handshake

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White Paper: Efficient transition to electronic forms in the pharmaceutical industry

Changeover in weeks and without millions in investment

Smart Document System

Introduction:

In the highly regulated and demanding pharma industry, precise documentation of production processes is an essential element. But while most companies still rely on paper-based systems or expensive and complex electronic solutions, there is a growing demand for more efficient, flexible alternatives.

For many companies, traditional Electronic Batch Record (EBR) systems such as those from the large software houses are a hurdle - they are often too extensive, cost-intensive and require long implementation times.

The solution from handshake offers a pragmatic alternative here. At a tenth of the cost and with an implementation period of just a few weeks, handshake makes electronic forms accessible to companies of all sizes.

Digital vs. paper

Switching from paper to electronic documentation systems offers a number of advantages that are particularly important in today's digital and networked production environment:

Complete traceability and full documentation	Electronic systems offer uniform and complete documentation of all production steps, which can be called up at any time.
No additional digitization steps required	Unlike paper records, there is no need to digitize documents retrospectively, which saves time and resources.
Direct availability of data for automated control and optimization	Production data is immediately available and can be used in real time for process optimization or quality control.
Location-independent access and review	Documents can be accessed independently of physical locations, which supports remote working or decentralized teams.
Legibility and independence from handwriting	Electronic documentation eliminates legibility problems that occur with handwritten records.
GxP Compliance	With digital time stamps and 21 CFR Part 11-compliant signatures, the handshake system meets the highest regulatory requirements and thus ensures compliance with GxP standards.

Challenges of traditional EBR systems

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

1 **High costs**

The introduction of traditional EBR systems can run into the millions, which represents a major financial burden in terms of margin and cost pressure.

2 **Long implementation times**

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

3 **Complexity & 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.

These challenges often lead companies to delay or avoid switching to a digital EBR system, even though the benefits in terms of efficiency and security are obvious.

The alternative of handshake

Smart Document System© from handshake offers a customized, easy-to-implement and significantly more cost-effective solution for the pharma 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

At just a tenth of the cost of fully EBR systems, handshake is particularly attractive.

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 production 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 through “Review by Excepetion” and the analysis of manufacturing data through advanced search functions and offers options for data mining, (AI) trend analysis and deviation reports.

Multifunctional range of applications

In addition to batch recording, Smart Document System© can also be used for other forms in various areas of the company such as laboratories experiments, incoming goods, product confection which includes also recurring checklist and protocols. One system with different application areas.

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.

A simple changeover - how the implementation process works

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

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.)

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

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 an efficient and flexible digital form system.

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.

Smart Document System

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