

Solutions Offered by Shimadzu Corporation

Data Integrity Compliance in the Analytical Laboratory



Strengthen Data Integrity with LabSolutions™ DB/CS

Data integrity means the completeness of data. It expresses an assurance that all the data is included and that there are no inconsistencies. LabSolutions DB/CS software enables compliance with data integrity requirements by providing a total system for managing analytical instruments and test information in a single location. It not only improves the efficiency of testing processes, but also prevents data tampering.

Data Integrity for Various Analytical and Testing Instruments

Data integrity can be improved not only for chromatography and spectroscopy instruments, but also for analytical balances and various other devices used in analytical laboratories.

Build a System Optimized for Each Specific Laboratory

From small standalone systems (devices and computers) to networked or cloud-based systems of large numbers of analytical and measuring instruments, LabSolutions DB/CS can provide systems optimized for the given laboratory scale and form of operation.

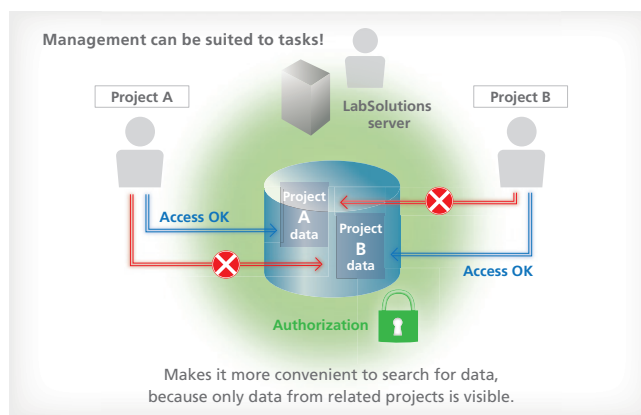
Manage Data Securely

Storing data files, method files, etc. in Windows® folders labeled with the analyst's name or arranged by date can result in the following.

- Files could be deleted, copied, moved, or renamed.
- Original data or data from postrun analysis could be overwritten.
- Identically named files could be saved in separate folders.

A system that provides highly reliable data, and prevents data tampering, can be built by centrally managing the various data obtained from the various analytical instruments in the laboratory in a LabSolutions DB/CS database.

- Use a database to manage instruments, users, and analytical data.
- Projects can be created in the database, based on given operations.

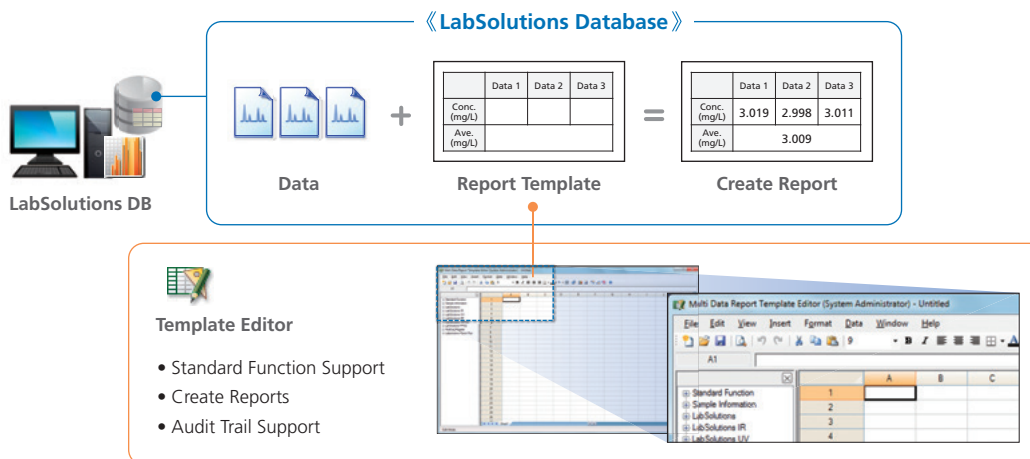


Using Projects to Manage Data More Securely

Automate Report Creation

Excel® is often used for quantitative calculation of analytical data, but that could prevent obtaining correct results due to errors or alterations, such as when transcribing analytical results, creating or storing Excel® files, or printing or storing Excel® reports.

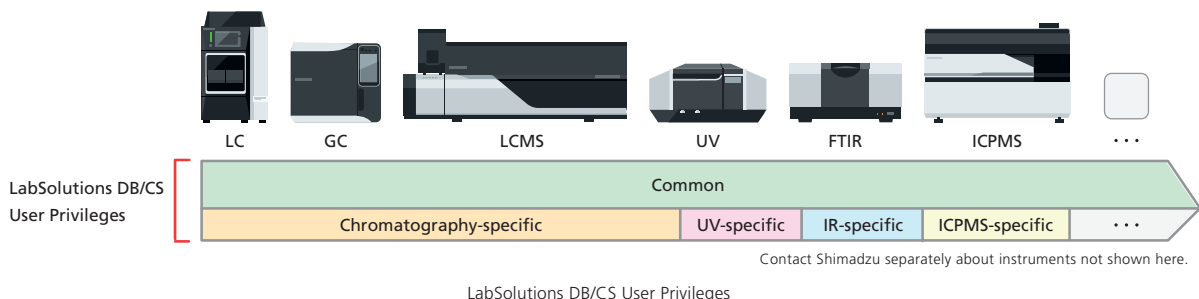
The multi-data report function in LabSolutions DB/CS can automate such processes and reduce the risk of errors and other problems. It can also consolidate the data from different instrument types into a single report.



Outline of the Multi Data Report Function

Standardizing User Management and Deploying User Privileges for Other Instrument Types

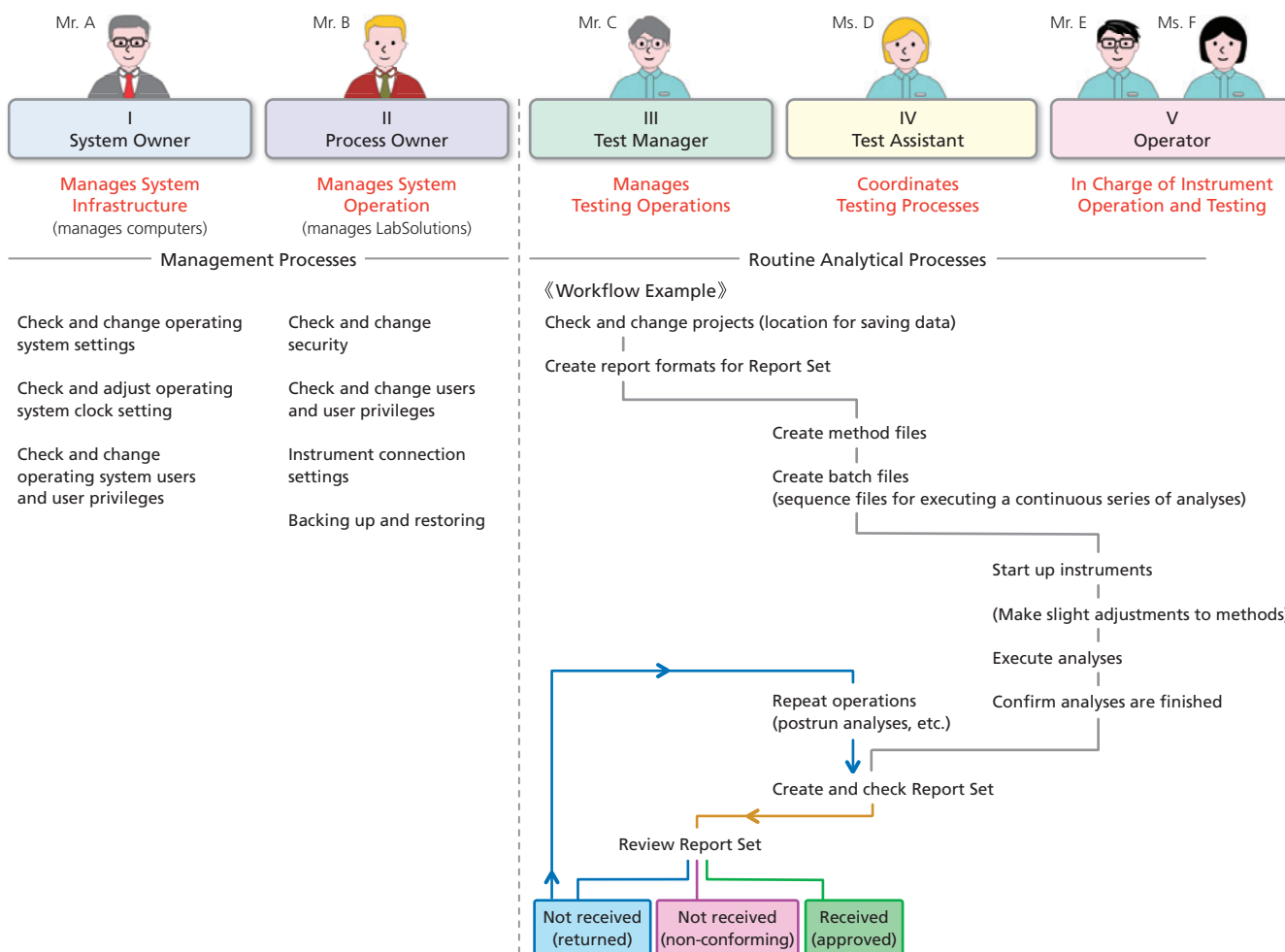
In addition to LC and GC systems, analytical laboratories use UV, FTIR, ICPMS, and other types of instruments. However, the process of managing the users of those instruments and assigning user privileges for each instrument type is extremely tedious and time-consuming. If LabSolutions DB/CS is used, user management operations can be standardized for all instruments and user privileges specified for LC or GC systems can also be deployed for other types of instruments.



Managing User Operations (Processes) Appropriately

Data integrity requires not only restricting access to laboratory analytical instruments, but also assigning specific user privileges to analytical laboratory personnel.

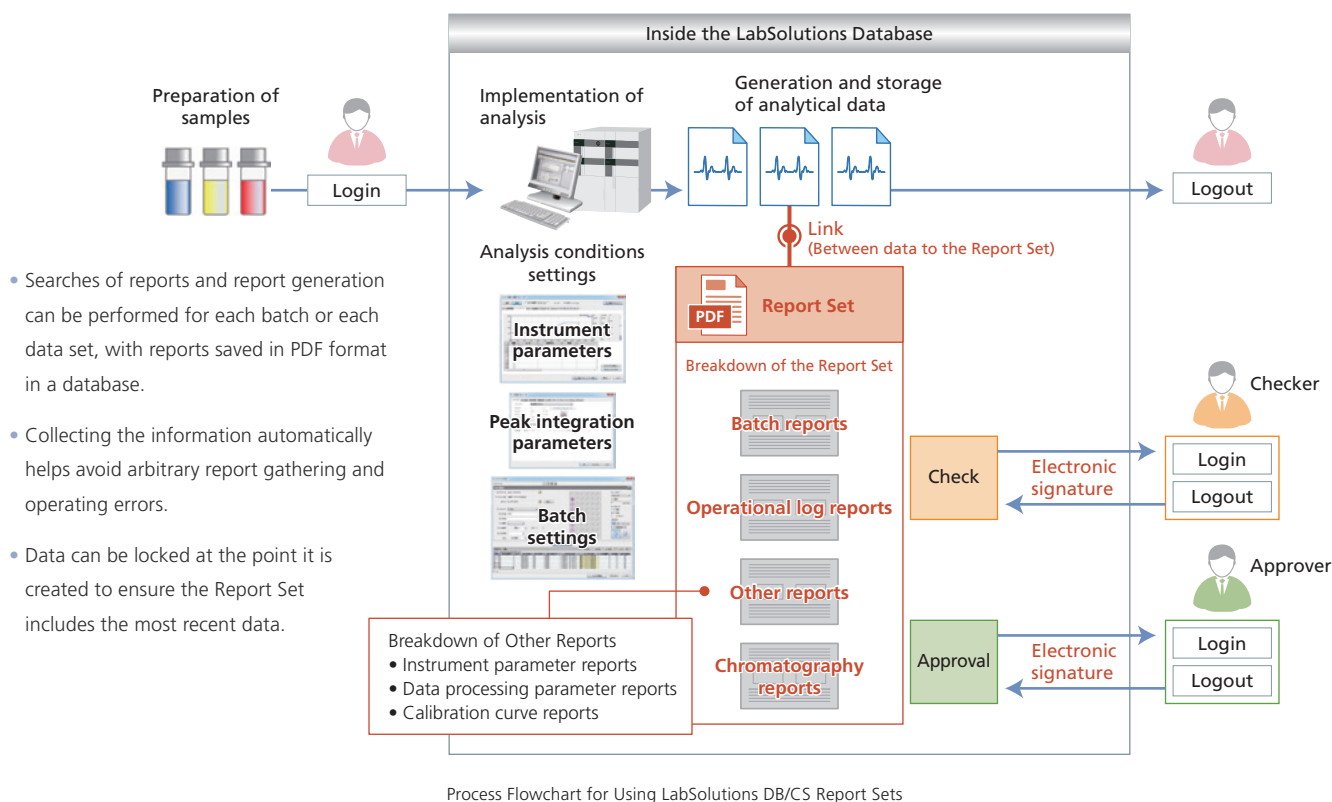
To ensure user privileges are specified appropriately, visualize the workflow by creating a process flow chart and then use LabSolutions DB/CS to register users and specify user privilege settings for implementing that workflow.



Example of User Privilege Groups and Workflow Recommended by LabSolutions DB/CS

Reducing Potential Risks in Analysis/Postrun Workflow - LabSolutions DB/CS Report Set

It is impossible to determine from looking at a chromatogram or other analytical data obtained whether or not the data was acquired using correct test parameter settings (such as instrument or data processing parameter settings). Furthermore, the possibility of test parameters being tampered with cannot be ruled out. However, LabSolutions DB/CS Report Set can be used to link analytical data with metadata (results from parameter settings, data analysis, and other processes that involve human intervention) and with the entire series of actions recorded in the operation log, so that the data can be reviewed in an electronically managed state. In other words, metadata and operation records are displayed in a visible form, so that they can be reviewed together with the analytical data.



Note: LabSolutions DB/CS Report Set functionality is compatible with HPLC, GC, LCMS, UV, FTIR, and RF devices.

Note: Contact Shimadzu separately about the specifications and functionality of specific instruments related to strengthening data integrity.

For more information about Shimadzu solutions for strengthening data integrity, go to the following website.

<https://www.shimadzu.com/an/industry/pharmaceuticallifescience/fda.html>

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First Edition: February 2019, Printed in Japan 3655-02902-20A1T