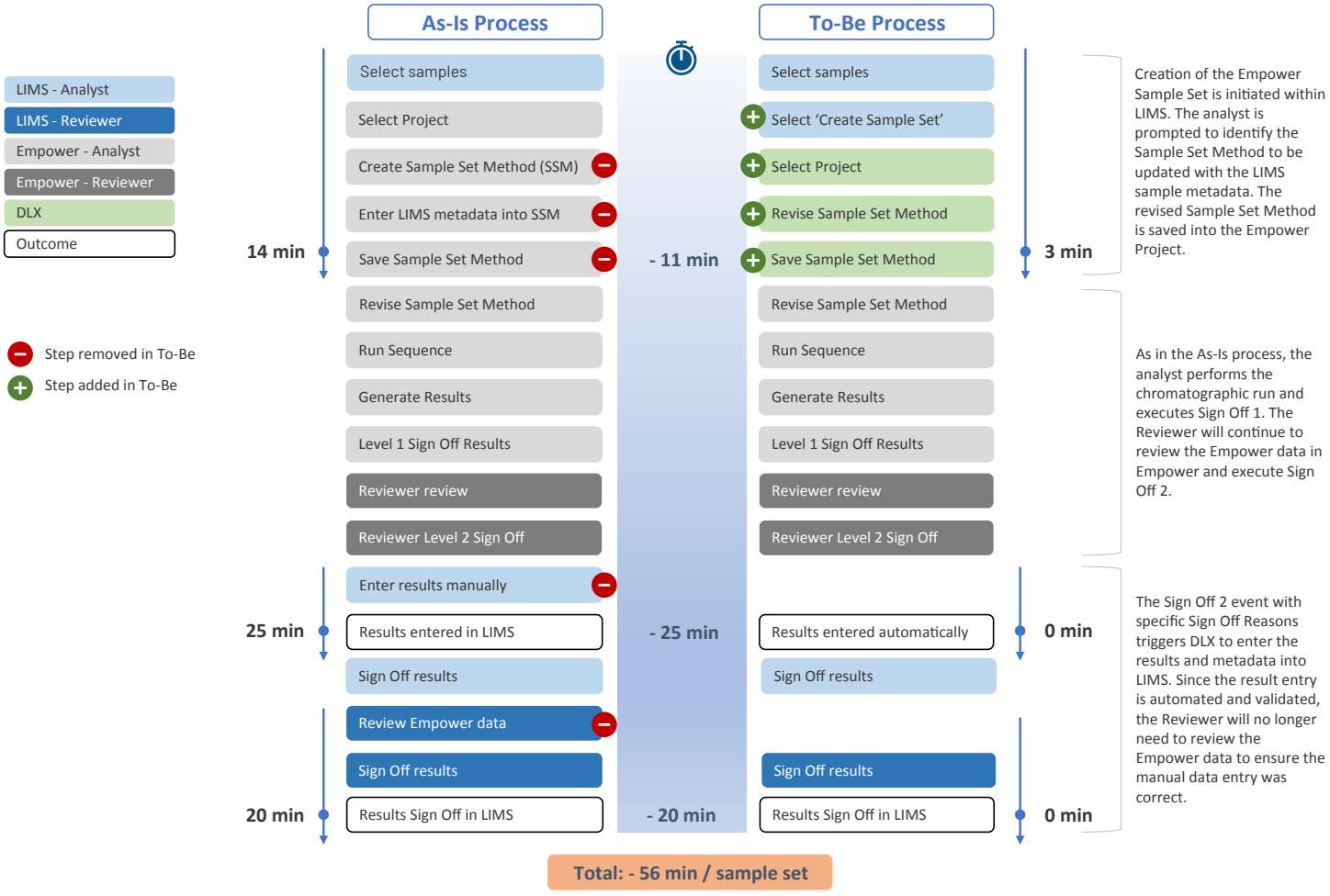


Figure 1 *Empower CDS and LIMS As-Is and To-Be process*

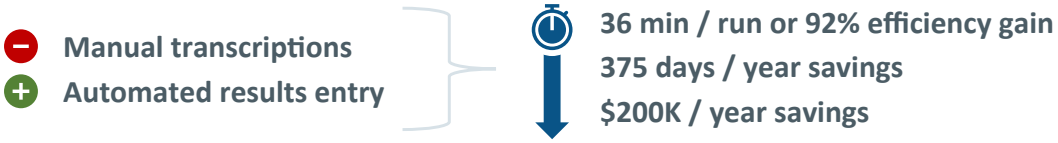
Value

The company discovered the value of the DLX solution in three distinct areas as described below.

1) Analysis Workflow Efficiency

Laboratory subject matter experts estimated an average time of 14 minutes to create a typical Sample Set for each of the four different analysis types. The team estimates an efficiency gain of 75% or a savings of 11 minutes/sample set. The step to enter results of a typical sample set, estimated as 25 minutes, is eliminated in the To-Be. Thus, the total time savings per sample set run is 36 minutes/run, a 92%-time savings for the steps directly impacted.

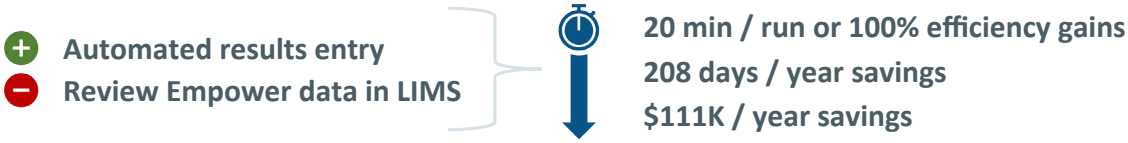
Using the total number of sample sets acquired at the representative site in 2023 (i.e., 5,000 sample sets), yields a total savings of 375 days/year. Assuming a loaded cost of $125,000/analyst, yields cost savings of $200K.



2) Review Workflow Efficiency

The value analysis looked at the workflow for the review of Empower data in LIMS. In the As-Is, the Reviewer performs a LIMS review of the Empower data. Laboratory subject matter experts estimated an average time of 20 minutes to review the results of a typical Empower sample set in LIMS. In the To-Be, the Reviewer's Level 2 Sign Off triggers the automated entry of data from Empower into LIMS eliminating the need for the Reviewer to review the Empower data a second time in LIMS, thus yielding a 100% efficiency gain.

Using the total number of sample sets acquired at the representative site in 2023 (i.e., 5,000 sample sets), yields a total savings of 208 days/year. Assuming a loaded cost of $125,000/reviewer, yields cost savings of $111K.



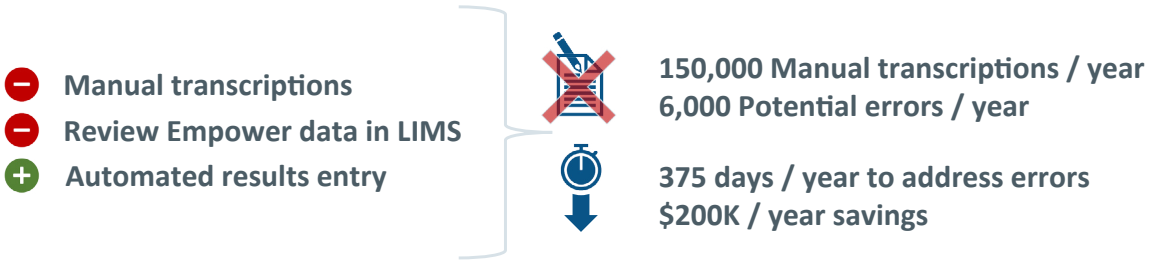
3) Data Integrity

Value discovery focused on elimination of errors made from manual data entry and transcriptions. The bidirectional integration eliminates 75% of the manual transcriptions at the Sample Set creation process and 100% at the results entry into LIMS process.

Using the total number of sample sets acquired at the representative site in 2023 (i.e., 5,000 sample sets), yields a total of 150,000 manual entries for the Analysis workflow. Laboratory subject matter experts estimated an average error rate of 4.0%, yielding 6,000 potential errors / year, and an average of 30 minutes to correct an error.

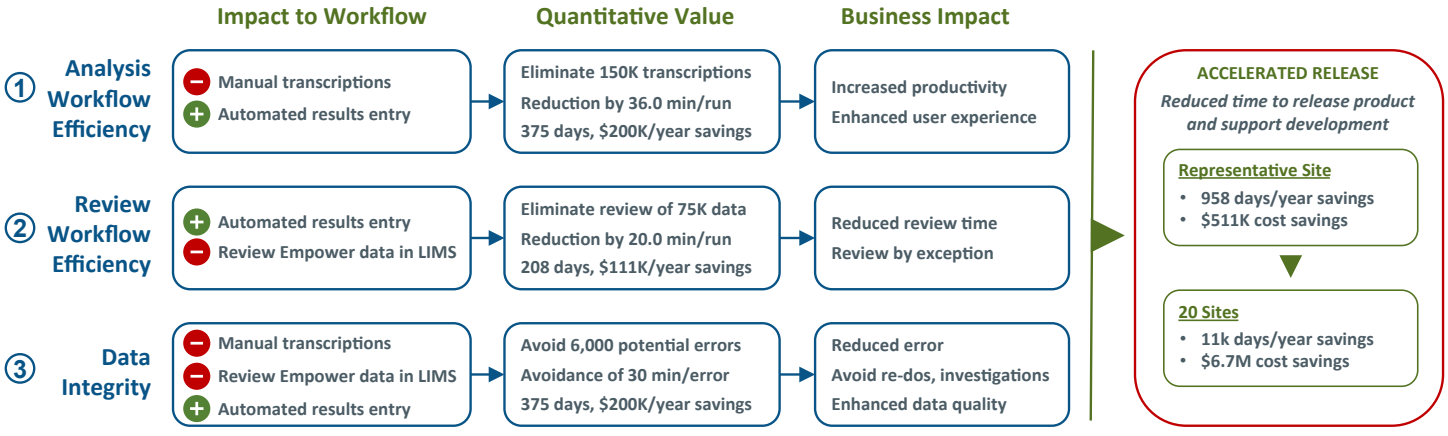
Using the total number of sample sets acquired at the representative site in 2023 (i.e., 5,000 sample sets), yields a total savings of 375 days/year. Assuming a loaded cost of $125,000 / analyst yields cost savings of $200K.

The analysis does not account for the significant time and cost avoidance value derived from eliminating the need to file a report and investigate a subset of the errors.



Conclusion

The Value Discovery Team focused on three target value areas: (1) Analysis Workflow Efficiency, (2) Review Workflow Efficiency, and (3) Data Integrity. The current processes (As-Is) were compared with the proposed solution (To-Be) to identify the impact of DLX on the workflow and derive quantitative value. The total potential quantitative value of the DLX-enabled Empower CDS to LIMS integration for the representative site is a total of 958 days/year savings and $511K cost savings. The calculation of value using the actual sample set volume for each of the 20 sites yields over 11K days / year savings and $6.7M cost savings.



scitara™

11 Apex Drive, Suite 300A, Marlborough, MA 01752 info@scitara.com P: +1 774-847-5034