

DATA INTEGRITY & COMPLIANCE FOR GXP ENVIRONMENTS & OTHER
HIGHLY REGULATED INDUSTRIES

Electronic forms, logbooks, data integrity & compliance for your equipment.

We support you in going paperless – and accompany you through the move
to data-driven working.



Pharma · Biotech · Chemicals · Cosmetics · Food · Medtech · Oil & Gas · Energy · Aerospace · Defense

August 2026



Contents.

01

The starting point

Three challenges we meet in almost every project

02

Our software tools

Smart Document System, Smart Audit Trail, Smart LogBook

03

Reference projects

What customers in pharma, chemicals and biotech achieved with them

04

IT consulting

Project management, infrastructure, validation and qualification

05

Partnership

Sales and implementation partners in the GxP environment

06

About handshake

In Vienna since 1993, ISO 9001-certified – and the next step



Outdated methods – three challenges we meet in almost every project.

Data integrity & compliance under pressure

Rising GxP requirements and missing system integration put data integrity at risk. Manual processes make compliance harder and considerably increase the risk in audits and inspections.

From paper to data: the media break remains

Paper-based logbooks, forms, checklists and records dominate everyday work in many places. The result: a lack of transparency, susceptibility to error and unnecessary effort in review, approval and archiving.

Review times are exploding

Every system brings its own software, every paper logbook its own way of working. Employees review information that is not relevant at all – costing hours, training and nerves.



Regulatory-proof, proven in practice – and in use within weeks instead of years.

As a specialist for digital documentation, data integrity and GxP compliance we accompany companies through the change – with tailored software solutions that are regulatory-proof and proven in practice. Our systems increase efficiency, reduce costs in the long run and make audits predictable. This starts with an overall view of where you stand today in terms of digital transformation.

As a specialist for server and data center infrastructures in highly regulated environments this also means: let us talk about your backend as well, to set it up for performance or to consolidate it sensibly.



1993

founded in Vienna –
GxP specialist ever since

ISO 9001

certified services
and our own software

3

own products plus
IT consulting from one source

Our own software.

Self-developed tools instead of third-party licenses –
integration included.

Regulatory work included.

Part 11 and Annex 11, validation and qualification
included.

Close to the process.

We map the way you work today – not the other way
round.

Our software tools at a glance.



Smart Document System©

Your AI readiness tool for a consistent data lake across departments.

- Electronic forms, checklists and records – no paper
- One tool with interfaces to MES, eQMS, ERP, LIMS and equipment
- Captured data immediately available in database format
- Forms are evolved by your own users



Smart Audit Trail©

Your retrofit suite for data integrity & compliance.

- 10–15× faster audit trail review per system
- Risk-based assessment of what is really audit-trail-relevant per system
- One central viewer across all retrofitted systems
- Retrofitting in the brownfield as well as the greenfield
- Secure raw data transfer & various tamper-protection features



Smart LogBook©

Your tool to digitize every paper logbook fast and pragmatically.

- Fast transfer of paper logbooks via fast import
- Review in parallel with use – the logbook stays in service
- On-prem and cloud, multilingual, Active Directory-based
- Full electronic approval by e-signature

One design principle: close to familiar working, regulatory-proof – and productive within weeks.

SMART DOCUMENT SYSTEM©



The power of intelligent digital forms.

Create a consistent data lake along your process chain – **AI readiness by design!**

THE PROBLEM

Paper-based forms, checklists and records are error-prone, hard to search and tie up valuable employee time.

Large standard systems are expensive, take months to years to introduce and require extensive customizing.

THE HANDSHAKE ANSWER

Smart Document System digitizes your forms in a tailored way – with open interfaces to MES / eQMS / ERP / LIMS / PMS and existing equipment.

Users evolve forms independently – the basis for analyses and the productive use of AI on your shopfloor data.

Weeks

to go live – instead of
months or years

up to 95 %

QC review time saved
through Review by Exception

Part 11

compliant signature,
seamless traceability

In weeks, not years.

Ready to use in weeks – including validation and training.

Without a million-euro budget.

Concurrent user model instead of a major project: areas are added.

Instead of customizing.

Form blocks are imported as templates and evolved further.

Where paper turns into data.

AREAS OF APPLICATION ALONG YOUR PROCESS CHAIN

R&D and laboratory.

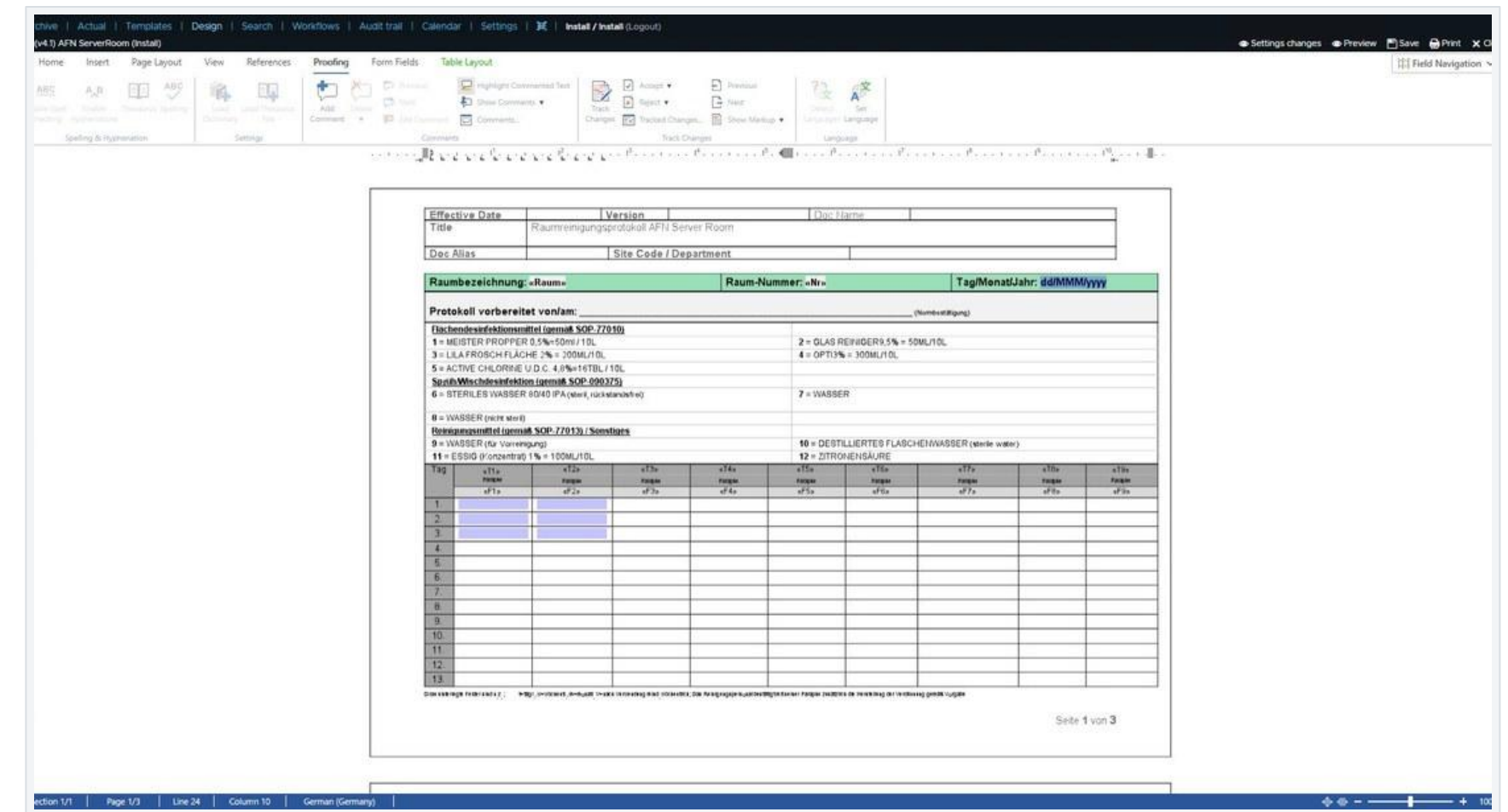
Goods receipt, inspection and cleaning records, maintenance and calibration checklists, documentation of laboratory trials.

Production.

eBR, buffer and sanitization preparation, manufacturing, packaging, cleaning and sterilization documentation.

Review & approval.

Process review, product releases, batch documentation as well as data integrity and reporting processes.



Form view: familiar layout, integrated calculations, plausibility check.

Plausibility checks run through automated calculations and defined limits – the basis for “Review by Exception”.

Digital forms for laboratory experiments.

Client: research laboratory of a German pharmaceutical company

The challenge

The client used paper-based templates for its laboratory experiments; a LIMS had just been implemented. Evaluation, analysis and the general error-proneness of the paper forms were the problem – a highly flexible system was sought.

The solution

With Smart Document System all templates were digitized and structured. The look & feel close to familiar office applications and the integrated calculation options were quickly accepted. LIMS and existing laboratory instruments were connected.

The result

Sample dilution and measurement capture are documented faster and more accurately. Laboratory documentation is fully digital, uniform and transparent. Data access improved, the error rate went down.



SMART AUDIT TRAIL©



Retrofit audit trail compliance – in the brownfield as in the greenfield.

Secure Windows-controlled installed systems – **without rip-and-replace!**
Make new devices GxP-capable – simply retrofit audit trail functionality!

THE MOST COMMON PROBLEM

Older GxP systems do not meet today's expectations for data integrity – replacing them is expensive and slow. Every manufacturer supplies its own audit trail software; reviewing each one separately costs review time, training and staff.

THE HANDSHAKE ANSWER

A data integrity assessment identifies the gaps, Smart Audit Trail closes them. A risk-based assessment determines what is really relevant per system – separating the wheat from the chaff. One central viewer bundles the review site-wide.

10–15×

faster audit trail reviews
up to 85 % less review time

€ 0

investment in
new devices

Days

installation, configuration
and qualification

Your data integrity & compliance solution to retrofit.

MORE THAN JUST AUDIT TRAIL

Secure raw data transfer

Raw data is transferred securely and in an automatable way – without manual intermediate steps.

Events on demand

Defined events generate triggered actions – efficiency and safety in ongoing operation.

Windows shell functionality

Access only to application-specific programs – drastically reduces validation effort.

Block USB sticks

Removable media can be blocked at system level – closing one of the most frequent data integrity gaps.

Hide drives selectively

Drives that are not needed are hidden so that data ends up where it belongs.

Validation included

Predefined scripts and an automated configuration report keep qualification lean.

SEPARATING THE WHEAT FROM THE CHAFF – WHAT THAT MEANS FOR THE REVIEW

Without Smart Audit Trail©



100 % audit trail review time

With Smart Audit Trail©



15 % review time – 85 % saved

One audit trail standard for grown, Windows-controlled system structures.

Customer: large pharmaceutical company, European site

The challenge

Several older machines in production had already been retrofitted with Smart Audit Trail. On that basis a standardized tool for audit trail functionality was to be created that works everywhere in the site infrastructure grown over many years.

The solution

A comprehensive analysis of the existing systems including an assessment of the installed – Windows-controlled – operating systems. A data integrity assessment was carried out for every device in order to identify all relevant aspects in a targeted way.

The result

A standardized tool for audit trail reviews across the entire site. Previously, employees had to be trained separately for every new device – often including yet another audit trail software. Today the company trains on one system.



SMART LOGBOOK®



An end to paper logbooks – digitized fast and pragmatically.

Well prepared, systematic and safe – **review in parallel with use!**

THE PROBLEM

Paper logbooks are hard to survey, tied to a physical location – and are often collected for the review. Exactly then they are not available for entries. Handwritten entries make legibility and traceability harder still.

THE HANDSHAKE ANSWER

Smart LogBook takes over existing templates via fast import and makes them reviewable in parallel with daily use. Permissions come from your Active Directory – on-prem or cloud, multilingual, with multi-level approvals.

900

logbooks imported
in 30 minutes

Part 11

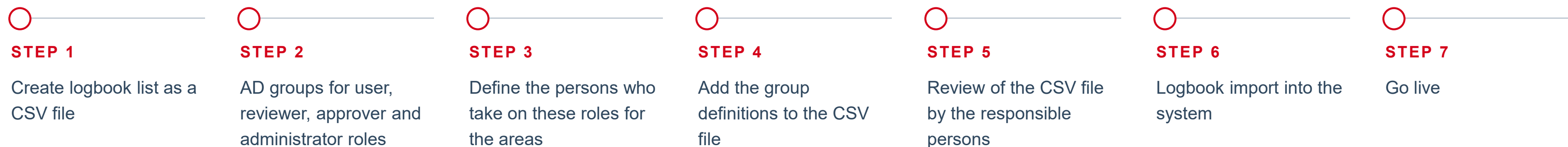
compliant electronic
signatures, multi-level

Weeks

from paper to go-live,
configuration included

A simple switch – in seven steps.

To make the switch as smooth as possible, the implementation follows a structured schedule.



900 logbooks in 30 minutes – the fast import turns the switch into a matter of weeks, not months.

Existing templates are screened and prepared, the logbook list is captured as a CSV file and extended by the AD group definitions. After the review by the responsible persons, the entire list moves into the system in a single session – configuration included.

Before the import.

Capture the logbook list, create AD groups and assign them to the areas.

During the import.

Review of the CSV file, then fast import of all logbooks into the system.

After go-live.

Workflows, e-mail notification and multi-level approvals are running – review in parallel with use.

Digital logbooks in the chemical supplier industry.

Client: mid-sized specialty chemicals company, site in Austria

The challenge

The plan was to introduce a digital, GxP-compliant logbook system for product-related documentation – including system validation. The goal: digitize all existing paper logbooks and meet both legal and internal quality requirements.

The solution

A locally installed instance of Smart LogBook with database and IIS server. The existing Excel logbook list was extended by fields for role assignment – user, process owner, reviewer and approver, all Active Directory-based.

The result

All logbooks are fully digital, GxP-compliant and audit-proof. Legibility and chronological traceability are ensured, manual processes and media breaks eliminated – with considerably better efficiency in time and cost.



An IT partner who understands your processes.

Rely from the start on an IT partner who knows regulated environments and accompanies you with foresight.

IT project management

Professionally led – from planning to execution, on schedule and within budget.

Future-proof infrastructure

From cloud migrations to fully validated systems.

Compliance in the project

IT projects focused on GxP qualification, validation and beyond.

Network architecture

Analysis, planning and implementation of efficient and future-proof network architectures.

Life cycle management

Reliable operation and operational safety in regulated environments.

Level 2 and 3 support

Support for your internal organization in project execution and operation.

Validation and qualification are part of the deal.

Complete validation documentation according to GxP – validation plan, risk analysis, test plans and reports. Together we develop a standardized qualification approach (DQ, IQ, OQ, PQ), tailored to system type and production process.

Reference projects from regulated environments.

Data center consolidation

European subsidiary of a Japanese pharmaceutical group

Analysis of all servers, services and applications, target architecture with a consolidated site structure. Result: six-figure annual savings, less maintenance effort.

Network life cycle in the GxP environment

Several European production sites

Replacement of outdated network components after technical and regulatory analysis. Result: higher availability, confirmed compliance in internal and external audits.

Validation projects

European subsidiary of a Japanese pharmaceutical group

Complete validation documentation and a standardized qualification approach. Result: audits without findings, rapid commissioning.

Storage migration on-prem to cloud

European subsidiary of a Japanese pharmaceutical group

Virtual infrastructure in the cloud including a backup and disaster recovery concept. Result: backup times halved, system availability close to 100 %.



Your GxP / digital change know-how is in demand.

handshake Sales Partner

You bring sound experience from various areas of GxP compliance with you, or you have many years of experience in the digital transformation of highly regulated industries? As an independent consultant or running a specialized consulting firm in the pharma and process industry?

We are in constant exchange with experts who encounter a need for digitization in their network – and address it together with us.

handshake Implementation Partner

Your company works in IT consulting or software development – with sound experience in the regulated GxP environment? You know the requirements for introducing computerized systems in laboratories and production areas?

Then let us talk about a partnership on equal terms – for IT specialists in GxP environments and in other industries with particular documentation and traceability demands.



In Vienna since 1993 – specialized in regulated industries.

handshake was founded in 1993 and quickly established itself as a specialist for IT products in the pharma and process industry. The services of the ISO 9001-certified company include self-developed software tools and their customer-specific integration – plus consulting, validation and operation in GxP environments.

Our own software tools.

Smart Document System, Smart Audit Trail and Smart LogBook – self-developed and validated.

IT consulting & projects.

Project management, network and infrastructure projects, cloud migration.

Validation & operation.

Validation according to GxP, qualification (DQ/IQ/OQ/PQ) and level 2/3 support.



Anton Neuber

Founder & Managing Director



Marco Albinus

Head of Sales, Marketing & Partnerships

Pharma

and biotech industry

Chemicals

and cosmetics industry

ISO 9001

certified services
and our own software

“Companies in the process industry face complex requirements every day – from documentation obligations to strict GxP specifications. This is exactly where handshake comes in.”

Mag. Anton Neuber, CEO handshake

Thank you!

If you are interested in our solutions and services, we look forward to a personal conversation. We like to start with a short evaluation call to understand your specific situation together. If there is a mutual go and interest, we look forward to a personal deep dive into our three tools and the consulting and implementation services that go with them.

Contact

Marco Albinus · marco.albinus@handshake.at
handshake Consulting G.m.b.H.
Schulgasse 12/Top 1, 1180 Vienna, Austria
www.handshake.at



APPENDIX

Digital forms and records – execution (DF&RE).

In depth: where companies stand today, what the path to automated, integrated forms looks like – and which value levers a system comparison reveals.

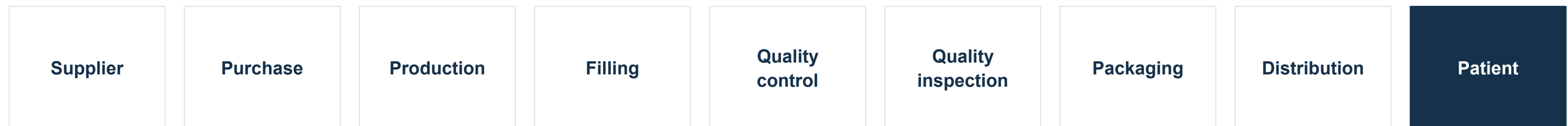


What is Digital Forms & Records Execution?

DEFINITION

Digital Forms and Records Execution involves the transition from manual, paper-based processes to fully integrated digital systems for managing all company forms and documents as linked digital assets throughout their entire life cycle, from creation to disposal, using a value-driven software platform.

ALONG THE ENTIRE VALUE CHAIN



Review by Exception (RBE) & Approval by Design (ABD)

Data flows in the background – without additional systems in the foreground. What stands out gets checked; what the process provides for gets approved. That shortens cycle times and makes first-time quality the rule.



Where are you – and where do you want to go?

Paper & manual

- Long cycle times
- Human interaction
- Manual workflows
- No system connections
- Manual DI & audits
- Storage cost for paper

Paper-on-glass & semi-manual

- Medium cycle times
- Partly digital input
- Semi-manual workflows
- Individual system connections
- Semi-manual DI & audits
- Lower storage cost

Automated & integrated

- Short cycle times
- Digital input
- Automated workflows
- Multi-system connections
- Automated DI & audits
- No storage cost

Cost & lead time go down →

Quality & right first time go up →

Smart Document System starts exactly where the leap from “paper on glass” to truly integrated data is made.

What a system comparison shows.

The basis is an NDA test in 2023/2024 at a globally active company with three systems and selected simple to complex forms and records.
We cannot guarantee a reproduction of the results.

1. Build time

How long it takes to design forms and records ready for production. Systems A and B needed considerably longer than SDS for the same forms – with an effect on total cost of ownership and schedule.

2. Turn around time

How long execution and changes take in ongoing operation. Longer execution times with A and B led to higher FTE cost and longer lead times.

3. Integration & value levers

Integration capability, advanced workflows, calculations and Review by Exception – plus self-service configurability that reduces the need for support.

35–65 %

shorter build time
in the test scenario

8–24 %

of the execution time
compared to paper processes

RFT ↑

right-first-time level rises
compared to systems A and B

The functional layers of the SDS platform.

USE CASES

GenForms – general forms & logbooks · EBR – D2D EBR Management · Q-Gate – Quality Form Management · ValiDEX – Validation Management

FURTHER MODULES

AuditTrail – Audit Trail for Compliance · DeviceConn – Device & Lab Integration · DigiChains – Connect any Data / System

INTEGRATION LAYER

OPC UA, Smart API, dynamic lists – connecting QMS, LIMS, ERP, MES, historians and equipment

PLATFORM LAYER

Central GxP-validated platform – cloud, on-premise or SaaS

One platform, several use cases – validated once, used across departments.