

Features of CLASS-Agent

User Administration and Access Control

Users accessible to the program are managed by Shimadzu user authentication tool, which are independent from used OS, for access control complying with FDA 21 CFR Part 11.

Functional operations can be limited according to the user, only designated, authorized users will be able to enter or modify information, reducing the probability of errors.

- ✧ When the number of failed attempts at login exceeds the preset number, login from that PC and with that ID is rejected for a specified period.
- ✧ Passwords shorter than the preset minimum password length are rejected for registration.
- ✧ A compulsory password change is required when logging in after the preset password validity period has elapsed.
- ✧ Password entry is required for data approval. Each data item has to be approved separately, prohibiting validating multiple data items as a whole. User verification can be specified as verification on the first time only or verification every time.
- ✧ Screen is automatically locked if key entry or mouse operation is not carried out for preset period
- ✧ Password complexity (whether it includes both alphabetic and numeral characters) is checked

Security and Audit Trail

When the number of failed attempts at login exceeds the preset number, login from that PC and with that ID is rejected for a specified period. When an unauthorized access occurs, an alert can be sent to specified terminals, as well as to specified e-mail addresses. This function allows the notification of unauthorized access even in LAN environments where e-mail cannot be used.

Data from analytical instruments are automatically registered to the database

Data acquired from Shimadzu's workstations for HPLC, GC, GCMS, LCMS, UV, FTIR, AA and electronic balances can be automatically registered to the CLASS-Agent database for integrated data management. Header information stored along with the analytical data, such as instrument name, sample name, analyst name, and other parameters, can be automatically read and entered into separate fields in the database.

Chromatogram, method, quantitation result file, report image file (pdf format), Andi format data are integrally managed. These data are all compressed into a single file for convenient and organized storage. CLASS-Public Agent works as an interface to register data acquired from other analytical instruments.

Data Search

The database search software (Agent Manager) allows you to easily search for data by entering keywords associated with the sample name, analysis date, instrument name, or analyst name. For example, the user could easily display all of the data associated with sample name ABC stored from 3/1/1998 to 5/31/1998, in tabular format.

Easy browse of chromatogram and report information

Data is converted to Analytical Instrument Association (AIA) format. Converted data such as chromatogram can be pre-viewed. Chromatogram and numeric data can be pasted to report by Word or Excel. Report files in PDF format can be browsed easily. *Note: Chromatogram of GCMSsolution and LCMSsolution are not displayed in 3-dimension. Import of PDF files is possible with CLASS-VP and GCsolution.*

Graph Creation and Report Generation

After locating the desired data using Agent Manager, simply cutting and pasting the data to Excel via mouse operation allows you to create graphs. Reports can be easily created combining a variety of

elements, such as chromatograms and quantitation results, data from various instruments, or associated analysis data.

Data Integrity and Electronic Signature

CLASS-Agent (Ver2.1) records instrument configuration, method and operational status along with data. All these parameters can be retrieved afterwards for data integrity. For all electronic records, electronic signature can be applied. Electronic signature are linked with analysis data and signer's name, date and reason are recorded

Data Backup

Data and related logs are backed up together and simultaneously. The log records the ID of the media on which the backup is made, facilitating subsequent retrieval. The backup data can be retrieved to the original database.<