

Role of Balances and LIMS in Data Integrity

“Does your company's electronic balance support data integrity?”

In recent years, we have been receiving more and more inquiries similar to the above quote. In the pharmaceutical industry, there is an increased need for ensuring data integrity for the safety and quality of pharmaceutical products. Since mass is extremely important data that is typically measured first in an analysis, it is naturally subject to data integrity.

However, data integrity usually cannot be complete with just balance data by itself. Comprehensive data management is required, including measurement results from other instruments such as GC, HPLC, and ICP.

We will now introduce how to ensure data integrity by connecting A&D's balances to YOKOGAWA's Laboratory Information Management System (LIMS), OpreX LIMS, which supports quality management operations.

What is Data Integrity?

According to the FDA (U.S. Food and Drug Administration) definition^{*1}, data integrity "refers to the completeness, consistency, and accuracy of data", and "complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate" (i.e., in accordance with ALCOA principles).

Due to a number of data falsification and fraud findings during GxP inspections, regulatory authorities such as the FDA, MHRA (UK Medicines and Healthcare Products Regulatory Agency), PIC/S (Pharmaceutical Inspection Cooperative Scheme and Cooperative Agreement on Drugs), and WHO (World Health Organization) have been strengthening their monitoring of data integrity. Accordingly, guidance on data integrity has been issued one after another by various regulatory authorities.

^{*1} 2018, 'Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry', p. 4

ALCOA+

Each guidance adopts the basic principles of data integrity, "ALCOA+". ALCOA+ is an extension of the traditional ALCOA and consists of the following items.

Attributable	The creator of the data must be clear.
Legible	Data must be readable and understandable for anyone.
Contemporaneous	Data must be measured and recorded at the same time.
Originality	Copied data must be the same as the original data.
Accurate	Results and data must be accurate and free of errors.
Complete	All necessary information to reconstruct events must be available.
Consistent	Data must be consistent and without contradictions.
Enduring	Data must be extant for the duration of the data retention period.
Available	Data must be accessible so that the data can be reviewed at any time during the data retention period.

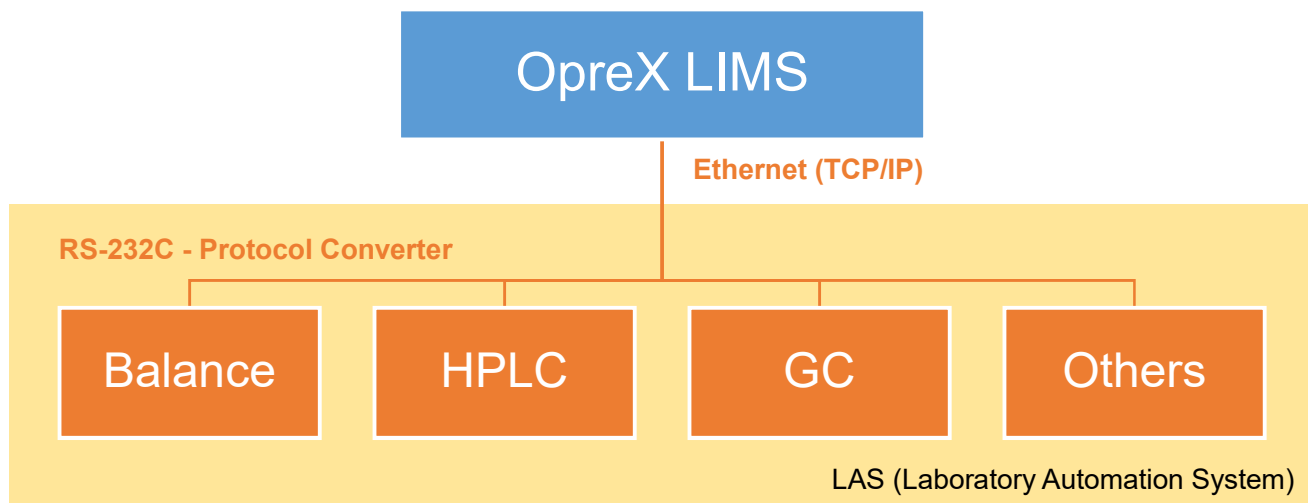
Trying to fulfill these requirements manually or on paper not only requires a great deal of time and effort, but also invites the risk of human error, such as transcription errors, omissions, calculation errors, and loss of data, which in turn leads to poor data integrity. In addition, as mentioned above, data from other instruments add to the scope and complexity. Therefore, in order to efficiently and holistically manage all data inputs in a centralized manner, a dedicated electronic system such as OpreX LIMS is highly recommended.

OpreX Laboratory Information Management System (OpreX LIMS)

*This section covers some of the solutions offered by OpreX LIMS when connecting to balances and ensuring data integrity. For more information on this system, please contact **Yokogawa Electric Corporation**.*

Using OpreX LIMS with a balance is quite simple as the balance is only required to output mass measurement data while OpreX LIMS handles the processes necessary to ensure data integrity. Users are just advised to verify by the IQ (Installation Qualification) of the balance in the initial setup that there are no problems with the balance's performance and that the values displayed on the balance match the values entered into OpreX LIMS.

A balance can be connected to OpreX LIMS by converting its RS-232C to Ethernet (TCP/IP) signals using a protocol converter.*² The LAS (Laboratory Automation System) will then automatically collect data from various instruments, including balances. This saves on the labor spent on manual data entry and prevents transcription errors and falsification of data.



In addition, the following solutions help ensure data integrity.

✓ **Regulatory compliance by security, tracking and traceability features**

By entering user IDs and passwords when logging on, approving, or making changes, etc., secure system operation can be achieved by setting appropriate permissions for each user.

OpreX LIMS has also Audit Trail and Change History Reference capabilities, such as an Operation History log, which tracks the reception, input, approval, and judgment of data, Data Movement log as well as System log.

✓ **Paperless operation and improved search speed**

The primarily online nature of OpreX LIMS means that operations are paperless. Test results data can be input online. The review, approval, and pass/fail determination of test result data are all also conducted online.

In addition, a database of various types of data is compiled which facilitates and speeds up data searching, comparison with other samples and past data, and trend analysis. It can also be utilized for product quality verification.

*² For details on connection methods, please contact Yokogawa Electric Corporation.

✓ **Calibration management of analytical instruments**

OpreX LIMS can also manage and maintain calibration records, calibration deadlines, and calibration histories for connected analytical instruments, balances, etc.

✓ **Conformance to regulations for electronic records and signatures**

In terms of management of electronic record and signature, OpreX LIMS conforms to FDA 21 CFR Part 11, ER/ES guidelines, and PIC/S GMP Guidelines.

Summary

Various issues related to data integrity required in the pharmaceutical industry can be solved by centrally managing data from balances and various analytical instruments with LIMS. A&D's balances have a proven track record of connecting to YOKOGAWA's OpreX LIMS. For users who have not introduced a LIMS yet, we can recommend OpreX LIMS with confidence.

Point of Contact

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■ OpreX LIMS and Data Integrity Solutions

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