Info paper: Retrofitting older systems in GxP operation with investment security & systematic closed gaps!

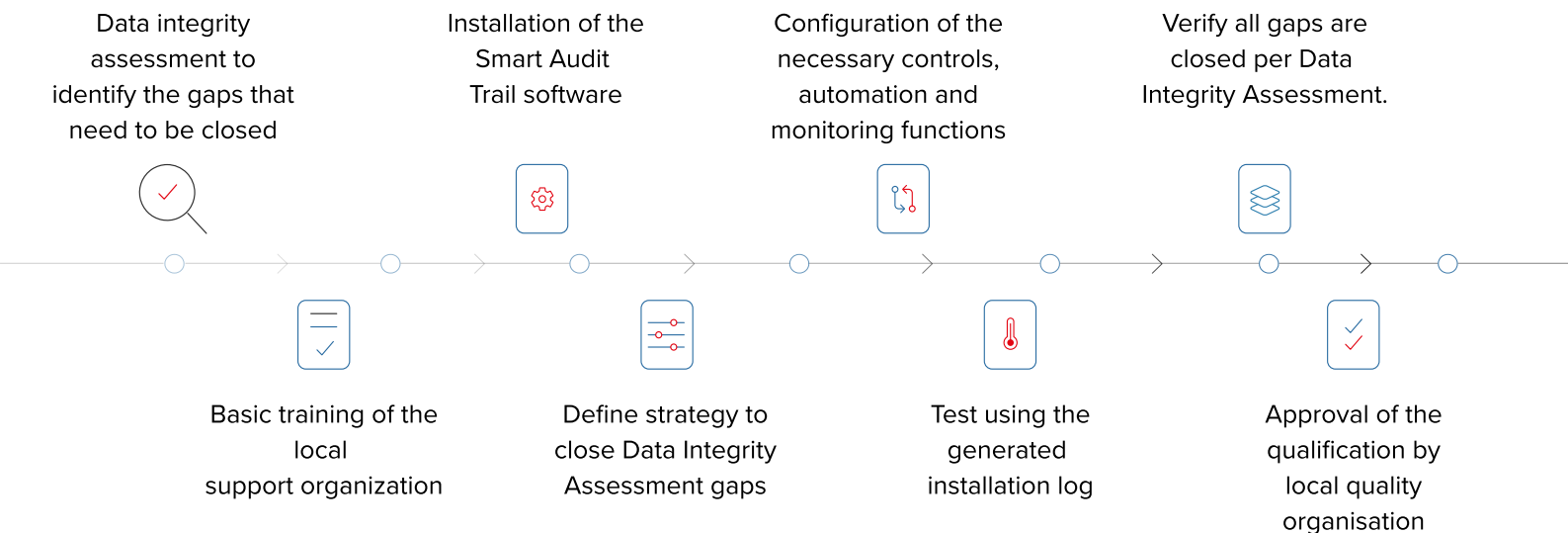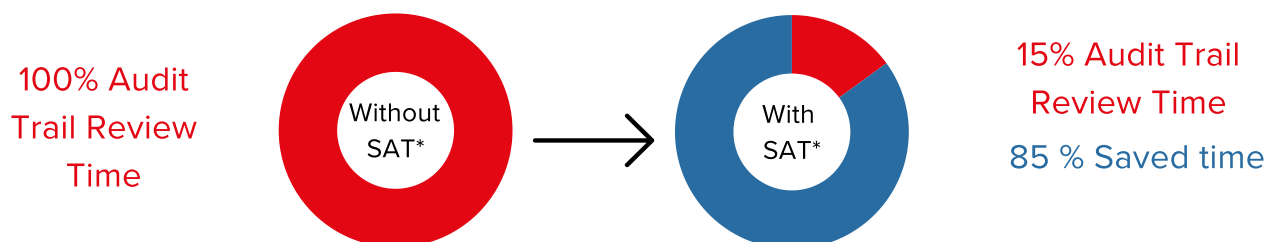## Retrofit Smart Audit Trail©

Smart
Audit
Trail

Introduction:

In the highly regulated and demanding pharmaceutical and process industry, cost and efficiency pressure is a constant area of tension. Once equipment has been put into operation at great expense in laboratory or production, it should remain in operation for as long as possible. Unfortunately, older devices and systems in particular only partially or inadequately meet the latest regulatory requirements, meaning that new investments are often necessary. Or do they not?

Smart Audit Trail© as a Windows-based add-on software to be retrofitted builds a bridge here. We systematically close corresponding gaps on the basis of a data integrity assessment and thus increase the data integrity and compliance level. Another important aspect is the drastic time saving in the mandatory audit trail review and the convenience of the audit trail review across multiple systems.

Retrofit of 1 single machine with Smart Audit Trail© license

Data integrity assessment to identify the gaps that need to be closed

Installation of the Smart Audit Trail software

Configuration of the necessary controls, automation and monitoring functions

Verify all gaps are closed per Data Integrity Assessment.

Basic training of the local support organization

Define strategy to close Data Integrity Assessment gaps

Test using the generated installation log

Approval of the qualification by local quality organisation

✓ 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.

100% Audit Trail Review Time

Without SAT*

→

With SAT*

15% Audit Trail Review Time

85 % Saved time

*SAT: Smart Audit Trail©

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.

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(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.

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(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 the software!

Smart Audit Trail©-A 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 review a fraction A of audit trail lines and B on top they use targeted filters. This can be done conveniently from the PC, even accessing other PCs, 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!

Ready for an initial personal meeting and a technical insight?

If you are interested in finding out more about Smart Audit Trail© and its benefits, we would be happy to talk to you personally.
Experience how easy retrofitting and convenient equipment retrofitting can be today.

Contact us for a demo:

Book an appointment now

About handshake

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