For more information please visit

www.smartaudittrail.at

to arrange a personal demo!

We are happy to offer the total package of validation including the test script generation according to customer requests and also data integrity related consulting and evaluation support.

Support and Demo requests:

support@handshake.at

Please contact us for more information!

Main Contact:

Mag. Anton Neuber
Marketing&Sales
❱ anton.neuber@handshake.at

Additional Contact Persons:

Alexander Draxler
Technical Support
❱ alexander.draxler@handshake.at

Bernhard Renner
Technical Support
❱ bernhard.renner@handshake.at

handshake

Smart**Audit**Trail©

quality assurance at the highest level

Audit Trail functionality for applications

With Smart Audit Trail© you can define and specify monitor the possible activities on your computers in production and other sensitive areas.

You have the possibility to set restrictions of user activities for system and also for applications, as well to monitor changes of files or directories in file system using a secure, extended Audit Trail functionality.

Application can - also retrospectively - be adapted to data integrity requirements.

Smart Audit Trail© is specifically developed as an efficient data integrity solution.

- Almost any software can be adapted to meet the requirements for data integrity, GMP and GLP - even the software does not provide such functionality natively.
- Reduces the validation effort
- Easy to install and handle
- Extensive reporting capabilities
- Manipulation Proof

Smart Audit Trail© Reports

Administrators can define which activities are logged in the audit trail. Every change on the system can be monitored if desired and shown in reports for review.

Smart Audit Trail© reduces time and costs for validation!

Smart Audit Trail© allows the restriction of functionality by blocking access of users to application controls. This reduces the testing and documentation effort required during validation.
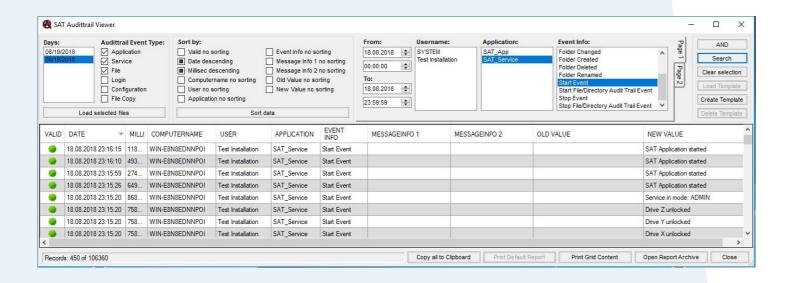
Smart **Audit** Trail

Does your software meet all Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) requirements?

GMP and GLP define the requirements of quality assurance for production processes and environments used for production of drugs and active ingredients. Also for cosmetics, food and animal feed production, this must be met. With the increasing demands on security, the demands on the documentation also increase.

A GMP-compliant quality management system also includes the IT rquipment and computers for controlling the processes in the production environment and in the laboratories:

- Computer systems must have an audit trail that records all actions, especially changes, in a tamper-proof manner
- Access protection: Access to electronic records must be restricted to a qualified and authorized group of people.
- Retention: Audit Trail of Systems must be able to be archived and protected. Also it is required to provide reports and information of the electronic records on demand for authorities.

With the SAT Audit Trail Viewer program, all entries in the audit trail can be displayed and sorted as desired.

Smart Audit Trail© can be customized to meet your needs. Configured and used in a targeted manner, Smart Audit Trail© is a versatile and efficient data integrity solution.
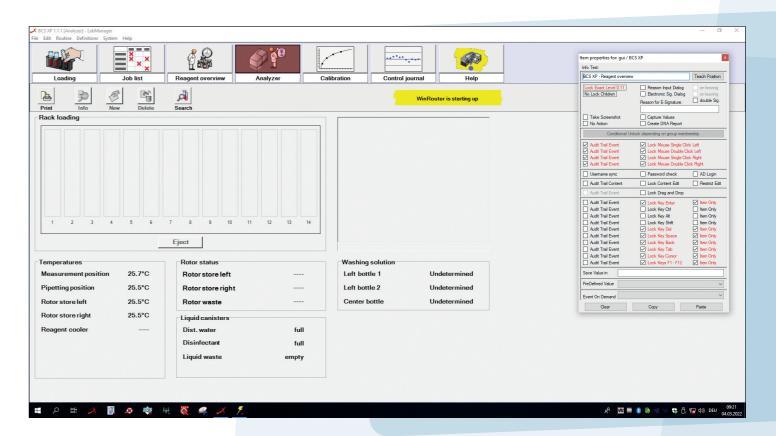
In addition to documenting user input, Smart Audit Trail© can also record and log changes to files and directories in the file system, both on local hard drives and on network drives.

Smart Audit Trail does not change the applications or files to be monitored in any way!

With the „Copy on Demand" functionality, Smart Audit Trail is able to copy files event-driven.
(e.g.: when a defined control in an application dialog is activated by a mouse click)

Examples of possible restrictions

- Within applications, controls and dialogs can be disabled.
- The execution of certain programs on a computer can be prohibited at will.
- Access to USB storage media and individual drives can be blocked.

Smart Audit Trail Reports

Administrators can define which activities are logged in the audit trail. Every change on computer system can be monitored if required and shown in reports if necessary.