

Info paper: Standardization-one audit trail software for your equipment & plant structures.

10-15 x faster audit trail review per equipment!



Introduction:

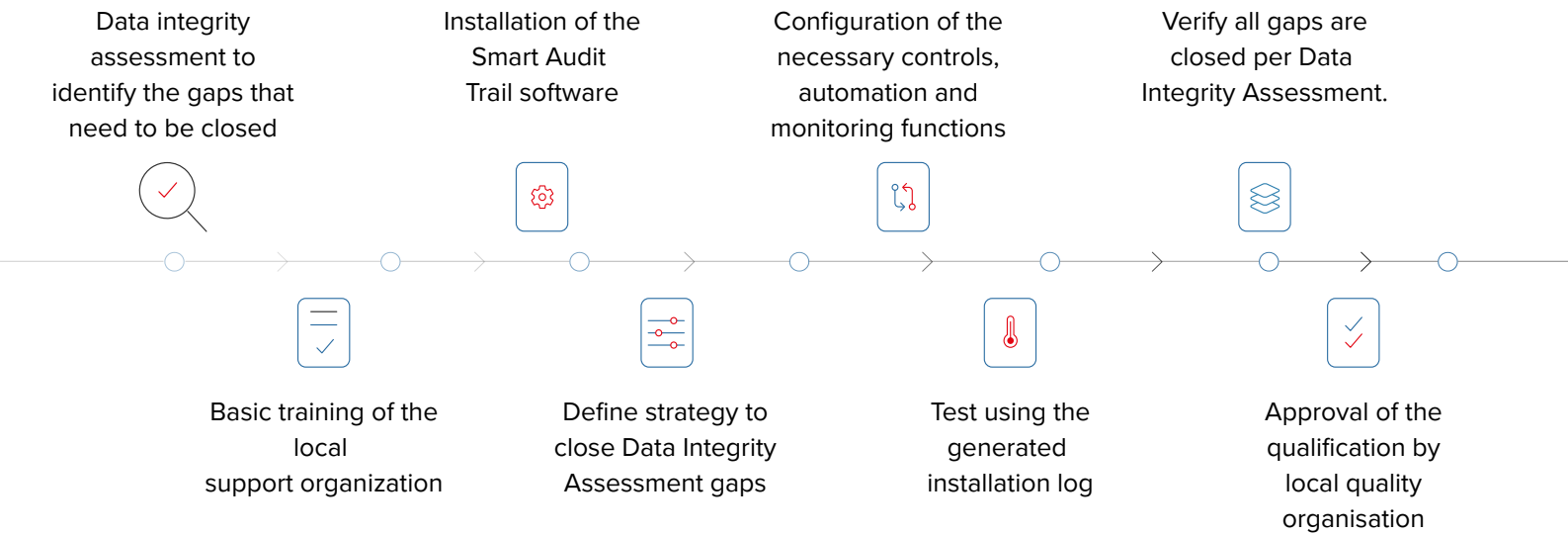
In the highly regulated and demanding pharmaceutical and process industry, digital standardization is an issue in a wide variety of areas. However, a wide variety of equipment and system suppliers are constantly supplying you with different audit trail software. And on top of that, this records all activities and that means 100% must be reviewed regularly!

How about using just one audit trail software as the standard tool in this area?

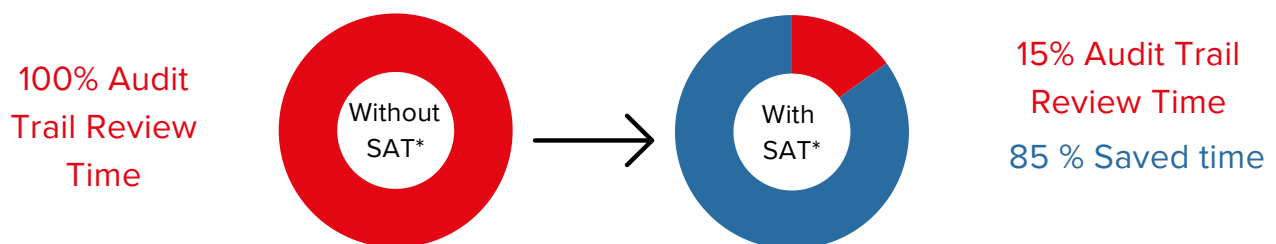
With **Smart Audit Trail**© from handshake, you can do just that.

Take advantage of the possibilities: Convenient review from a PC on various devices right up into the cleanroom and significantly faster. Integrate devices without audit trail functionality into GxP operation or close specific gaps of existing equipment. One tool - one standard training.

Typical installation of 1 single machine of Smart Audit Trail©



- ✓ 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©. 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.

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: **One 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!

Concerns about the switch and how handshake addresses them



Employee acceptance

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



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

handshake fulfills all regulatory requirements such as 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.



Integration problems

The system has open interfaces and supports open source integrations, which enables smooth integration into existing systems.

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 convenient equipment monitoring 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.



Smart
Audit
Trail

