



handshake

Innovative IT Solutions for Pharmaceutical Compliance

Pharmaceutical products typically pass through various production cycles and processes before finding their way into 'patients' cabinets. Ensuring the quality and safety of these life-saving products in each stage of the production lifecycle is vital, making adherence to good manufacturing and laboratory practices (GxP) integral for pharmaceutical businesses. This demands them to fulfill various legal and FDA requirements, document and control production processes and reduce validation efforts.

However, navigating the complex waters of these technical and regulatory needs is daunting for most businesses. Here, the assistance of a pharmaceutical IT specialist is their only guiding star.



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handshake, a specialist in pharmaceutical IT, assists clients in meeting all their regulatory needs for GxP compliance, data integrity and qualification. It has developed a suite of proprietary software products that enable pharmaceutical companies to document and control the production processes, ensuring the quality and safety of products in all stages of their lifecycle. This IT troubleshooter's focus also extends to reducing its clients' validation efforts, with an unwavering commitment toward compliance and facilitating smooth project execution—all supporting pharmaceutical innovation and patient safety.

"Our goal is to help clients to be fully compliant executing their production related activities by offering an ideal IT solution that yields the best experiences and results to all," says Anton Neuber, founder and managing director of handshake.

Its portfolio encompasses three products: Smart Audit Trail©, Smart Log Book©, and Smart Document System© — all crafted with precision to address the specific pain points in the GxP practice environment. The Smart Audit Trail© is a tamper-proof solution for access protection that helps limit access to selected people for enhanced security. It allows for rigorous monitoring and assists clients in setting up user permissions, activities and applications.

Smart Audit Trail© can be incorporated into a Windows-based system that lacks native Audit Trail support, ensuring compliance with FDA and various other legal requirements. Clients can seamlessly capture critical data to make the review process more streamlined, efficient and less time-consuming. It also comes with a remote audit trail review that eliminates the need for personnel to physically access clean room environments.

handshake's Smart Log Book©, on the other hand, helps replace all manual paper-backed logbooks with an electronic alternative that effortlessly tracks the events and manages documentation. It prevents the risks of lost or damaged logs and enables efficient event tracking, service requests and testing procedures. Entries to the Smart Log Book© can be created using Smart Audit Trail© and clients can easily access these log books from any location. It can keep note of the system's time stamps and user-based electronic signatures to enhance data integrity and accountability while simplifying the review processes.

handshake delivers Smart Document System© to simplify form based pharmaceutical process documentation by replacing paper-based forms with web-based management solutions. Training requirements are reduced by using the look and feel of well-known Office suites and its ability to interface with instruments directly to capture data eliminates human errors and streamlines the documentation. This ensures controlled process flow and restricts changes on already created and approved documents.

Client-centricity is at the heart of handshake's operational excellence. It begins an engagement with one-on-one sessions, where the team spends significant time upfront to better understand customers' needs. Before embarking on project setup, its project managers conduct workshops involving stakeholders to facilitate open communication, allowing everyone to provide valuable insights and gain an organization-wide buy-in to the project's objectives. This establishes a sense of purpose and aligns everyone's efforts toward project success.

Mr. Neuber's project management skills are at play, making handshake adept at delivering solutions that best meet the industry standards. Its dedication to data integrity, qualification and documentation has positioned itself as a trusted partner for numerous clients. Backed by this sterling reputation and a proven track record, it continues to drive excellence in pharmaceutical operations by adopting GMPs to ensure products are developed and delivered with the utmost quality.



Anton Neuber,
Founder & Managing Director

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*The annual listing of 10 companies in Europe that are at the forefront of providing
Pharmaceutical Quality Assurance services and impacting the marketplace*