

Info paper: Smart Document System© - the power of intelligent digital forms

Changeover in weeks without investment of millions



Introduction:

In the highly regulated and demanding pharmaceutical and process industry, precise documentation of development and production processes is an indispensable element. At the same time, protocols, checklists and the like have to be kept at various peripheral levels.

Companies of all sizes are introducing systems, some have digitised processes and many are still working entirely on paper. The processes are well-worn and have been reduced, but everyone knows that they are often not very efficient in terms of retrieving information, the human error rate and ultimately the enjoyment of working.

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 customise in detail at second glance? Have you been trying for a long time to adapt cumbersome standard software to your company's specific processes?

Smart Document System© from handshake offers a pragmatic alternative.

Objections to the switch and how handshake addresses them

Companies often face considerable obstacles when they want to convert paper-based documentation to electronic systems:

High costs

The introduction of known standard systems can run into the millions, which represents a major financial burden for medium-sized companies in particular.

Long implementation times

The introduction of such systems often takes months or even years and can massively disrupt existing processes and production workflows.

Complexity and need for customisation

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

Employee acceptance

Users with the appropriate authorisation 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 fulfils 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 recognised by authorities, the handshake system offers digital time stamps and tamper-proof documentation - a plus point for audits and inspections.

Integrations-Probleme

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

The alternative of handshake

Smart Document System© from handshake offers a customised, easy to implement and significantly more cost-effective solution for the pharmaceutical & process industry. Compared to conventional systems, it is characterised 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 customised 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 analysed 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 customisation options

Users with the appropriate authorisation 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 analyses and deviation reports.

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: Digitalisation

- 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

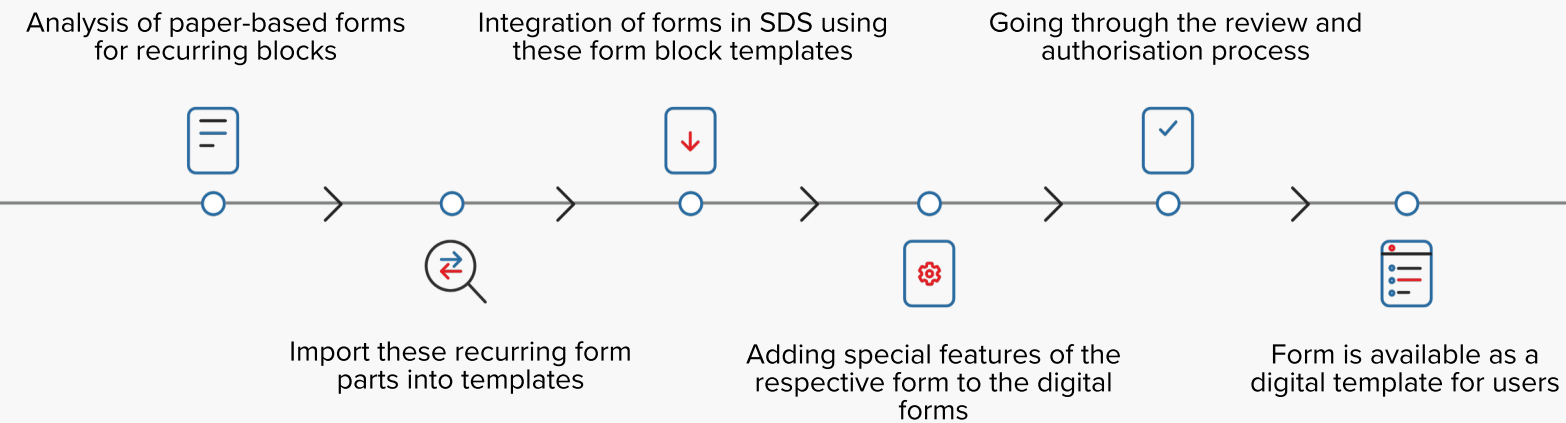
- Users can fill in the form with data
- Equipment data can be transferred directly to the form
- MES / eQMS systems can be supplied with data from the form
- ERP / LIMS / PMS systems can be connected bidirectionally

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 analyses, for quick countermeasures or as a basis for further processing in existing systems.

Changeover - How the implementation process works



Scope-Definition

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



Identify optimisation options

Identify analysis and optimisation 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

Organise information events and training for employees to ensure rapid and safe adaptation of the system.



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



Adaptation of the process definition and all affected SOPs

Revision of all relevant SOPs (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 reworking

Import of prepared forms and customisation 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.

Fields of application

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.

Research & Development

- ✓ Preparation
 - Incoming goods inspection
 - Test protocols
 - Room cleaning protocols
- ✓ Engineering
 - Maintenance logs
 - Checklists for recurring activities
 - Calibration protocols
- ✓ Research
 - Documentation of laboratory experiments
- ✓ Quality
 - Data integrity and compliance
 - Documentation of recurring checks
- ✓ Reporting
 - Distribution of the results

Production

- ✓ Preparation
 - Buffer preparation
 - Incoming goods inspection
 - Sanitisation with steam
- ✓ Production
 - Manufacturing documentation
 - Production assembly
- ✓ Quality
 - Process review and documentation of product testing
 - Product release
 - Documentation of recurring checks
 - Cleaning and sterilisation protocols
 - Request for raw materials
 - Product releases
- ✓ Serialisation
 - Batch documentation
 - Packaging

Ready for an initial personal meeting and a technical insight?

If you are interested in finding out more about Smart Document System© and its benefits, we would be happy to talk to you personally.

Experience how easy it can be to switch to intelligent forms which get & exchange data in the background to gain user centric work with outstanding efficiency.

Please contact us for a demo. We look forward to understand your specific requirements:

[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.

