# Smooth and secure integration of Cerity for Pharmaceutical QA/QC with LIMS systems using Labtronics LimsLink$^{CDS}$

## Application


### Abstract

Laboratories can improve the efficiency of their operations and ensure the accuracy of their data reporting, by automating the transfer of information between their chromatography data system (CDS) and their laboratory information management system (LIMS). In addition, the security of their chromatography data is enhanced when this automation is accomplished within the security framework established by regulatory guidelines such as the U.S. Food and Drug Administration's ruling on electronic signatures and electronic records (21 CFR Part 11). This case study describes how Labtronics LimsLink$^{CDS}$ enables laboratories to, smoothly and securely, integrate Agilent Cerity for Pharmaceutical QA/QC with any LIMS.


### Introduction

Historically, data has been either manually transcribed to the LIMS or custom code has been developed to address each unique interfacing situation. Neither of these choices has proven to be an effective solution in today's laboratory. Manual transcription is simply no longer a viable option. Facilities that have chosen to develop custom code to automate the process have generally found that they have been saddled with a system that is difficult to maintain and modify. In 1994, Labtronics Inc. introduced LimsLink as the first configurable solution for interfacing laboratory instrumentation with LIMS. LimsLink has been widely accepted by the LIMS industry for instrument-to-LIMS interfacing. LimsLink$^{CDS}$ was developed by Labtronics to address the specific needs and requirements of interfacing with chromatography data systems. Labtronics and Agilent Technologies have now joined forces to develop an interfacing method between LimsLink$^{CDS}$ and Agilent Cerity. The LimsLink$^{CDS}$ – Cerity interfacing method provides Cerity users with a configurable format for creating secure, bi-directional interfaces between Cerity and any LIMS.

## Automated sequence creation

### Downloading sample lists from LIMS

All sample information, including sample IDs and tests that need to be run, is typically retained in the LIMS. Rather than having an analyst manually create a sequence file for their CDS, it is more efficient to automatically retrieve that information from the LIMS, reformat it and upload it to the CDS as a sequence. The first step in the automated sequence creation process is for LimsLink$^{CDS}$ to query the LIMS for a list of samples pending analysis. The query can be based on a specific test, the current date or any other parameters specified by the user. The information from the LIMS is placed in the LimsLink$^{CDS}$ worksheet.

### Expanding the sample list

A powerful LimsLink$^{CDS}$ Expansion Function automatically adds "special" samples such as standards and controls to the sample list coming from the LIMS.
The Expansion Function allows the user to identify special samples that are to be added at the start of a run, samples that are to be included at regular intervals throughout the run and samples that are to be added at the end of the run. For example, a laboratory may always include standards at the beginning and end of their sequence and run control samples after every 4 regular samples. At run time the Expansion Function will automatically add the standards at the beginning and end of the sample list from the LIMS and then insert the control samples after every 4 samples. The Expansion Function also includes a parameter that specifies how many replicates of regular samples need to be run. The completed sequence will automatically include the specified number of reps. Without having to manually add the additional samples, the analyst is able to automatically generate a full and complete sequence that includes all of the required replicates, standards and controls.

### Use XML to transfer sequences to Cerity

The completed sequence is transferred directly to Cerity by clicking on the "Export to Cerity" button in LimsLink$^{CDS}$ or by choosing the "Generate XML Sequence Import" menu option. Either option automatically formats the completed sequence into a checksum-secured XML file (figure 1). The contents of the XML file can be defined by the end user. Any field that is part of the Cerity sequence information can be included as part of the XML file. This can include information such as the instrument name, the Cerity Method, sample type, sample amount, number of injections, and so on. The analyst working in Cerity simply selects the XML File Import menu item and imports the completed sequence into their Cerity database (figure 2). Automating the creation of the sequence file not only reduces the analyst's workload, automation also ensures that all samples that are scheduled in the LIMS are included in the sequence, and that all of the required sample information is accurately included in the sequence.

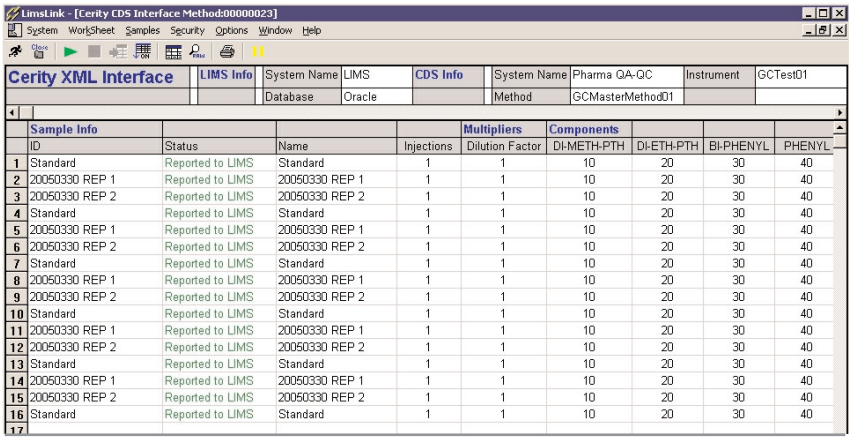


**Figure 1**
**LimsLink$^{CDS}$ automatically exports a completed Cerity Sequence in XML format.**

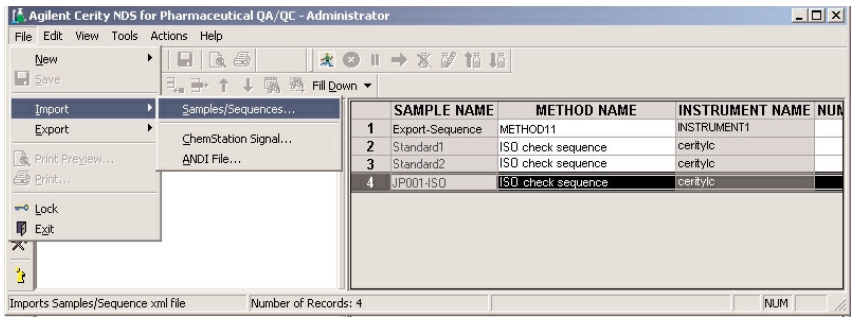


**Figure 2**
**Analysts import their sequences using the Cerity XML File Import.**

## One touch reporting from Cerity to LimsLink$^{CDS}$

The LimsLink$^{CDS}$ interface allows Cerity users to report their sample results to LIMS using their standard reporting procedures. Any printed report from Cerity can be captured by LimsLink$^{CDS}$ and transparently transferred to LIMS, to the printer or to other data management or ERP systems – all at the same time, with a single click of the mouse (figure 3). LimsLink$^{CDS}$ automatically removes all non-text items such as font information, borders, graphics, etc., creating a text only version of the report. A header can be added to the data that includes the date, time and user ID obtained from the Operating System. This provides verification of when the report was generated and who was logged onto the system at the time. The calculations performed by Cerity while generating the report are preserved and transferred to LimsLink$^{CDS}$. Results are transferred from Cerity to LimsLink$^{CDS}$ without creating files, simplifying compliance with regulatory requirements.

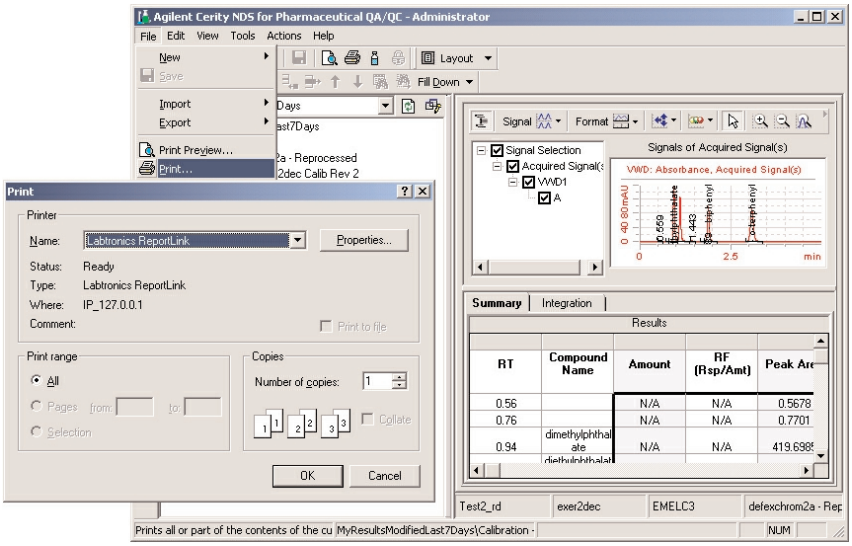


**Figure 3**
**Analysts use standard Cerity reporting procedures to transfer sample results.**

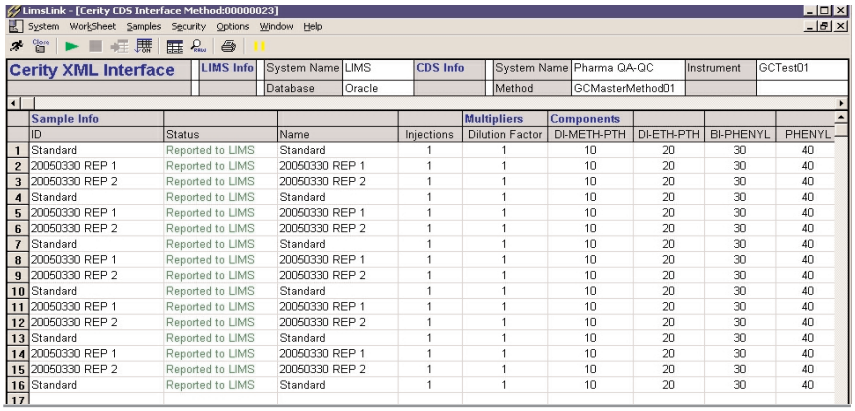


**Figure 4**
**LimsLink$^{CDS}$ worksheet with an entry in the status column showing that the sample results have been sent to the LIMS.**

## Reporting results to LIMS

When LimsLink$^{CDS}$ has collected the result data from Cerity, the data is automatically reformatted to meet the LIMS requirements and sent directly to the LIMS (figure 4). In this "black box" scenario, LimsLink$^{CDS}$ runs in the background, transferring the data from the CDS to the LIMS with no intervention by the analyst. If required, LimsLink$^{CDS}$ can also be configured to display the sample results, allowing for final review and approval of the data by the analyst before transferring the results to the LIMS. In either case, the LimsLink$^{CDS}$ worksheet can be automatically updated to show that the sample results have been sent to the LIMS.

## LimsLink$^{CDS}$ special functions

Special Functions are additional LimsLink$^{CDS}$ modules that extend the ability of LimsLink$^{CDS}$ to reformat the data to meet the specific requirements of the LIMS. Some of the additional capabilities that LimsLink$^{CDS}$ Special Functions provide are:

- addition of a comment or flag to a result before sending it to the LIMS,
- conversion of units such as µg/L to mg/L,
- conversion of compound names in situations where the LIMS uses a different naming convention.

## A secure solution – Agilent Cerity for Pharmaceutical QA/QC and LimsLink$^{CDS}$

LimsLink$^{CDS}$ incorporates electronic signatures, password protection, and a full audit trail, providing the level of security and accountability required by the FDA ruling 21 CFR Part 11.

## Conclusion

The LimsLink$^{CDS}$ interface for Cerity for Pharmaceutical QA/QC is a full featured, configurable interface that provides for the secure transfer of information between the Cerity chromatography data system and any LIMS. The major benefits to analysts are a decrease in their workload and the assurance that the integrity and accuracy of their data is maintained. Features of the LimsLink$^{CDS}$ – Cerity interface are:

- interfaces that are configured, not custom coded,
- automatic creation of sequence files from LIMS worklists,
- regular Cerity reports can be used to transfer results to any LIMS and,
- LimsLink$^{CDS}$ security meets 21 CFR Part 11 compliance requirements.

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