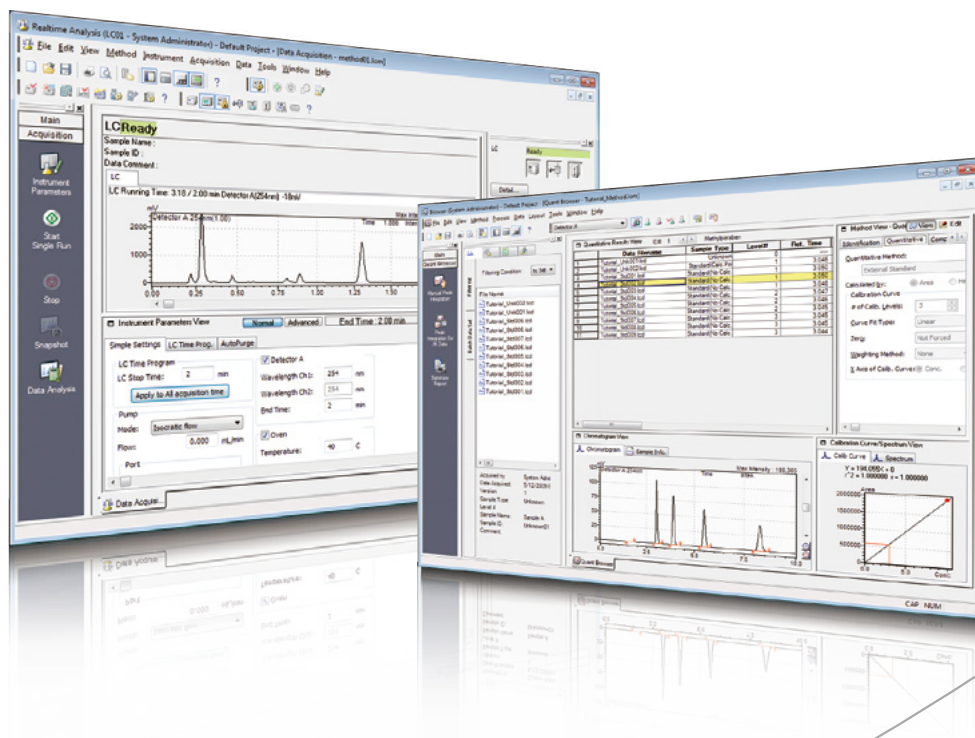


Analytical Network Data System Compliant with ER/ES Regulations  
Progress Configuration of LabSolutions System

# LabSolutions



# LabSolutions™

**LabSolutions features an innovative operating environment and provides complete data management to ensure secure information in networked laboratories.**

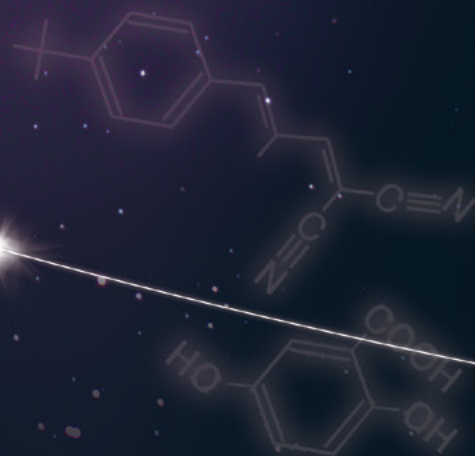
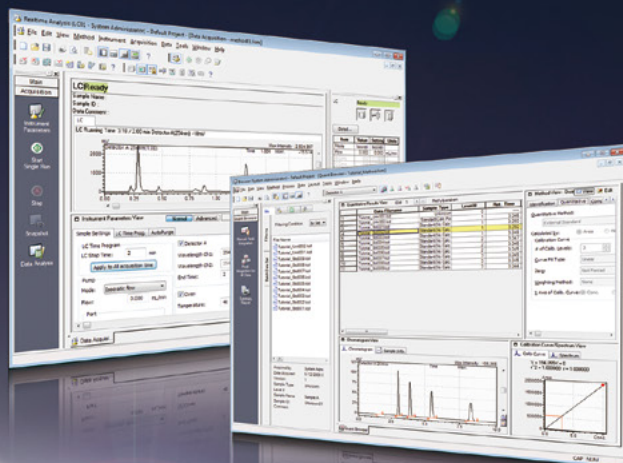
LCs, GCs and MSs are used extensively in quality control and research and development departments in a wide range of industries, including pharmaceutical, chemical, and food.

Recently, an increasing demand for food safety and environmental analysis and measurement has led to a dramatic increase in the number of samples being analyzed. This, in turn, has resulted in demands for faster, easier-to-use instruments and software.

In the pharmaceutical industry, compliance to regulations and guidelines, such as CSV and PIC/S GMP and U.S. FDA 21 CFR Part 11, and the proper, efficient management of instruments and analytical data are required.

With this background, faster, more efficient management of instruments and data is essential. LabSolutions is a network-compatible analysis data system capable of meeting these needs.





# LabSolutions

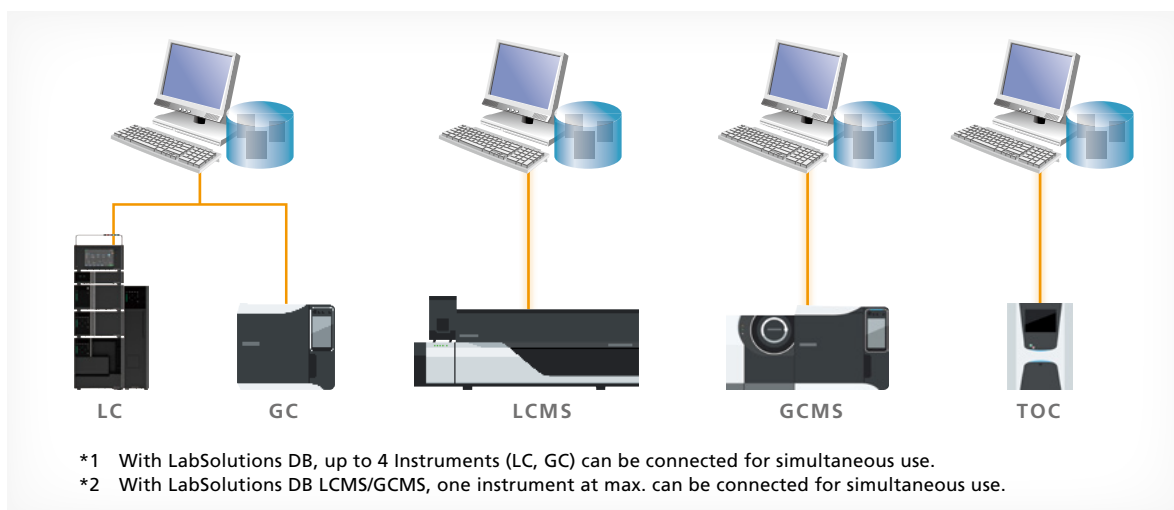
## LabSolutions DB

Secure Data Management with a PC

LabSolutions DB integrates a data management function with LabSolutions LC/GC and is compliant with the ER/ES Regulations. It is optimally configured for customers using a PC.

Recommended for the following customers

- Facilities with only a few instruments (maximum of three units/PCs)
- Facilities where network connections are not required
- Facilities interested in ER/ES compliance and limited to stand-alone systems



## LabSolutions CS i-Package

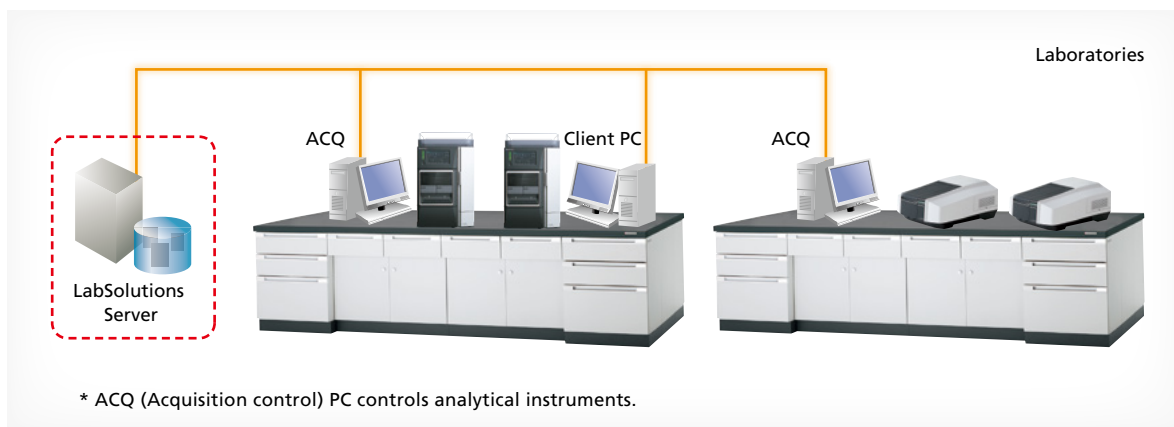
Install a server in the same manner as a computer

LabSolutions CS i-Package includes all the items necessary for building a network easily in one convenient package.

Using it to configure a closed network inside the laboratory significantly reduces the work involved in managing the server.

Recommended for the following customers

- Facilities with only a few instruments (10 or fewer per computer)
- Customers that want to manage instruments centrally from the server





# LabSolutions CS

Freely Accessible to the Analysis Network

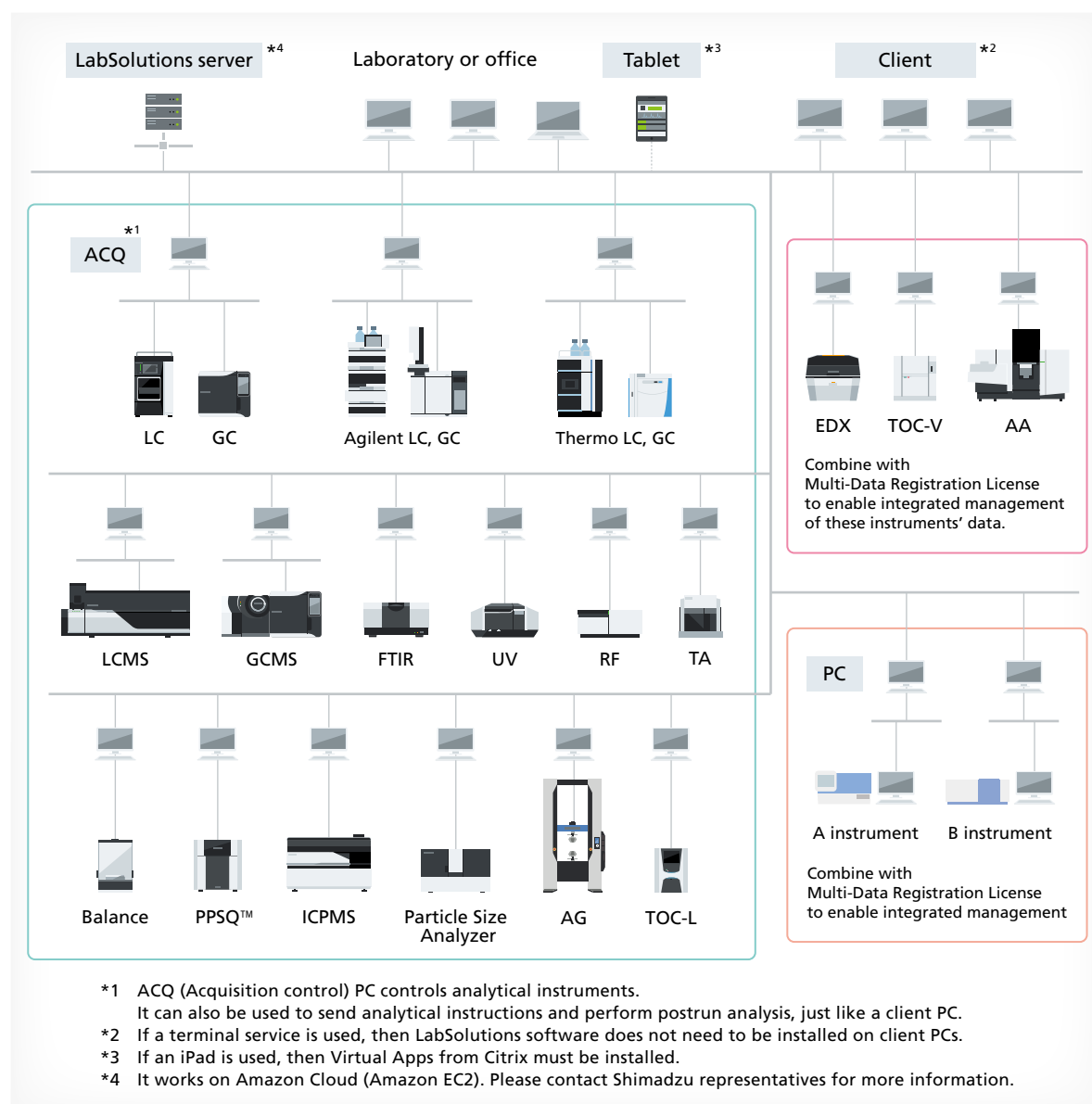
Since all analytical data is managed in the database of a server computer, LabSolutions CS can read data from any personal computer on a network. In addition, it allows users to perform instrument monitoring and control from a personal computer (client PC) not connected to the instruments. Furthermore, it allows direct control of another vendor's LCs and GCs.

Moreover, client PC functions are performed on a server and client PCs corresponding to a Windows® terminal service do not need to install LabSolutions software.

Lastly, LabSolutions CS is compatible with Citrix Virtual Apps and can perform more advanced server management.

Recommended for the following customers

- Facilities with a large number of instruments and users
- Facilities interested in enhancing managerial efficiency
- Facilities interested in controlling other vendor's instruments from the same software.
- Facilities interested in enhancing procedural efficiency
- Facilities where existing PCs can be used as client PCs



# Solutions Achieved with LabSolutions

LabSolutions is designed to solve problems that can arise in laboratories!

## Problems in laboratory

### Poor Procedural Efficiency

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- Software operations differ for each instrument and by vendor.
- Managing the variety of instruments requires a lot of work.
- It is difficult to assess which instruments are currently operating.
- The PC is occupied until analysis is complete.
- Confirming audit trails is difficult.
- Checking data involves a lot of work.
- As the amount of data increases, searching for data of interest becomes difficult.
- Analysis is impossible when the server is down.
- Analytical results must be transferred manually when creating reports in Excel®.

### Data Management is Uncertain

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- With files, there is a risk that important data may be deleted or changed.
- Security measures are uncertain.
- Wants to link to a host system.

### Heavy Burden on Administrators

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- User-management and backup procedures are time and labor-consuming.
- Management is not directly suited to tasks.

### Regulatory Compliance is a Difficult Burden

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- The burden is greater than for primary duties.
- CSV\* procedures for each client PC increase costs.

## Solutions by LabSolutions

### Provides a Comfortable Operating Environment

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- Integrates LC, GC, LCMS and GCMS software.
- Integrates management of a variety of analytical instruments.
- The equipment operating status in a network is available at a glance.
- Provides visibility for a series of analytical process.
- Electronic format improves efficiency of confirmation processes.
- Control and analysis are possible from PCs other than the analysis PC.
- An enormous quantity of data can be quickly searched.
- Analysis is possible for LC and GC even when the server is down.
- Automatic creation of spreadsheet format reports (multi-data report creation)



### Safe and Secure Data Management

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- Database management prevents mistakes.
- Solid security
- Interface supports linking to an LIMS system.



### More Efficient Managerial Procedures

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- System information, including data and users, is integrated with a server.
- Pertinent information is managed for every project.



### Total Support for Regulatory Compliance

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- Support functionality for CSV\* (IQ/OQ validation) procedures
- With terminal service, the configuration management of LabSolutions software in a client PC is unnecessary.
- Support creating documents

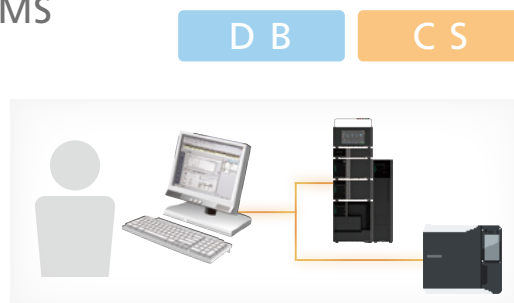


\* CSV: Computerized System Validation

# Comfortable Operating Environment

## Integration of LC, GC, LCMS and GCMS Software

LabSolutions is integrated software for LC, GC, LCMS and GCMS systems. As LabSolutions integrates acquisition, data analysis, report creation, and other operations in the same interface, it offers enhanced operability and is easier to learn and operate. Furthermore, switching from LCSolution™, GCSolution™, LCMSsolution™ and GCMSsolution™ is easy because of the same operability it inherited from those software.



## Integration of Management of a Variety of Analytical Instruments

There has been increasing interest in Data Integrity, not only for chromatography instruments, but for other analysis instruments as well, in accordance with their complexity. Multi instruments data registration license enables integrated management of data from various analytical instruments.



## Check Equipment Operating Status at a Glance

The LabSolutions operating monitor enables confirming the operating status of connected instruments, and the estimated analysis completion time for each instrument. Assessing the operating status at a glance is possible at a glance even when multiple LC/GC instruments are operating at the same time. This is helpful for scheduling analysis procedures to match equipment availability. In addition, equipment icons are displayed to match the grouping or location of instruments in a laboratory.

### Table View

Instrument	Type	Analysis	Status	User	Project	Current C...	Estimated En...	Instrument
GC01	GC	All Operat...	Running	System Ad...	Default Project	1	9/29/2011 7:3...	
GC02	GC	All Operat...	Ready	System Ad...	Default Project	0		
GC03	GC	All Operat...	Ready	System Ad...	Default Project	0		
GC04	GC	All Operat...	Initializing	System Ad...	Default Project	0		
LC01	LC	All Operat...	Ready	System Ad...	Default Project	0		
LC02	LC	All Operat...	Running	System Ad...	Default Project	1	9/29/2011 7:3...	
LC03	LC	All Operat...	Ready	System Ad...	Default Project	0		
LC04	LC	All Operat...	Ready	System Ad...	Default Project	0		

### Icon View

C S

..... Features provided by LabSolutions CS.

D B

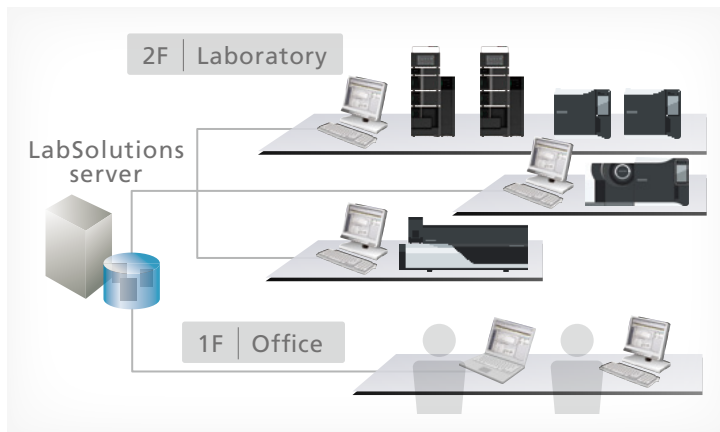
..... Features provided by LabSolutions DB.



## Control and Analysis are Possible from PCs Other than the Analysis PC

CS

With LabSolutions CS, equipment can be accessed freely, from any location, while maintaining security. For example, before starting an analysis, the equipment can be operated from a PC in the laboratory. After analysis starts, a PC in the office can be used to confirm operating status, control the equipment, and analyze the data. This improves the efficiency of analysis status monitoring, equipment control, report creation and other procedures.



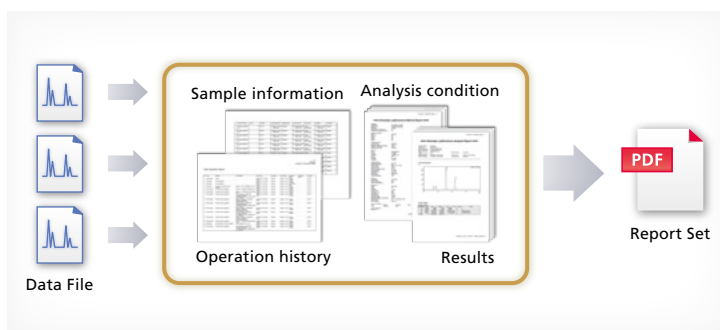
## Visualization of the Sequence of Analysis Operations

DB

CS

Creating a report set\* provides visibility of the individual analytical operations involved in the overall analytical process. When analytical operations are visible, it is easier to check for operating errors, which helps improve the efficiency and reliability of checking processes.

\* Report sets include test methods and test results for a series of samples analyzed, and also a corresponding operation log (a record of all operating events from login to logout), which are automatically extracted from the data and summarized in a single report.

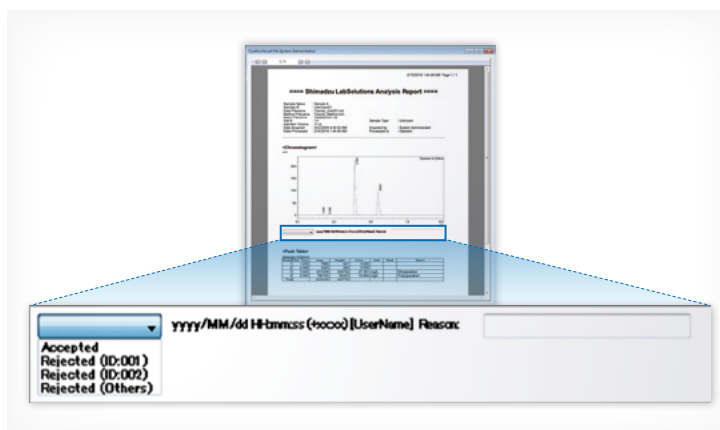


## Electronic Format Improves Efficiency of Confirmation Process

DB

CS

A record of checking the report content can be included anywhere in the test results report, which is output in PDF file. Even if a certain element of the report was not checked, an error notification function notifies the user that the item was not checked. Consequently, the system also improves the work flow of checking processes, which can be performed easily on-screen to improve efficiency. In addition, the ability to perform all processes electronically means it supports migration to a paperless operation.



# Comfortable Operating Environment

## Quickly Search an Enormous Quantity of Data

CS

It can be inconvenient to search for specific data on a LabSolutions DB/DB LCMS system, because it involves viewing data on the same computer normally used for analysis.

LabSolutions CS provides integrated, server-based

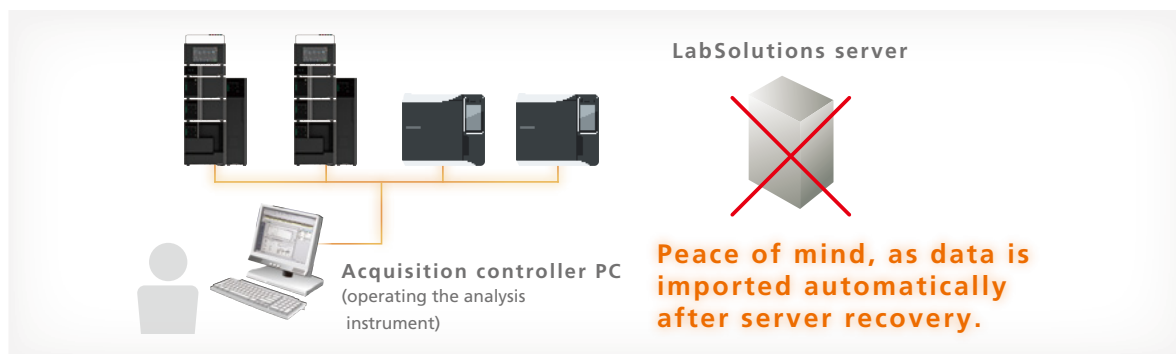
data management, which means that data can be browsed from anywhere. In addition, the data obtained from the analysis schedule can be looked for collectively and a wealth of search functions makes it easy to search for data of interest.

## Capable of Analysis Even When the Server is Down (LC, GC)

CS

With general systems, when the server is down, analysis stops. With LabSolutions CS, even if a problem with the server occurs, analysis can be performed using the acquisition controller PC. In addition, after server

recovery, the data from analysis results are saved automatically in the LabSolutions server via the acquisition controller PC.



## Multi-Data Report Creation

DB

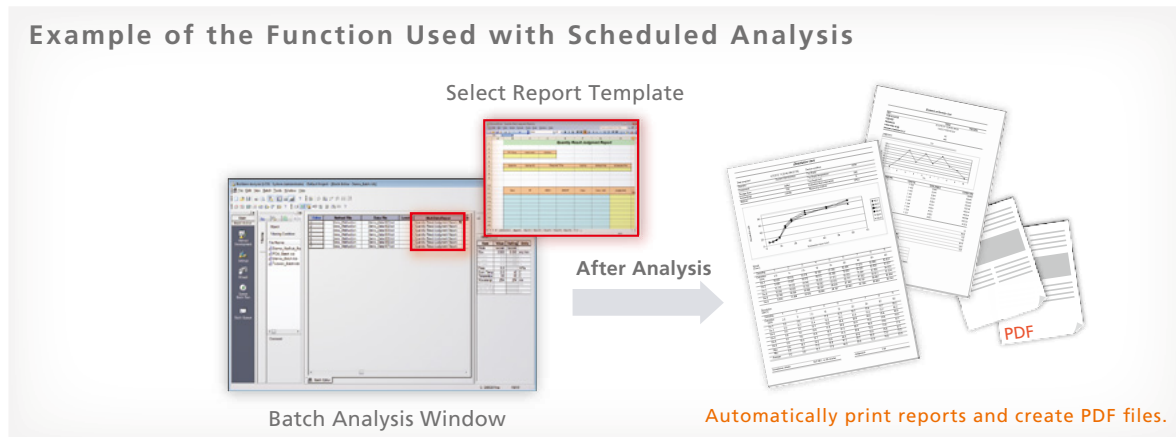
CS

In addition to the normal analysis report creation function, LabSolutions CS and DB / DB LCMS offers the multi-data report creation function that allows the user to prepare reports with combined data from various instruments. It provides report templates for system conformance, content uniformity, elution, and

other standard tests as standard. The operational environment is the same as for Excel®, making it easy to prepare report formats for various standard tests. In addition, this function supports automatic report printing and automatic generation of PDF files.

Multi-data report software is available as an option. For details, contact your Shimadzu representative.

### Example of the Function Used with Scheduled Analysis



# Safe and Secure Data Management

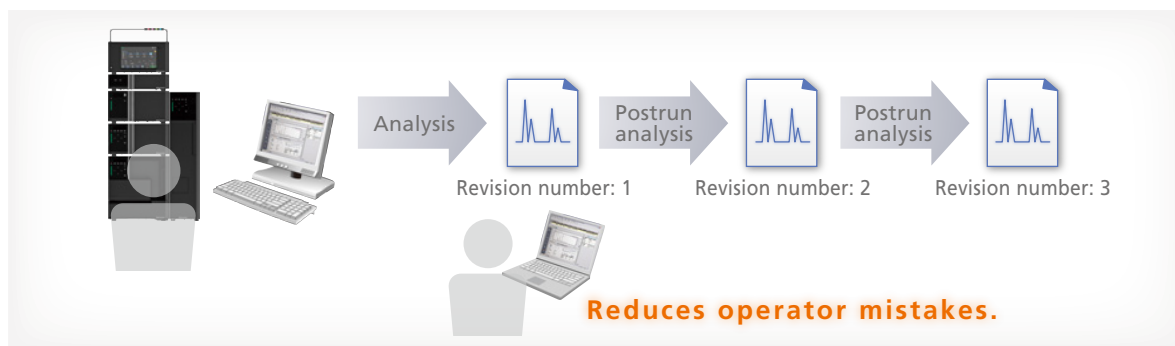
## Database Management Prevents Mistakes

DB

CS

With LabSolutions DB and CS, the analysis data is managed securely by the database. Overwriting, deletion and other mistakes typical of data file management do not occur. In addition, when postrun

analysis is performed using the acquired data, postrun analysis data revision numbers are automatically assigned, preventing the accidental overwriting of raw data. It is easy to display earlier data.



## Solid Security

DB

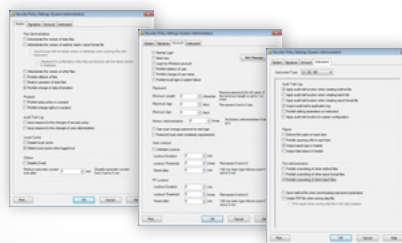
CS

Allows setting up an audit trail to ensure the reliability of data and document e-mail transmission functions when any event occurs in the system.

User accounts are managed using passwords, where password length, complexity and term of validity must satisfy specified requirements. It is also possible to set lockout functions to prevent illegal access, and set a registered user's deletion and change.

In addition, a box can be selected to prevent overwriting a data file, and outputting an item to a report can also be performed.

### Security Policy



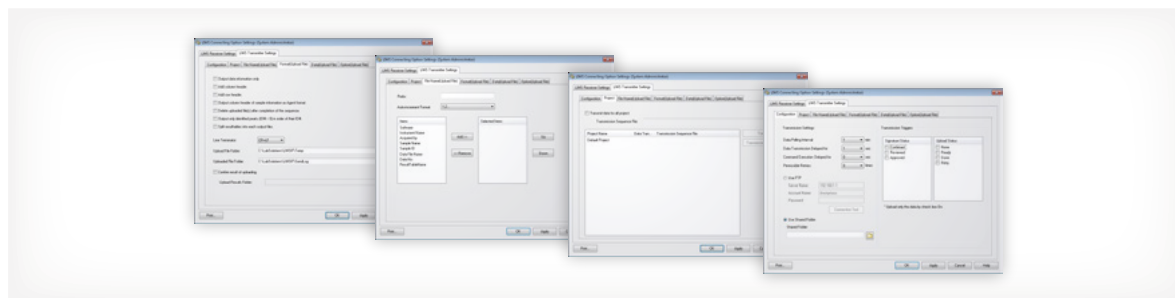
## Interface Supports Linking to LIMS System

DB

CS

The software includes an interface for linking to a laboratory information management system (LIMS). That means measurement results do not need to be entered manually to a host system, which should help avoid human errors, improve work efficiency, and improve data reliability.

Note: An additional license is required to enable the LIMS interface. Contact Shimadzu for further details.



# Improving Managerial Efficiency

## System Information, Including Data and Users, Is Integrated with a Server

CS

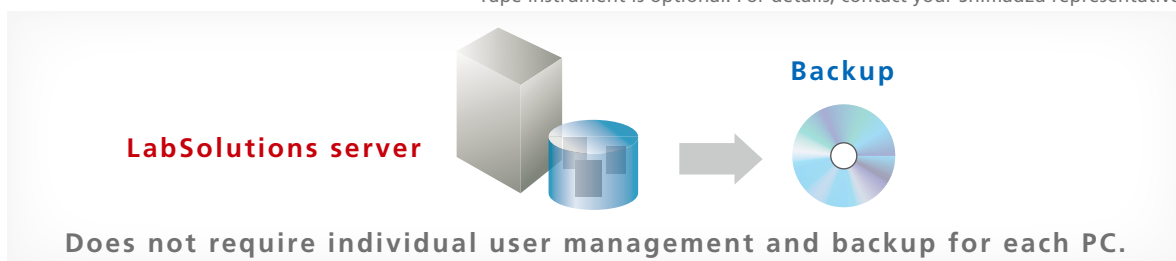
Currently, since user information is managed for every PC, as the number of PCs managed increases, so too does the burden on the administrator. LabSolutions CS provides integrated server-based management of user information, so user management is not required individually for each PC, thereby reducing the administrator's time and effort.

Data backup is also important. Since the data can

be managed with a server, data does not remain in each PC. It can be stored on the server or saved to media such as a DVD. The data can be referred to directly, without returning to the original database. (Restoration unnecessary)

In addition, if tape library equipment is used, it can overcome server trouble etc., thereby achieving even more efficient management.

Tape instrument is optional. For details, contact your Shimadzu representative.



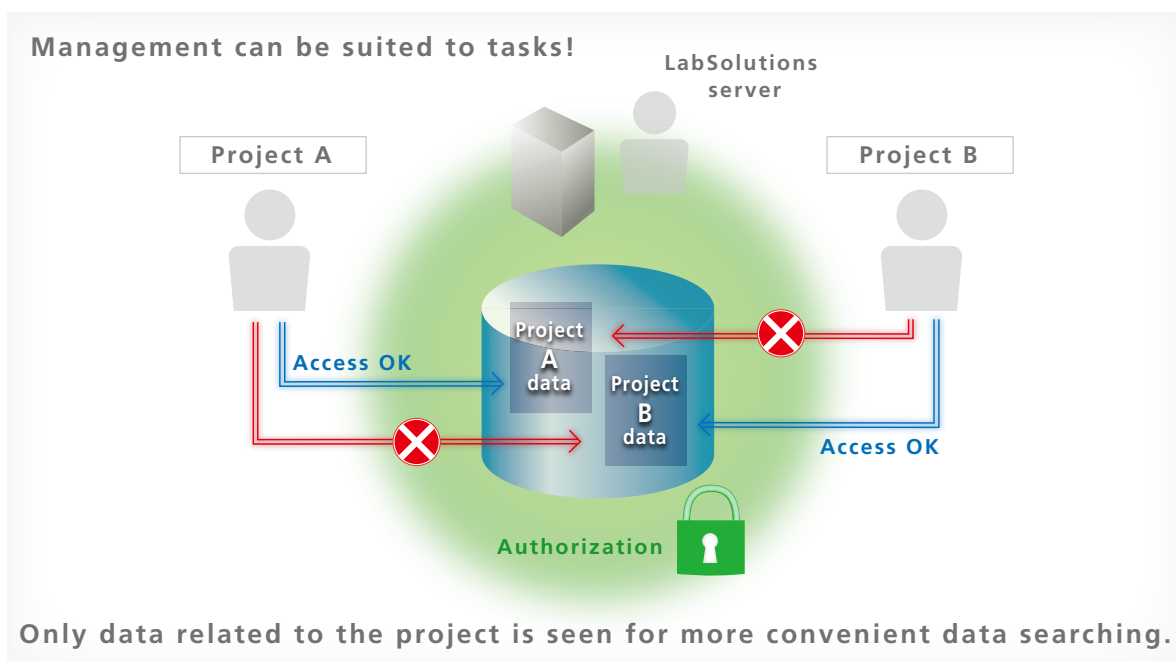
## Pertinent Information is Managed for Every Project

DB

CS

LabSolutions DB and CS provide a project management function enabling management suited to tasks and system operations. This function enables equipment and user management, security policy, and data

processing to be set on a project by project basis, thereby improving the efficiency of data searches and management tasks.



# Total Support for Regulatory Compliance

## Support Functionality for CSV (IQ/OQ Validation)

D B

C S

With conventional LCsolution / GCsolution / LCMsolution / GCMsolution software, CSV procedures involve confirmation and transcription of OS versions and software settings across multiple windows.

With LabSolutions, Windows® OS security patches and other PC and software installation information is integrated for display, and can be printed. In addition,

LabSolutions security policy, numerical rounding settings, and other system information, as well as user information and equipment information, can be integrated for printing from a single window. As a result, operators can confirm this information without opening a number of settings windows. This reduces operator mistakes and improves efficiency.

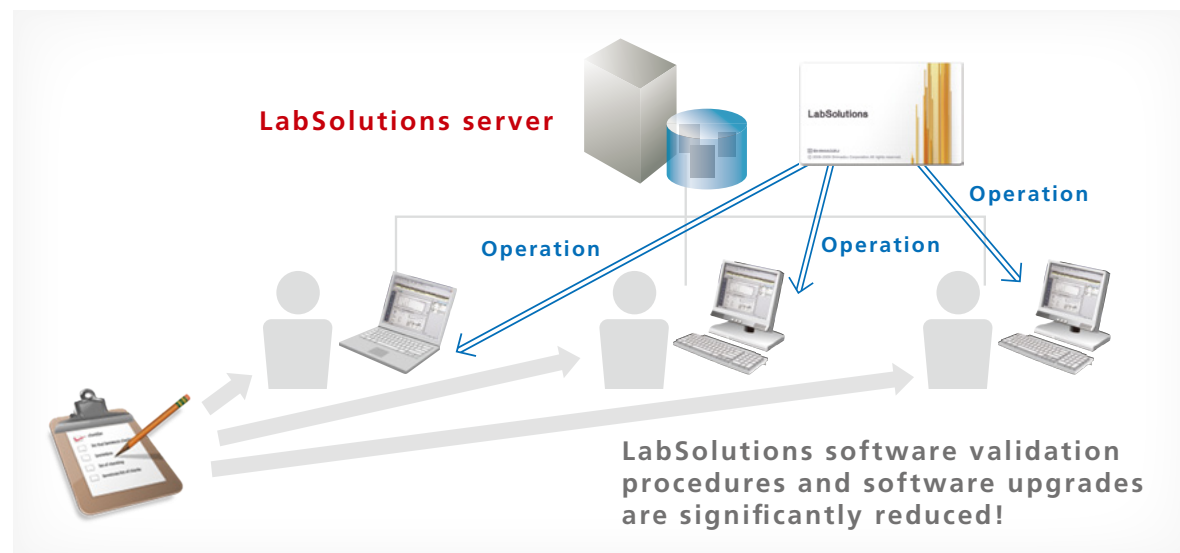


## Configuration Management of Client PC LabSolutions Software Not Required

C S

LabSolutions CS is compatible with the Windows® terminal service (RemoteApp). Since LabSolutions software is not installed on a client PC, this significantly reduces validation procedures and software upgrades for client PCs.

The terminal service function enables remote use of LabSolutions software installed on the server. The server-based LabSolutions software can be operated with the usual degree of user friendliness as is.





# Total Support for Regulatory Compliance

## Support for Document Creation

D B

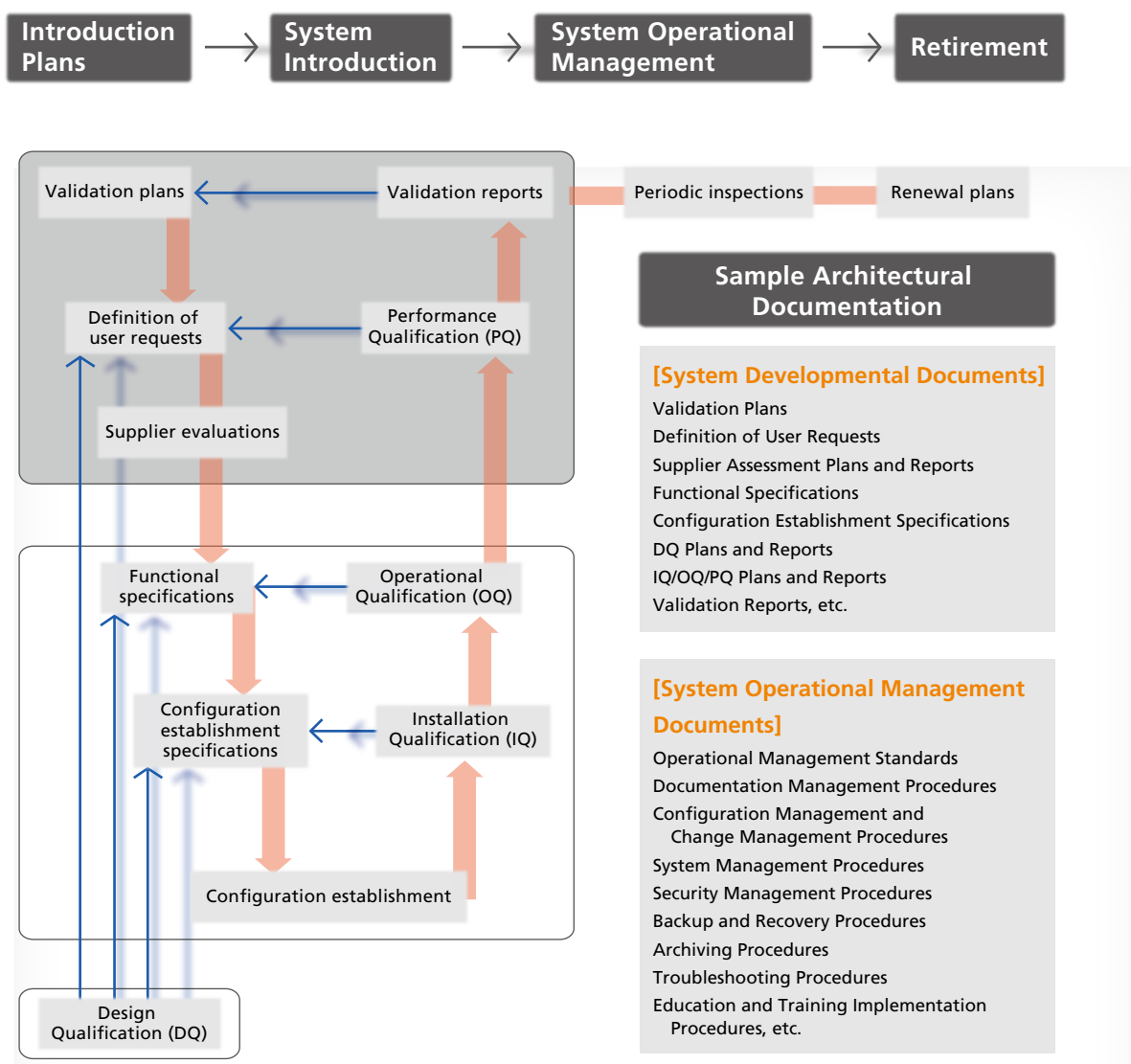
C S

To ensure regulatory compliance, system and operational management procedures must be documented, and the equipment must be operated in accordance with these procedures, necessitating operational conditions besides the functions that the equipment being used possesses.

In addition to the many procedures generally administered by the equipment manufacturer, Shimadzu also provides services to support the creation of documents that should be created and

maintained by businesses subject to regulation. We provide detailed, total support across the entire system lifecycle, from discussions prior to system introduction to periodic inspections after introduction, and even system upgrades. In addition, we respond promptly to trends in the world, such as new requirements from regulatory agencies, thereby maintaining a flawless support organization always capable of responding to customer requirements.

This is an optional service. Total support as described is only available in certain countries. Please contact your local Shimadzu representative for clarification and details.



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