C191-E047A

SHIMADZU
Excellence in Science

Solutions Offered by Shimadzu Corporation

Data Integrity Compliance in the Analytical Laboratory

Strengthen Data Integrity with LabSolutions™ DB/CS

Data integrity refers to maintaining data completeness, consistency, accuracy, and reliability throughout the product life cycle. LabSolutions DB/CS software offers powerful support for ensuring compliance with data integrity requirements by comprehensively managing analytical instrument information.

Strengthen Data Integrity for Various Instruments

LabSolutions DB/CS software enables stronger data integrity for all types of instruments in analytical laboratories, such as LC, GC, LC-MS, GC-MS, UV, FTIR, spectrofluorophotometers, protein sequencers, ICP-MS, AA, EDX, thermal analyzers, particle size analyzers, AG, TOC systems, Rigaku X-ray diffractometers and analytical balances.

Configure Systems Optimized for the Given Laboratory Size

LabSolutions DB/CS systems can be optimized for a wide range of laboratory sizes and operating styles, from small standalone systems (with an instrument and computer) to networked or cloud-based systems with many analytical or measuring instruments.

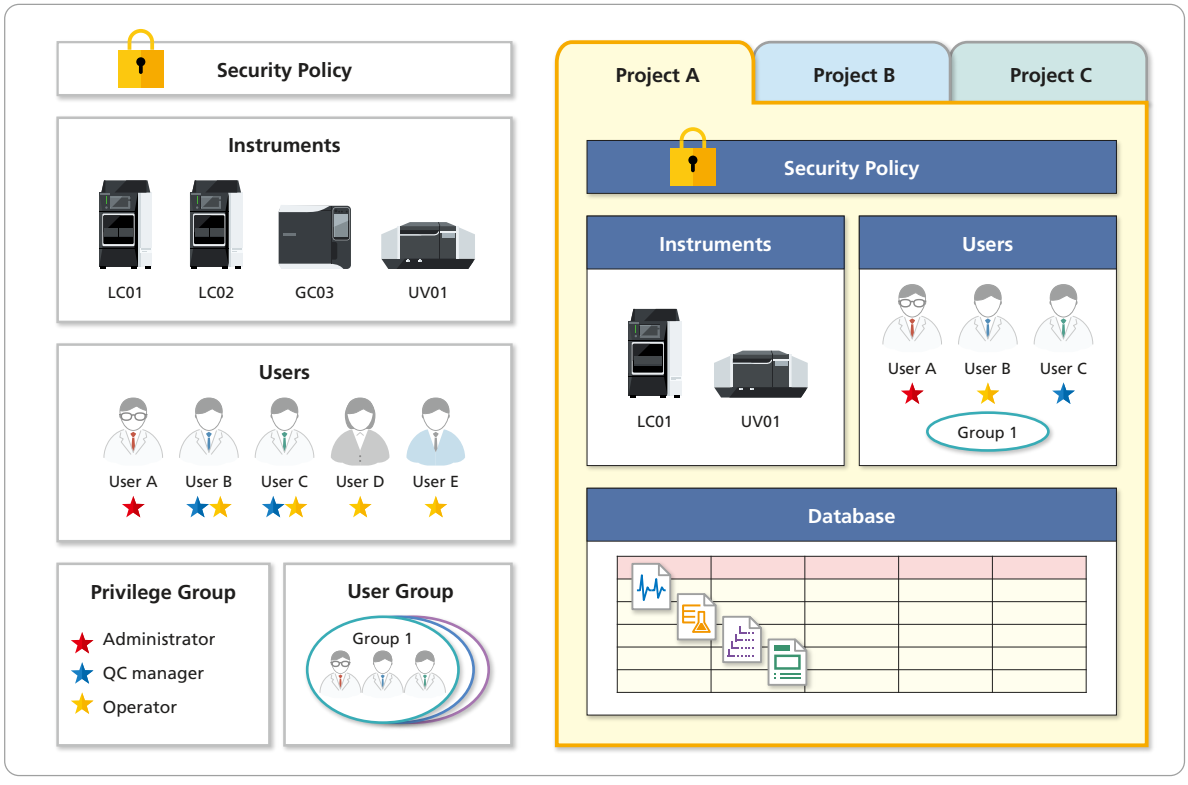
Managing Data Securely

Systems can provide highly reliable data, including preventing data falsification by using a LabSolutions DB/CS database to centrally manage the data obtained from various analytical instruments in the laboratory.

- Instruments, users, and analytical data are managed in a database.
- Projects can be created in the database based on operating practices.

Commonizing User Management and User Privilege Settings for All Instruments

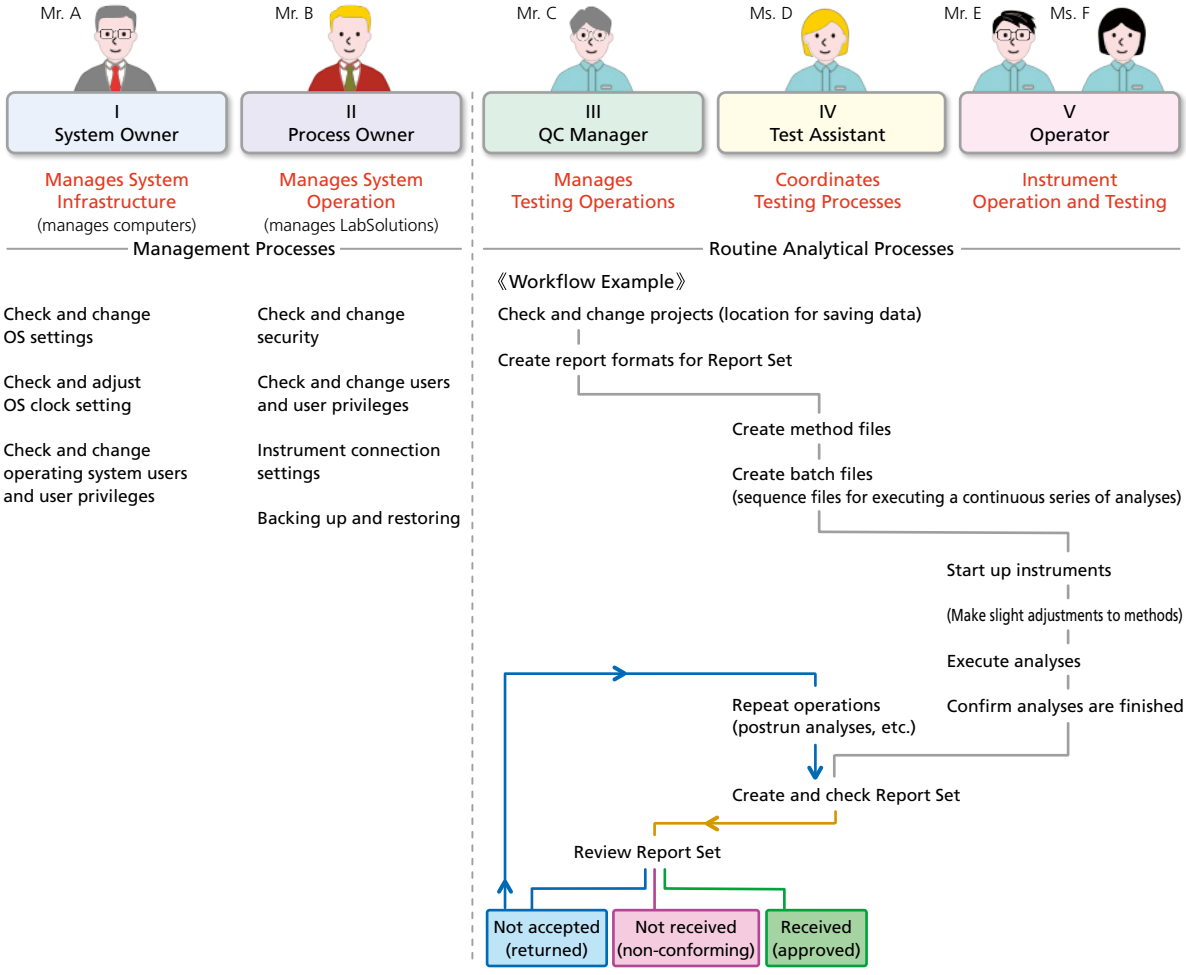
A wide variety of instruments other than LC and GC systems, such as LC-MS, GC-MS, UV, and FTIR systems, are also used in analytical laboratories. Managing the users and user privileges for all those instruments to ensure they are used appropriately is extremely tedious and time-consuming. LabSolutions DB/CS can reduce the time and trouble required for user management by commonizing the user management system for all instruments and specifying all user privilege settings.



Managing User Operations (Processes) Appropriately

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

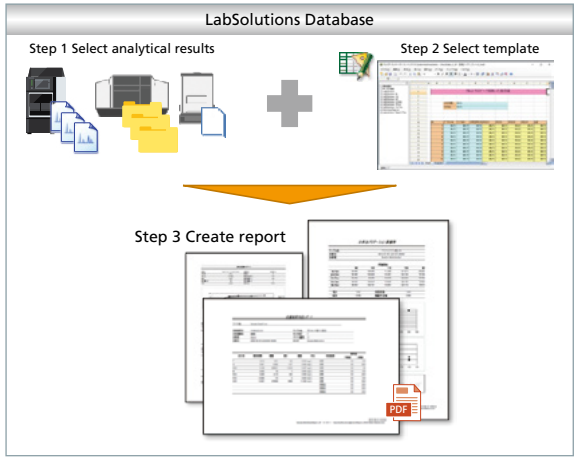


Example of User Privilege Groups and Workflow Recommended by LabSolutions DB/CS

Automating Report Creation

Spreadsheet software is often used, such as for quantitative calculations of analytical data, but that can prevent obtaining proper results due to errors or alterations, such as when transcribing analytical results, creating or storing files, or printing or storing reports.

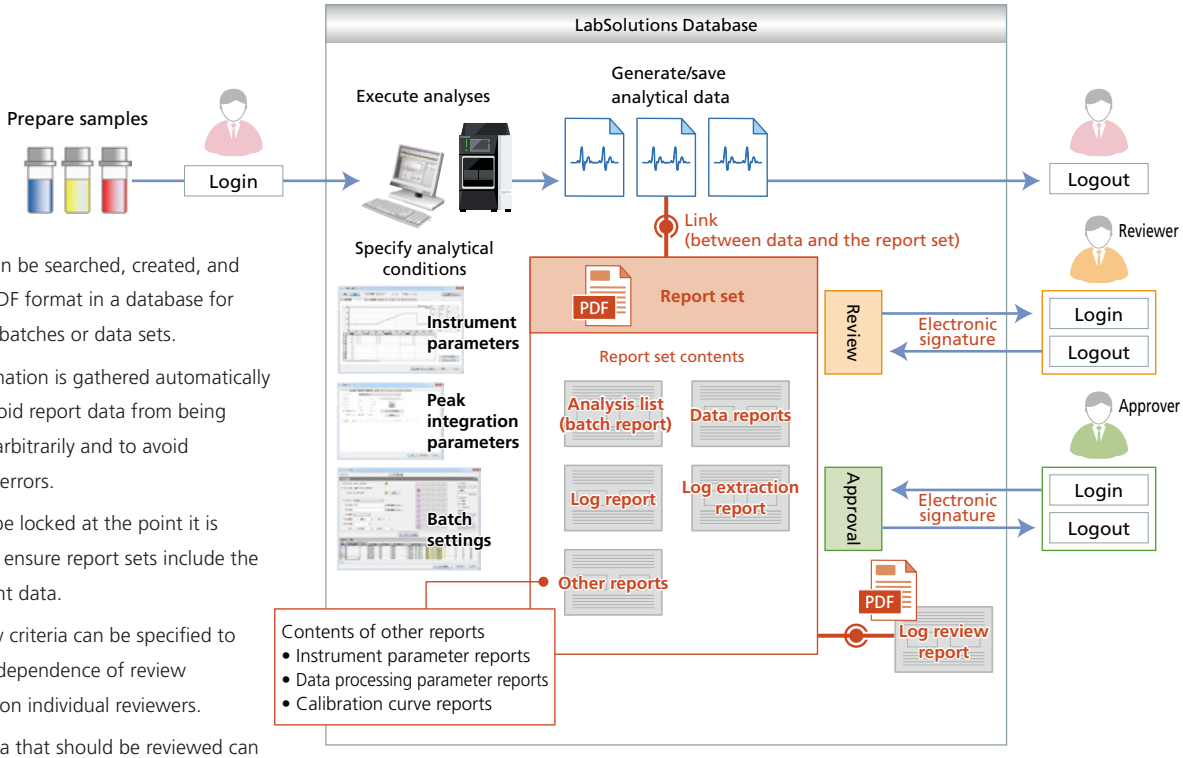
The multi-data report function can create reports for the selected analytical results using the selected report template and then automatically create and save the report in the database. That eliminates the need to transcribe data, reduces the risk of errors, and can prevent data alterations or falsification. It also means reports with a combination of LC, GC, MS, FTIR, UV, analytical balance, and other instrument data can be created more efficiently using three easy steps.



Reducing Potential Risks in the Data Acquisition/Analysis Workflow - LabSolutions DB/CS Report Set

It is impossible to determine from simply looking at an acquired chromatogram or other analytical data whether the data was acquired using correct test parameter settings (such as instrument or data processing parameters) or rule out the possibility of the test parameters being falsified. Furthermore, log reviews are required to guarantee that electronic records do not include any fraudulent or suspicious data. By using LabSolutions DB/CS report sets, analytical data can be electronically managed and linked to metadata (results from processes that involve human intervention, such as specifying parameter settings or data analysis) and to the entire series of corresponding log data. In other words, metadata, log data, and analytical data can all be reviewed within a single report. In addition, by specifying all log events that should be reviewed in advance, all log events that need to be reviewed can be automatically extracted to enable efficiently checking for fraud or suspicious content in log data. Additionally, when review records are signed, they can be linked to data as a log review report. That means the entire series of process steps from data acquisition to data log reviews can be managed electronically.

- Reports can be searched, created, and saved in PDF format in a database for individual batches or data sets.
- The information is gathered automatically to help avoid report data from being gathered arbitrarily and to avoid operating errors.
- Data can be locked at the point it is created to ensure report sets include the most recent data.
- Log review criteria can be specified to eliminate dependence of review standards on individual reviewers.
- All log data that should be reviewed can be reviewed at the same time to significantly shorten review times.



Proposed Process Flowchart for Using LabSolutions DB/CS Report Sets

Note: LabSolutions DB/CS report set functionality is compatible with all Shimadzu LC, GC, LC-MS, GC-MS, UV, FTIR, RF, SALD, TA, AG, TOC-L systems and Rigaku X-ray diffractometers.
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/industries/small-molecule-pharmaceutical/data-integrity/index.html

SHIMADZU
Shimadzu Corporation
www.shimadzu.com/an/