How a new LIMS interface may soon streamline data integrity in bioanalytical laboratories

Precision and compliance are key aspects of performing bioanalytical tests. To ensure the quality of results, bioanalytical laboratories must have complete management and oversight of items, such as sample management, study protocols, assay development and validation, analytical runs, and the flow of data. Data integrity is a key component of both scientific and regulatory rigor. Software, like laboratory information management systems (LIMS), can support laboratories with this by optimizing data transfer processes throughout the bioanalytical workflow.

In this article, we discuss how advanced LIMS software can support bioanalytical laboratories to ensure their data is maintained, transferred, and stored securely, and how a new interface can streamline data transfer and the validation of that transfer, all of which improves the integrity of data.

Principles of data integrity

Data integrity in the laboratory has always been vital. However, its importance is growing exponentially as more high-tech instruments with data sharing capabilities are integrated into the laboratory. Data must be reliable, which is why the US Food and Drug Administration (FDA) originally proposed a set of principles – ALCOA+ – to ensure data integrity. Almost all software vendors have implemented these basic principles into their systems. In other words, each data source 'island' covers the data integrity principles well. However, when individual systems operate as part of a larger information network, data integrity becomes a major challenge.

The ALCOA+ Principles

ALCOA is an acronym for the original five principles of data integrity:

- Attributable – data must be identifiable with a person or computer system
- Legible – data should be kept in consistent, straightforward language that will be easy to understand in the future
- Contemporaneous – information should be recorded at the time it takes place
- Original – original data, rather than copies, should be recorded
- Accurate – data should reflect the reality of what happened, error free and without edits

The + in the ALCOA principles refers to further additions:

- Complete – All recorded data requires an audit trail to show nothing has been deleted or lost
- Consistent – Data has a date and time stamp to ensure it is chronological
- Enduring – Data is available long after it is recorded, often for decades
- Available – Data must not only exist for a long time, but it must be accessible in open file formats

The challenges of data integrity in data transfer

A major challenge of data integrity is around data transfer. One example is the transfer of data between laboratory instruments, like a liquid chromatography-mass spectrometry (LC-MS) system, and LIMS. In an interconnected laboratory with multiple data-generating instruments, LIMS is a crucial node, improving the security and integrity of data in the system.

However, current LIMS software doesn't necessarily ensure data integrity for data in transit. There are no standardized formats for bi-directional communication between LIMS and instruments, meaning each LIMS-instrument combination requires a unique data transfer solution. Part of the challenge here is that laboratories usually have instruments and software from multiple vendors, and this heterogenous environment causes a lack of standardization.

As a result, users often resort to transferring data between LIMS and instruments in TXT files, which can be the only common format between the two systems. TXT files, however, are non-secure data files, and users must perform manual quality control checks to ensure integrity. This is time consuming, requires expertise and is open to errors, which can introduce unintended, incorrect results into datasets.

There are also other issues when it comes to software updates and how these impact communication between LIMS and other systems in the network. For example, when software updates come into place, other instruments might need to be reconfigured and re-validated to enable data transfer, which adds a huge burden on laboratory staff.

A data integrity solution with a near-zero impact on users

The crux of the issue is how instruments and LIMS interface, and how users in the laboratory interact with these interfaces. Using the principles of ALCOA+ as a guide when setting up data transfer between systems can improve data integrity in the laboratory. For example, a data transfer system built around the ALCOA+ principles could help to improve traceability and accessibility of data coming in and out of systems. This data transfer system would create a solution to the challenges of data integrity in the laboratory by reducing the manual processes of data transfer, all the while reducing the burden to users.

A new project involving multiple industry vendors is creating this exact solution. Originally proposed by the European Bioanalytical Forum (EBF) e-environment working group, vendor groups are continuing the work through pilot schemes.

The project aims to kill two birds with one stone: the first by standardizing data formats, and the second by creating securing logic that ensures data integrity and security when transferring data

This eliminates the need for manual quality control of data between instruments and vendors, and the need to purchase proprietary interfaces, saving significant costs and time for laboratories.

One of the key aspects to this solution is replacing TXT files with digitally signed XML files that are accessible between all systems in the network. The interface uses public-private paired hash-key mechanisms, whereby locking a file can only be done with a private key and unlocking only by users that have a corresponding public key. This creates standardized formats where users control data access and have a more secure system of digital signatures, so users can see who created the data signature, whether data has been changed, and have data automatically validated by the interface.

What can the industry do to demand better data transfer systems?

Maintaining the integrity of data when it is transferred between laboratory devices and LIMS is currently an onerous task. A lack of file compatibility and the need for proprietary interfaces drains time and financial resources. A set of vendors are collaborating to show how data transfer can be changed, aiming to achieve more streamlined solutions to ensure data integrity in the laboratory.

However, the project is still in pilot-phase and needs buy-in from more vendors to see improvements in the standardization of data transfer. That's why, when scientists and laboratory managers want to implement new software or instruments, it's important they demand changes in data transfer integrity and standardization from vendors. The more people ask, the quicker it will be put on the roadmap of system development. With industry wide commitment, there could be big time and cost savings across the industry, and an improvement to data integrity, ultimately, supporting the delivery of accurate results.