

Data Integrity Software HORIBA PLATINALINK ~Development of a platform that ensures data integrity for analytical instruments in the pharmaceutical industry~

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In the pharmaceutical industry, accuracy and reliability of measurement data (data integrity) are required, and compliance with GMP (Good Manufacturing Practice) is essential. To address this, HORIBA has developed a new platform, HORIBA PLATINALINK (“PLATINALINK”), which complies with the international data management standard “ALCOA+” and integrates functions such as record accuracy, data retention, and tamper resistance. This platform aims to reduce user workload and enhance reliability. This article introduces the features and functions of PLATINALINK.

Keywords

GPM, Data Integrity, ALCOA, 21CFR Part11, CSV

Introduction

GMP (Good Manufacturing Practice) establishes standards for quality control and quality assurance in the manufacturing of pharmaceuticals and related products to ensure public safety within the pharmaceutical industry. Among these standards, data integrity refers to the assurance of completeness, consistency, and accuracy of data, which is essential for maintaining product traceability and guaranteeing product quality, safety, and efficacy. In recent years, inappropriate actions such as data falsification and manipulation have become social issues not only in the pharmaceutical sector but also across various industries, increasing the demand for reliability in data throughout the industrial landscape.

At HORIBA, data integrity functions have been individually implemented in products such as the particle size distribution analyzer (LA series). However, this product-specific approach has led to inefficiencies in design and development, inconsistencies in functionality across products, and cases where user requirements could not be adequately met, revealing significant issues.

To address these challenges, HORIBA has undertaken the development of a common application that standardizes and integrates data management functions, providing consistent features across multiple products (Figure 1).

ALCOA+ Principles and Correspondence with PLATINALINK

In the pharmaceutical industry, data integrity is evaluated based on the ALCOA+ principles. “ALCOA” represents five fundamental requirements for data integrity—Attributable, Legible, Contemporaneous, Original, and Accurate—first introduced by the FDA in 1994 and reaffirmed in the latest guidance, “Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry”^[1]. The “+” component refers to additional, more comprehensive requirements—Complete, Consistent, Enduring, and Available—introduced in FDA guidelines and further expanded in the latest EMA guideline, “Guideline on computerised systems and electronic data in clinical trials”^[2], published in 2023.



Figure 1 Application image of a common platform centered on Data Integrity.

PLATINALINK is a platform application designed and developed to comply with these principles, supporting users in managing data in accordance with regulatory requirements. Table 1 presents the ALCOA+ principles and the corresponding functions provided by PLATINALINK.

By incorporating a comprehensive set of functions that address all these principles, PLATINALINK ensures users can maintain data reliability in daily operations and facilitates audit compliance and internal quality assurance.

Background and Design Philosophy of PLATINALINK Development

Unified Design Based on User Challenges

Traditionally, HORIBA products have individually implemented data integrity functions, expanding features in response to specific user requirements, resulting in a lack of standardization and differing specifications across products.

In addition, HORIBA’s medium- to long-term business plan has declared a strategic focus on the pharmaceutical market. There has also been a growing need for data integrity support in existing products, such as the XGT-9000, previously used in quality testing laboratories.

Consequently, it was determined that data integrity support should be unified company-wide rather than handled on a per-product basis, leading to the development of PLATINALINK as a cross-product platform.

Design Concept and Application Structure

PLATINALINK is designed according to the following principles:

- Provision of standardized data integrity functions
- Ensuring compatibility for deployment across various analytical instruments
- Securing future expandability and maintainability as a DX (Digital Transformation) platform

The application is provided as a web application. In a networked configuration, it does not require installation on client PCs and can be accessed via standard web browsers, offering the following advantages:

- Accessibility from anywhere on the network, reducing administrator burden and improving maintainability
- Unified operability across different analytical instruments through the common PLATINALINK platform
- Operation on servers utilizing the customer’s internal network ensures alignment with the customer’s security policies
- Centralized data management by aggregating data from multiple analytical instruments

Table 1 Principles of ALCOA+ and Corresponding Measures in PLATINALINK

Principle	Description	Example of PLATINALINK Compliance
Attributable	It must be clear who recorded, changed, or deleted which data and when.	Audit trail function records user operations and system processes, enabling identification of the recorder.
Legible	Data must be recorded in a format that is easy to read and can be clearly understood when necessary.	Standard format files such as PDF, JPEG, and PNG can be saved and viewed.
Contemporaneous	Data must be recorded simultaneously with the actual work.	Automatic data acquisition and recording via real-time integration with measurement devices.
Original	Data must be the original record or an accurate copy equivalent to the original.	Automatic saving of measurement data, tamper-proof log management, and encryption for tamper prevention.
Accurate	Data must be accurate and complete, without errors.	Consistent recording methods, automatic backups, and data integrity verification functions included.
Complete	All data must be recorded without omission or deletion.	In principle, deletion and modification functions are not implemented; all data is saved and managed as logs.
Consistent	Data must be recorded and managed in a consistent manner.	Unified data recording method adopted across multiple devices.
Enduring	Data must be preserved in a state that allows long-term access.	Periodic automatic backups and log storage, as well as account control, enable long-term use.
Available	Data must be accessible whenever needed.	High availability ensured through access permissions, search functions, and web-based accessibility.

Figure 2 illustrates an example of PLATINALINK operation. In a standalone configuration, the analytical instrument and PLATINALINK are installed on the same PC for operation. In a network configuration, a server is installed within a closed network, such as an internal company network, with PLATINALINK installed on the server, allowing access from analytical instruments and other PCs within the network.

Currently, operation is limited to standalone and local network environments, but the web application architecture enables remote access within internal networks and centralized management of multiple products. In the future, the system is envisioned to support cloud-based multi-site integration and data utilization.

Main Functions of PLATINALINK

User and Permission Management

PLATINALINK enables unified user management and flexible permission settings, realizing role-based access control. This allows each organizational role—such as IT administrators, measurement device operators, and approval personnel—to access only the necessary operational scope.

Through this mechanism, clear traceability of “who did what and when,” as required by GMP and other regulatory requirements, is ensured, while also serving to prevent unauthorized access and operations.

Security Policy Settings

PLATINALINK implements password policy management functions to maintain and reinforce the overall security level of the system, with compliance to GMP and other regulatory requirements as a prerequisite. In particular, strict user authentication is a vital element in ensuring data integrity.

Administrators can flexibly configure the following parameters to align with organizational security policies:



Figure 2 Example of PLATINALINK configuration.

- Minimum password length setting (e.g., at least 8 characters)
- Mandatory use of uppercase letters, lowercase letters, numbers, and symbols
- Enabling periodic password changes (e.g., every 90 days)
- Prevention of reuse of previously used passwords
- Setting a maximum number of failed login attempts and account lock functionality
- Automatic logout after a certain period of inactivity

Additionally, login history and password change history are recorded as audit trails, providing a mechanism for early detection of signs of unauthorized access.

These functions are designed to maintain system robustness while ensuring user convenience, further enhancing the reliability and consistency of data managed by PLATINALINK (Figure 3).

Electronic Signature Function for Reports

PLATINALINK is equipped with report management functions after measurement completion, enabling PDF-format storage and electronic signature records.

These reports can be used directly as audit documentation, and since storage and retrieval are completed within PLATINALINK, the need for paper output and physical storage is eliminated. As a result, storage space and operational costs are reduced, and risks of record tampering or loss are minimized (Figure 4).

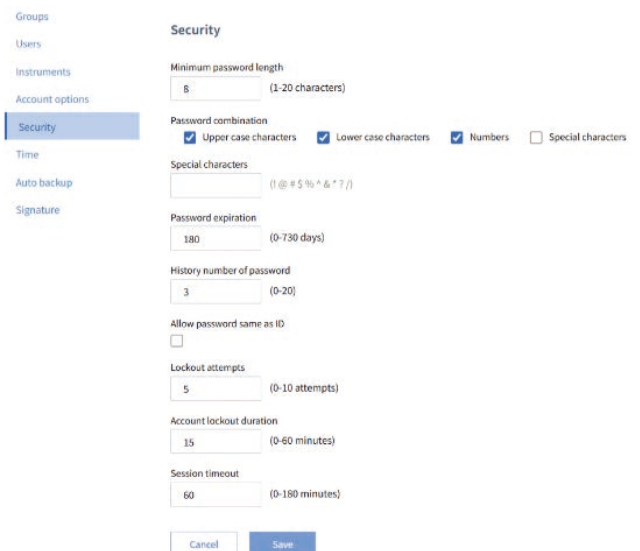


Figure 3 Security policy setting screen.

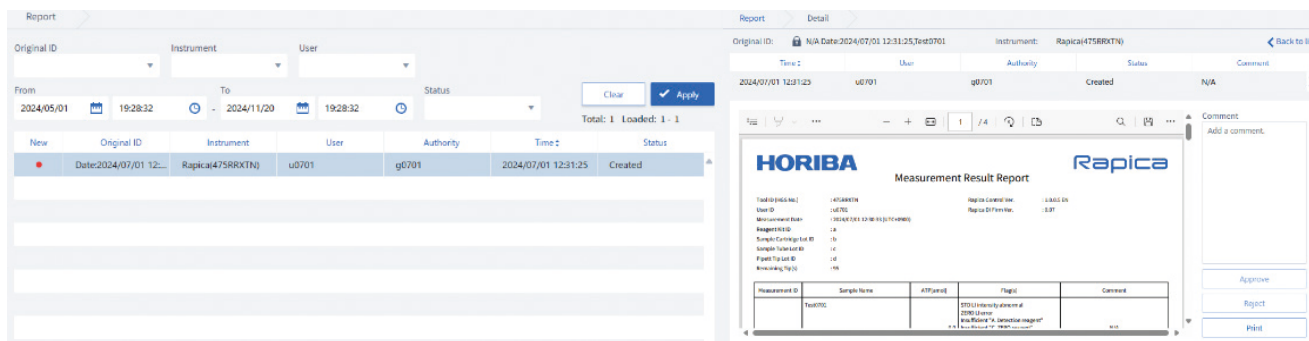


Figure 4 Management screen for report search and display.

Audit Support Functions

In accordance with the ALCOA+ principles, PLATINALINK incorporates advanced audit trail functions. All operations are automatically recorded, and search/filtering features (by user, date/time, operation type, etc.) enable rapid information presentation during audits. This also allows for visualization and improvement of business processes in daily operations (Figure 5).

Data Management Functions

PLATINALINK provides an environment where users can centrally manage operation logs, measurement data, and analytical reports automatically collected from measurement devices. Automatic backup and related features reduce the risk of data loss, establishing a data storage system that complies with the “Enduring” principle of ALCOA+.

Future Prospects

PLATINALINK currently supports multiple products as a common platform, underpinning data integrity assurance and operational efficiency in pharmaceutical settings, and its role is expected to further expand.

In the future, we plan to increase the number of analytical instruments linked to PLATINALINK and expand sales, thereby incorporating more feedback from the field to enhance functionality.

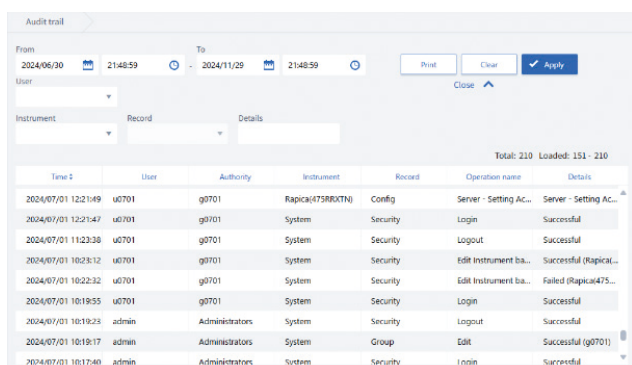


Figure 5 Audit trail list screen.

Although PLATINALINK is presently positioned as HORIBA’s data integrity platform, future developments are expected to include the following expansions as a web-based unified management system:

- Integration with devices from other manufacturers
- Introduction of automatic alert functions through user behavior analysis and anomaly detection
- Enhanced support for electronic records, such as electronic signatures for data

Furthermore, leveraging the reliability, scalability, and versatility of PLATINALINK, deployment to other industries where data reliability is critical—such as environment, food, chemicals, and semiconductors—is also envisioned. Through these efforts, HORIBA aims to contribute to improved quality and transparency across society.

Conclusion

PLATINALINK, developed by HORIBA, is a common platform that achieves both data integrity and operational efficiency required in the pharmaceutical industry. Its robust design, compliant with ALCOA+ principles, provides consistent data integrity functions across multiple products, contributing to reduced user burden and enhanced reliability.

Additionally, through working groups established within the company to address the pharmaceutical market and feedback from users, we will continue to pursue ongoing improvements that address real-world challenges.

* Editorial note: This content is based on HORIBA’s investigation at the year of publication unless otherwise stated.

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