

Laboratories in focus: Eliminate paper forms, logbooks checklists & protocols at last!

Efficient laboratory tools that support your way of working and don't want to change so much.



Introduction:

Laboratories & laboratory groups of all sizes are still skeptical about the change to a data-driven digital way of working and remain with established paper-based processes. On the other hand, we see that both external and internal laboratory customers in large organizations want data-based evaluations, monitoring and results delivery.

On the other hand, there are very specific equipment structures that allow you to specialize in certain topics.

Audit trail yes/no, paper forms and their versions, cleaning logbooks etc. etc. - in addition, the laboratory must maintain numerous protocols, checklists, and similar documentation across various peripheral levels.

We encounter companies of all sizes that are introducing systems, have partially digitized processes and many that still work entirely on paper. These processes are well established and have been accepted, but everyone knows that they are often not very efficient when it comes to providing or retrieving data.

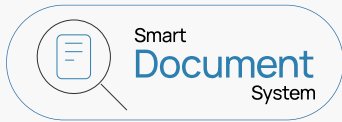
We believe that today's paper-based forms and checklists should be exciting efficiency levers and, above all, data hubs in your company tomorrow.

Does it always have to be the expensive overall system, which is often expensive to customize in detail at second glance? Have you been trying for a long time to laboriously adapt cumbersome standard software to your specific company processes?

We would like to introduce you to 3 alternative software tools and their range of applications in the laboratory.

Our software tools at a glance:

1



- Not another DMS! A dedicated solution for all your forms; web & database based. Simple and fast changeover from paper; integrated version management as well as your own further development of the forms with regard to layout, approval and release!
- Analyzable data!
- Strong for: all types of laboratory experiments; user focus with integrated interfaces to existing systems such as LIMS /ERP etc.
- Documentation - GxP and 21 CFR Part 11 compliant!

2



- Add Audit Trail functionality to MS-Windows based systems.
- Use non-native GxP compliant equipment by retrofitting Audit Trail functionality Audit Trail functionality securely in GxP operation.
- Retrofit older equipment and systematically close data integrity gaps in the process - thus securing your system investments in the long term.

3



- Multilingual e-logbook solution with fast import function!
- Modular workflow architecture - easy to adapt to your current structure adaptable.
- Quickly replace all existing paper log books and even combine it with Smart Audit Trail© to automate logbook entries!
automated!



Data security and compliance

handshake fulfills all regulatory requirements for GxP, including the 21 CFR Part 11-compliant signature, and ensures complete traceability. Data security is guaranteed by state-of-the-art encryption and protection mechanisms.

Acceptance by authorities

While paper-based systems are familiar and recognized by authorities, the handshake system offers digital time stamps and tamper-proof documentation - a plus point for audits and inspections.

Complexity and need for customization

Standard solutions from the large software houses are complex and often require extensive customization to meet the individual requirements of a company.

The alternatives of handshake

Smart Document System© from handshake offers a customized, easy-to-implement and significantly more cost-effective solution for laboratories throughout the process industry. Compared to conventional systems, it is characterized by the following features:

Implementation in a few weeks

Instead of months of implementation processes, the handshake system can be up and running within weeks.

Significantly lower costs

A system geared towards concurrent users can be used successively for different areas of the company. Super users can be set up specifically on request. Medium-sized and large companies alike can benefit from this.

Flexibility during implementation

The system is available both on-premise and in the cloud and can therefore be individually adapted to the company's infrastructure.

Integration and expansion of existing systems

It allows paper forms to be supplemented or replaced by open interfaces and open source support, which enables devices to be integrated and data to be transferred directly.

Parallel data acquisition

Employees can record laboratory, production and other important peripheral data directly and digitally in real time, which ensures more efficient documentation as part of existing company processes. This data can be analyzed in real time and/or linked to other existing IT systems.

Low training costs

The look and feel of the system is similar to familiar Office applications, which significantly reduces the amount of training required.

User-friendly customization options:

Users with the appropriate authorization can develop forms independently without having to rely on technical support.

Advanced analysis functions

The system supports a quick review and analysis of entered data through advanced search functions and offers options for data mining, trend analysis and deviation reports. Create a system-driven review process — scalable up to a “review by exception” strategy.

Versatile areas of application along internal processes

Think about your current processes. Where do you still use paper forms, checklists or other protocols? Be it in development, in production, in process or project monitoring or in various control and testing areas. Where do you see hubs where your processes can be significantly accelerated by switching to data-based work? Wherever paper is finally to become data, we design the path with you and with and for your employees, close to the paper and in stages. In this way, the changeover will succeed according to your wishes.

Our two-stage process - from paper to linked data

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Stage 1: Digitization

- Conversion of existing paper-based templates (forms, checklists, protocols, etc.)
- Integration of these templates in Smart Document System©

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Level 2: flexible data exchange

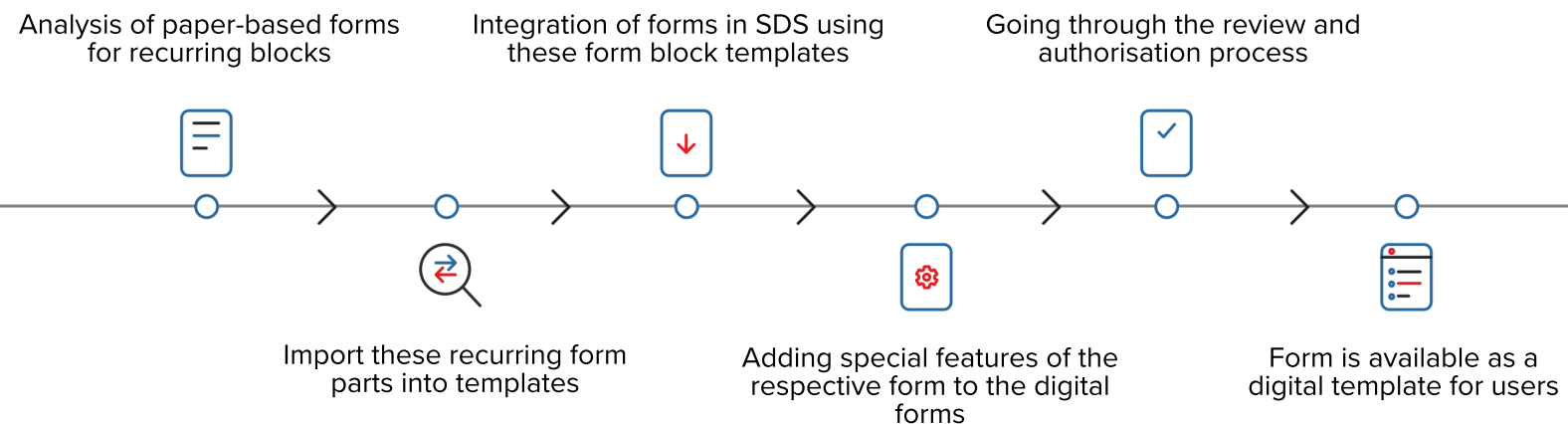
- Users can fill in the form with data
- Equipment data can be transferred directly to the form
- eQMS systems can be supplied with data from the form
- ERP / LIMS systems can be connected bidirectionally

Intelligent forms that simplify everyday work and speed up processes.

Data flows in the background - without any additional systems in the foreground. Familiar activities are retained, but automated processes make them noticeably more relaxed and at the same time significantly more productive.

Teams benefit from usable data: for early analysis, for quick countermeasures or as a basis for further processing in existing systems.

A simple changeover - how the implementation process works



Scope-Definition

Identification and documentation of all forms that are to be digitized.



Identify optimization options

Identify analysis and optimization potential by connecting analysis and production systems for the automated transfer of data to the forms, including calculation options directly in the form.



Define project plan and responsibilities

Development of a project plan for smooth implementation and definition of responsibilities.



Employee training

Organize information events and training for employees to ensure that the system is adapted quickly and safely.



Preparation of the server infrastructure

Depending on the choice of infrastructure (on-premise or cloud), the necessary server preparation is carried out.



Installation and device integration

Installation of Smart Document System© including the connection of defined production and analysis devices.



Adaptation of the process definition and all affected SOP's

Revision of all relevant SOP's (Standard Operating Procedures) and approval of the documents to ensure the regulatory background of the use of the system.



Testing and qualification

Comprehensive tests and qualification measures to ensure the functionality and compliance of the system.



Form import and post-processing

Import of prepared forms and customization of fields and calculations to ensure seamless functionality.



Final approval and GxP release

System owners and quality assurance give the final approval and ensure GxP compliance.



GoLive and interface implementation

After approval, the system is made ready for use and optional interfaces to other systems can be integrated to streamline data flows in the background. (LIMS/ERP/MES etc.)

Applications fields in the Lab Environment

A user-centric system that can be used wherever paper-based forms, checklists, and protocols are still used in processes, and where the transition to intelligent data hubs is to be implemented step by step.

- | | |
|---|--|
| <p>✓ Preparation</p> <ul style="list-style-type: none">• Incoming goods inspection• Test protocols• Room cleaning protocols | <p>✓ Research</p> <ul style="list-style-type: none">• Documentation of laboratory experiments |
| <p>✓ Engineering</p> <ul style="list-style-type: none">• Maintenance logs• Checklists for recurring activities• Calibration protocols | <p>✓ Quality</p> <ul style="list-style-type: none">• Data integrity and compliance• Documentation of recurring checks |
| | <p>✓ Reporting</p> <ul style="list-style-type: none">• Distribution of the results |

One tool – versatile in use, highly integrative, and requires minimal training. It leverages your existing templates — now digital and data-generating!

Smart Audit Trail©. A Data Integrity Suite - various expansion levels!

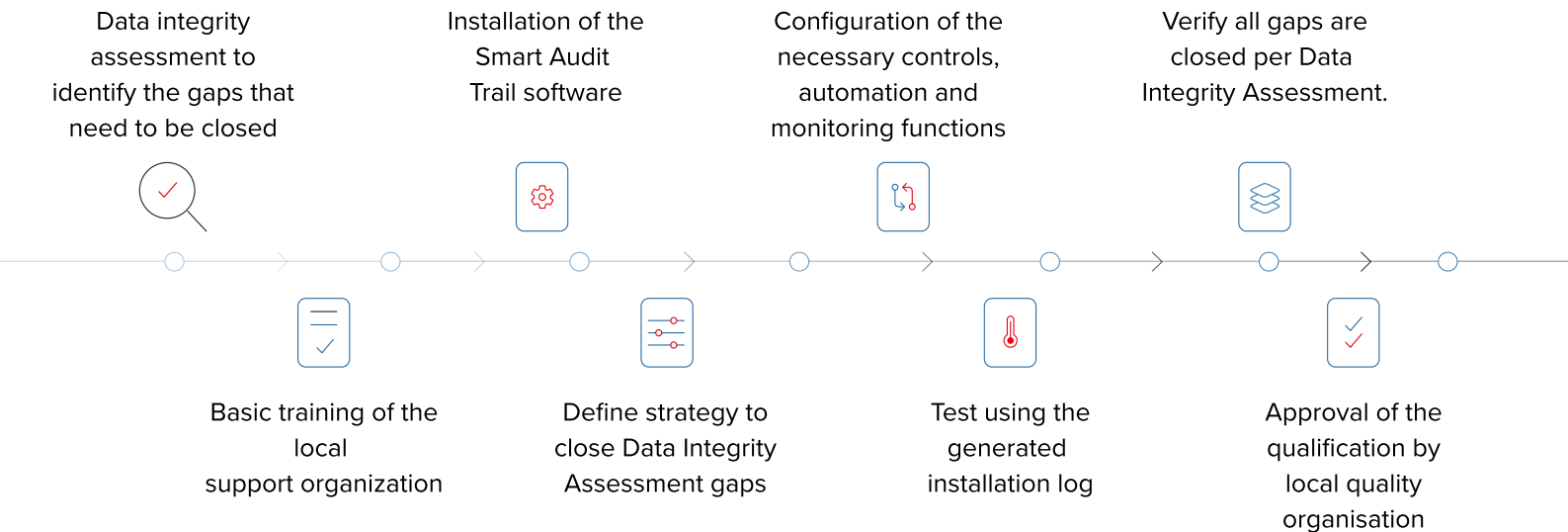
- 1 Case 1: **Retrofitting - We bring equipment and devices** (e.g. high-performance analysis devices) **without audit trail** functionality into GxP operation by retrofitting Audit Trail functionality.

- 2 Case 2: **Retrofitting - We upgrade your older equipments/systems** in a targeted manner and increase the data integrity and compliance level. Equipped in this way, nothing stands in the way of secure continued operation and expensive investments are optimally utilized in the long term.

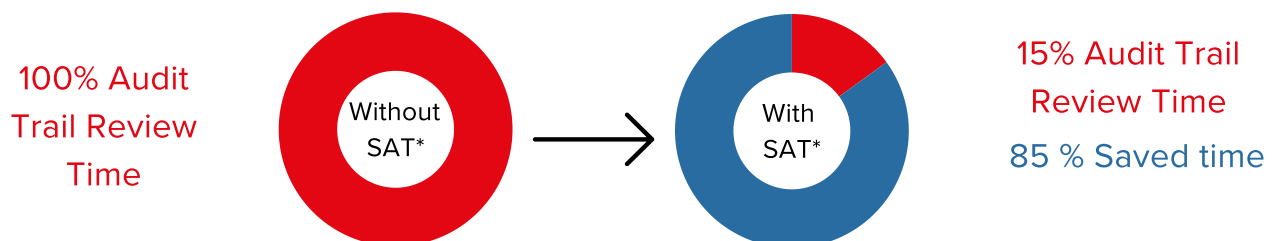
- 3 Case 3: **A standard audit trail tool for targeted legacy monitoring** at site level: How often do you have equipment and system structures that have grown over the years? Think of the different audit trail software per manufacturer and device.

Think of the expensive working hours of your employees and the training effort per software. And above all, think of all the wasted time your employees spend today reviewing information that is not relevant, but which needs to be reviewed because the audit trail information is completely recorded by that software!

Retrofit of 1 single machine with Smart Audit Trail© license



- ✓ Based on a Data Integrity Assessment, all critical and audit-relevant information of a machine is systematically identified and documented.
- ✓ Smart Audit Trail© (SAT) is capable of isolating this relevant information from the rest of the data typically recorded in an audit trail.
- ✓ With a highly configurable settings menu, user activities, system access, and potentially manipulation-relevant actions can be monitored down to individual keystrokes.
- ✓ The result: Audit trail reviews that are 10 to 15 times faster per device — while at the same time increasing the data integrity & compliance level.



*SAT: Smart Audit Trail©

Smart Audit Trail© - One Data Integrity Suite with many operational assets!



Training requirements

Used as the standard audit trail system used in the company, employees only need to be trained on a single system, which creates standardization and makes employee groups specifically flexible.



Comfortable review

Employees only have to A review a fraction of audit trail lines and B on top they use targeted filters. This can be done conveniently from the PC, even accessing other PCs via our included Audit Trail Viewer, without data being exchanged. This is possible even in the clean room. (no more inward/outward transfer necessary)



Targeted closing of gaps

Based on a Data Integrity Assessment, we can provide critical systems with targeted support for their gaps and thus close these gaps. In this way, systems can be operated for a long time with investment security.



Time savings in operations

We want to give you and your employees time back. Time that means joint effort at the beginning YES, but which is quickly amortized in Operations and allows employees to work on meaningful topics WITH created TIME. Stress in the workforce is reduced and the precision of the work is gradually increased.

Minimum system requirements for the use of Smart Audit Trail©:

- ✓ Windows operating systems from Windows 7 (Windows XP supported with reservations)
- ✓ Sufficient hard disk capacity to store the audit trail data for the required retention period (terminal server solution possible)

Basically, the decisive element for us is the joint precise analysis with your team of the underlying very individual requirements and therefore central to our quality promise. On request, this goes far beyond this specific pure audit trail retrofit.

We work with you to narrow down the information actually required in the audit trail to the essentials. Result: 10-15 x faster audit trail review per system. So think about savings in terms of review time, monitoring and personnel costs across your site or even your entire company!



The alternative of handshake

Smart LogBook© by handshake offers a tailored, easy-to-implement solution specifically designed to support laboratories transitioning from paper-based systems. Quickly convert your existing room and equipment logbooks and optimize your processes by customizing integrated workflow modules.

Fast implementation

We sift through the log book templates that are often available and, if necessary, prepare them so that they can be transferred directly into our system using our fast import function.

Flexible design of your existing processes

You can map existing departmental and company structures very flexibly and assign corresponding authorizations in the system using existing authorization structures via Active Directory accounts.

Flexibility during implementation

The system is available both on-premise and in the cloud and can therefore be individually adapted to the company's infrastructure.

Integration with Smart Audit Trail©

Entries can be created automatically via Smart Audit Trail©. If you also use Smart Audit Trail© from handshake, we will be happy to design a time-efficient interface. This avoids duplicate documentation.

Review possible parallel to use

Paper logbooks are often collected in companies and are then not available for entries during the review period. This problem is eliminated.



Low training costs

Naturally, Smart LogBook© includes email notifications, for instance to alert the next team responsible for actions like reviews, approvals, and other tasks.

Security:

Smart LogBook© meets the exceptionally high documentation requirements of the pharmaceutical industry in the areas of data integrity and security, as well as those of the medical laboratory sector.

Concurrent User Model

You can create as many logbooks as you need. Our priority is to give you maximum flexibility throughout your workflow and thereby contribute to your company's growth. That's why our licensing model is based on the concurrent user approach — meaning it depends on how many colleagues are actively using the system in daily operations.

Multilanguage support

The solution comes pre-equipped with a variety of languages and can be expanded upon customer request. The language is selected when users are created via Active Directory accounts, allowing each user to access the system in their preferred language from the start.

Benefits of the solution:



It adapts to you — not the other way around

Users with appropriate permissions can flexibly create and monitor logbooks based on existing departmental and company structures. This is also enabled by the system's concurrent user licensing model.



Training requirements

The intuitive operation of the system significantly reduces the amount of training required, and training can be carried out quickly and in line with requirements.



Data security and compliance

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Acceptance by authorities

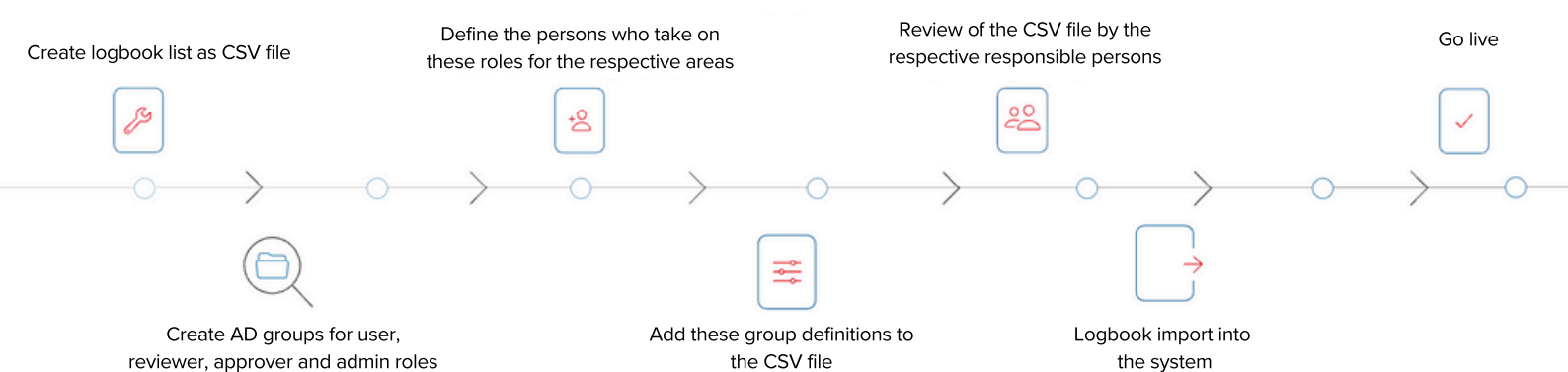
While paper-based systems are familiar and recognized by authorities, the handshake system offers digital time stamps and tamper-proof documentation - a plus point for audits and inspections.



Configurable Workflows

Based on your existing hierarchy and approval structures, you can utilize workflows according to the actual workload. Using predefined and customizable workflow modules, colleagues become more operationally productive. For example, if issues are identified and corrective actions are required, these modules allow you to quickly initiate a remediation process to work on it effectively and in a coordinated manner. Through Active Directory accounts and integrated audit trail functionality, all involved employees and their entries are uniquely and chronologically recorded.

A simple changeover - how the implementation process works



To make the changeover as smooth as possible, the implementation of Smart LogBook© follows a structured schedule:

- ✓ Enter logbook list as CSV file.
- ✓ Create Active Directory groups to assign roles for users, reviewers, approvers and system administrators.
- ✓ Definition of the persons who assume these roles for the respective areas.
- ✓ Add these group definitions to the CSV file.
- ✓ Review of the CSV file by the respective persons responsible.
- ✓ Logbook import into the system.
- ✓ Go Life.

Ready for an initial personal meeting and a technical insight?

If you're interested in how we can specifically address your individual "digital challenges" in the laboratory, we would be happy to arrange a personal consultation.

Discover how easy it can be to switch to mature standard tools that, when configured to your needs, deliver significant efficiency gains through data-driven workflows.

Contact us for a demo:

[Book appointment now](#)

About handshake

handshake Handelsges.m.b.H. in Vienna has been offering specialized IT solutions for the pharmaceutical & process industry since 1993. With ISO-certified services and software, handshake supports data integrity and efficient compliance processes and specializes in documentation & archiving of regulated processes. Details at handshake.at.

