handshake

IT SPECIALIST FOR THE PHARMA INDUSTRY

For more information please visit

www.handshake.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:

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Please contact us for more information!

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handshake – IT Specialist for the Pharma Industry

handshake is an IT troubleshooter specially designed to help companies in the pharmaceutical industry meet their technical and regulatory requirements.

We develop innovative solutions to ensure your existing production processes, IT and networks are completely failsafe.

Our rock-solid software knowledge and many years of expertise in processes and quality assurance will make sure you get the best results every time.

Improve your IT structure

- Our handshake planning system keeps production stoppage to a minimum during an IT migration, or prevents it completely, ensuring significant savings.
- Even in the decision-making stages, handshake offers advice and planning assistance for necessary IT updates and helps minimise the risk of problems caused by outdated IT.
- handshake handles projects alongside normal IT operations without any negative impact (keyword: redundancy).
- Come to handshake with all your IT problems. We offer Level 3 support to strengthen your existing resources and increase your project capacity.

Ensure compliance

- We help our customers strictly adhere to all the necessary requirements.
- We scrutinise and streamline auditing, documentation and quality assurance.
- We ensure quality, validation and data integrity by providing continuous updates while maintaining document security.
- We retrofit an Audit Trail onto Windows-based systems that do not fully comply with FDA and AGES requirements.
- If findings from an audit require immediate action, we will be right there to provide advice and support.
- Our electronic document system ensures processes are followed and reduces errors.
- We analyse and manage complex tasks, including ones that span various departments, which require technical knowledge, communication skills, knowledge of human nature and leadership qualities.

Protecting your investments

- Low-tec and high-revenue: Even something as small as retrofitting your control PCs can delay the need to invest in a new production plant, saving you millions.
- Faster return-on-investment with our electronic logbook solutions – review online and save time.
- Fewer rejections and faster approval processes result in huge cost savings.
- Avoid expensive operational interruptions with improved maintenance and planning, which can demonstrably reduce sources of error.
- Business case: Depending on the project, you could save thousands, or even millions, of euros.
- Peak coverage for system migrations.

handshake - our company

handshake was founded in 1993 and quickly established itself as a leading specialist in IT products for the pharmaceutical industry. The company continues to grow to this day. The services provided by this ISO 9001 certified company include comprehensive IT support; peak coverage for system migrations; the creation, documentation, qualification, validation and maintenance of IT solutions; and complex full-service project management.

handshake also develops and sells its own software products Smart**Audit**Trail, Smart**LogBook** and Smart**Document**System, which handle documentation, qualification and validation of IT systems for production control and production documentation.

The company has gained a good reputation for its expertise in designing and creating workplaces for disabled people.

SmartAuditTrail©

Audit Trail functionality for applications

SmartAuditTrail© can monitor and restrict activities on your computers in production and other sensitive areas.

You have the possibility to set restrictions of user activities for specific applications or for the whole system. Changes to the files and directories can be monitored using a secure, extended Audit Trail functionality.

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

SmartAuditTrail© 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 if the software does not provide such functionality natively.
- Reduces the validation effort
- Easy to install and handle
- Extensive reporting capabilities
- Manipulation Proof

SmartAuditTrail© 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.

SmartAuditTrail© reduces time and costs for validation!

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

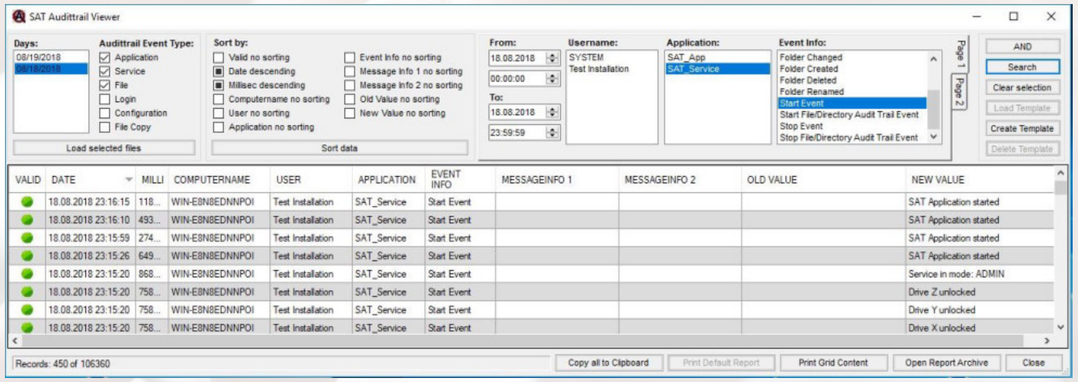
Does your software meet all Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) requirements?

GMP and GLP define the requirements of quality assurance for production processes and environments used for production of drugs and active ingredients. These requirements must also be met for cosmetics, food and animal feed production. The increasing demands on security lead to a higher demand on the documentation as well.

A GMP-compliant quality management system includes the IT Equipment and the computers that are used 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 Trails 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.



SmartAuditTrail© can be customized to meet your needs. Configured and used in a targeted manner, **SmartAuditTrail©** is a versatile and efficient data integrity solution.

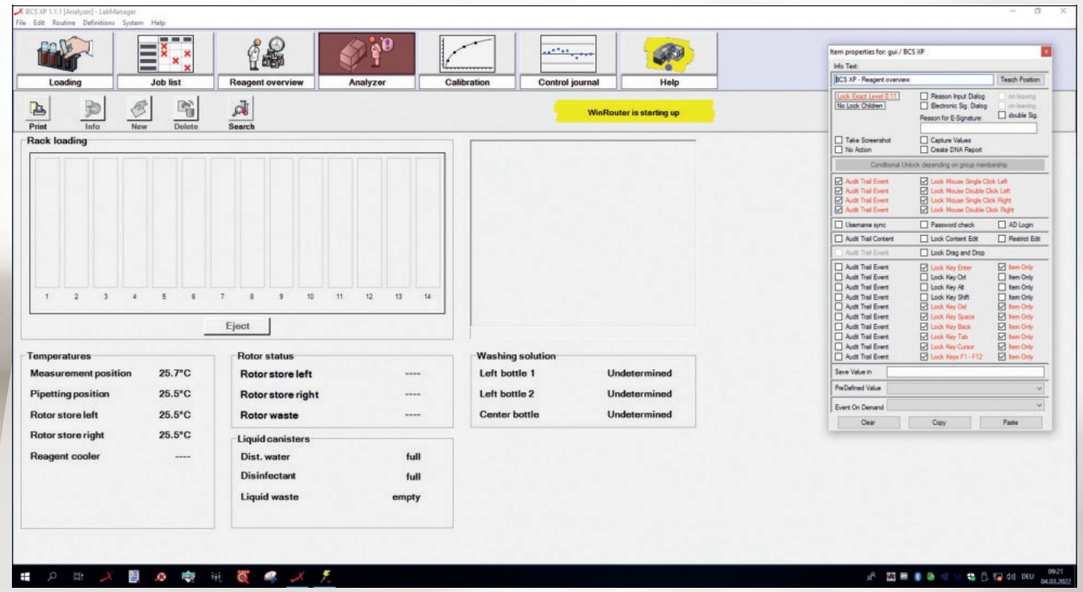
In addition to documenting user input, Smart**Audit**Trail© can also record and log changes to files and directories in the file system, both on local hard drives and on network drives.

Smart**Audit**Trail© does not change the applications or files that are 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

- Controls and Dialogs can be disabled within applications.
- 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 the computer system can be monitored and shown in reports if necessary.

Smart**LogBook**©
elektronic Log book solution

Smart**LogBook**© was developed as a „tailor made" solution to meet the requirements of the pharma industry and chemical laboratories. The input of records is possible using a web client or an iOS App being available for iPhone or iPad as well as an Android App for other smartphones and tablets.
This client server solution can be implemented as a cloud based solution as well as in-house hosted service.

The data is stored in a referenced file structure and does not necessarily require the implementation of a database. However it will be possible to use databases as storage for log book entries in a further stage of development.

During development, the focus was to fulfill the high requirements in respect of data integrity and security, being obligatory for the pharma and chemical industry. To allow workflows with dedicated functions of the persons involved, users are grouped as „SystemOwner", „Approver", „Reviewer" and „Author". Microsoft Active Directory authentication as well as local user Authentication is supported.

The numbers of Log Books being handled by a **Smart****LogBook**© Server is just limited by the available hard disk space storing the log book related entries. Each Log Book is stored as a separate object that is attached to it entries and attachments. Attachments like documents and pictures can be assigned to each log book entry individually.

By defining workflows (modes) it is possible to address special requirements and different situations requiring documentation in the log book. By default the following modes are available:

Simple
Generate an entry and sign by e-signature (Username/ Password).

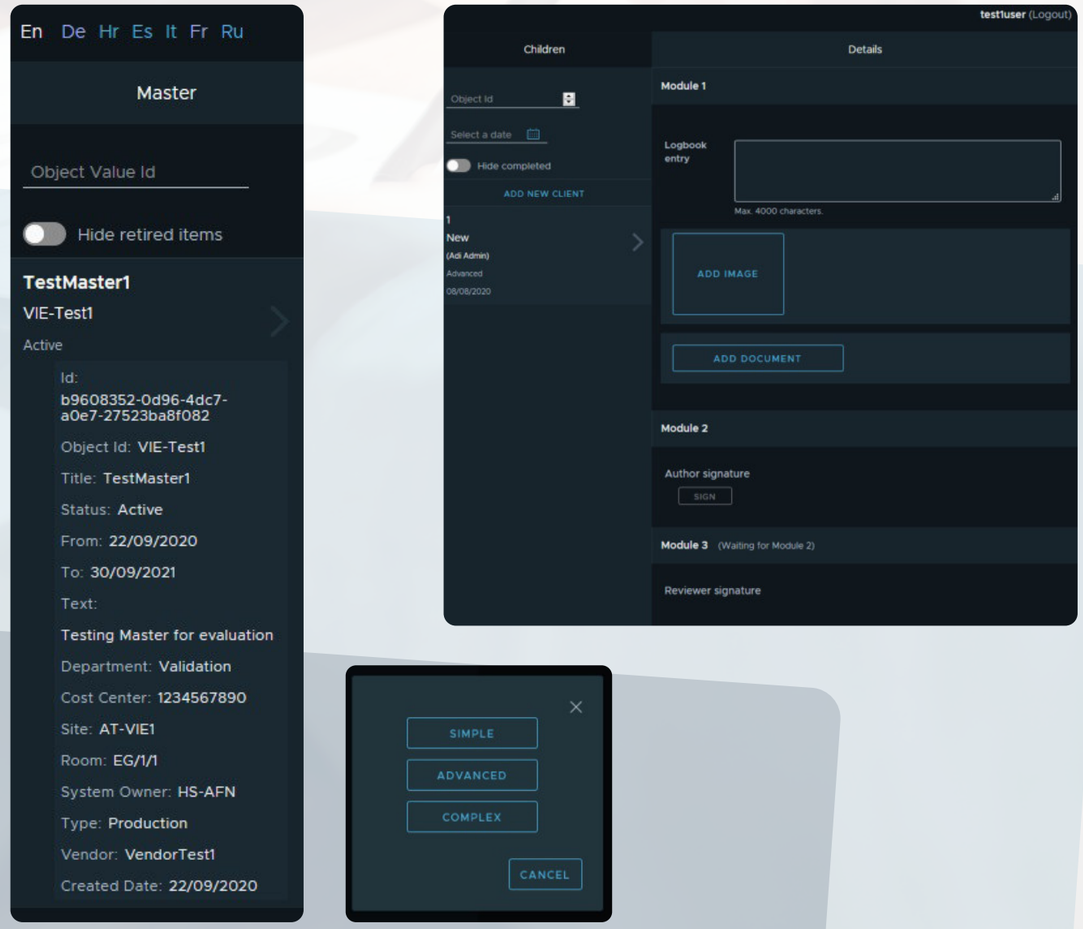
Advanced
Generate an entry and sign by e-signature (Username/ Password). The entry is routed automatically to a quality related person for approval by e-signature.

Complex
Generate an entry and sign by e-signature (Username/ Password).
X-check by another person is required (System Owner / Quality) to approve this entry. This is intended to allow pre-approval of activities to be documented in the log book together with the documentation of the respective activity after being performed.

After the described activity is performed, the log book entry must be updated and signed by the User that did the work with his/her e-signature (Username/Password). To close workflow of this mode, the log book entry must then be approved by a member of the System Owner / Quality Group, using e-signature.

e-Mail notifications can be activated to ensure automated notification of approvers to make them aware of **Smart****LogBook**© entries awaiting approval.

Web Client



General design of Web Interface

Smart**LogBook**© creation is only possible using the web interface of Smart**LogBook**© and requires membership of the Smart**LogBook**© Administration group.

To support the handling during daily use the general design of the Smart**LogBook**© user interface is intentionally very simple and reduced to the required elements. For even more simplicity Smart**LogBook**© will support Nymi Band for authentification and e-signature.

The Smart**LogBook**© user interface is currently available in the following languages: German, English, Spanish, Italian, French, Russian und Croatian.

It is possible to switch between these languages any time dynamically.

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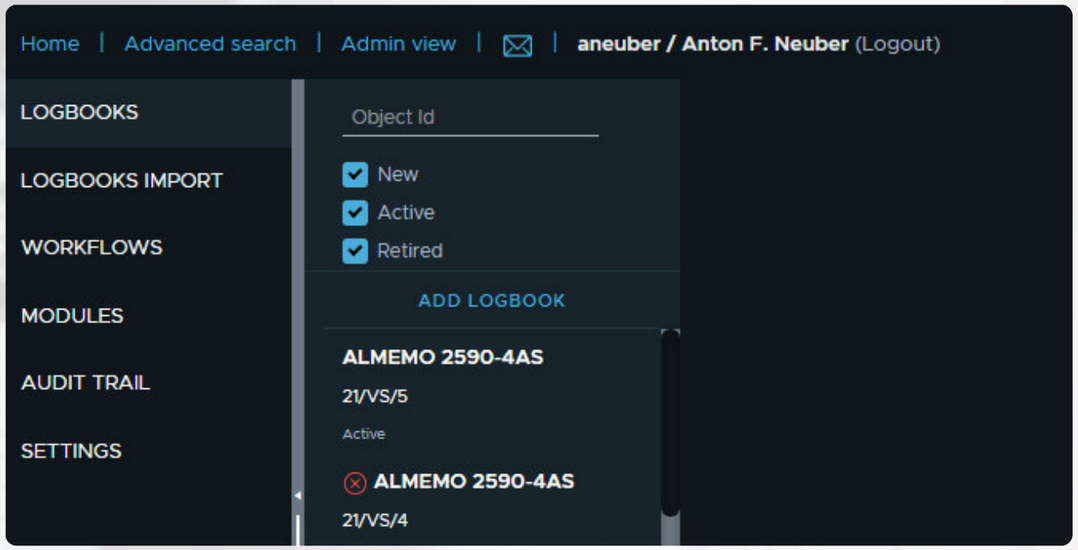
The Benefits

- Notes cannot be lost or physically destroyed
- Handwriting issues are completely eliminated
- Documents and pictures can be used easily as attachment
- QR-Codes on devices ensure that updates and entries are performed in the corresponding thread
- Chronology of entries is absolutely solid
- Workflows allow enforcement of predefined processes
- Electronic Signature implementation ensures data integrity requirements compliance



For Admins

- modern functional Design
- LogBook management
- LogBook Import from .csv
- Workflow Designer
- Modules Designer
- Audit Trail

On devices with camera capability (tablets, smartphones, iPad/iPhone, ...)
QR-Code scan functionality can be used to ensure that entries are assigned to the correct system. Scanning the code located on the devices will automatically activate the proper log book and allows immediate documentation accordingly.

SmartDocument System©

SmartDocumentSystem© (SDS) is a web based document and form management system, designed to reduce paper in laboratories and other GXP relevant areas. Templates for documents can be imported into the system to be available after approval for documentation and further approval purposes. The users can work with these templates, similar to MS-Office documents, in a web browser environment being installed either on site or in a Cloud based server infrastructure. Authentication against the companies Active Directory infrastructure ensures controlled and managed access to the workflows as well as to created documents and templates.

The main features are:

- Users can select templates to streamline work processes.
- Use & Feel similar to MS-Office documents.
- Calculations are possible in tables, similar to Excel worksheets.
- Predefined workflows enforce approved processes.
- Predefined approval structures for the full document life cycle ensure seamless documentation about changes in document templates and the approvals required and available to have another version effective.
- Camera access to add pictures to the documentation on specified regions of forms.

Integration abilities:

- Existing MS-Office based templates can be imported into the template designer.
- Document Life Cycle (Design Document - Create Template - use Template as active Document - Store Document).
- Documents can be assigned to predefined review and approval cycles.
- Document header and footer can be adapted according to customer requirements and will be assigned to the document automatically when set active.
- Workflows can contain both parallel and sequential activities and can be managed by defined approval processes.

- Ad Hoc workflows can be initiated if unexpected occasions require additional approvals to keep Data Integrity or GxP requirements.
- SDS includes an OPC Client to support data exchange with other systems supporting this infrastructure.
- For each document there can be rules to gather data from other systems automatically.
- Rules for automated import and/or export to other systems can be defined.
- SDS is able to interact with **SmartLogBook©**, another product to provide paper less log book functionality. This allows automated log book entries while documenting the results in SDS.
- Any state of the art client device that provides a web browser can be used to log into and use **SmartDocumentSystem©**.