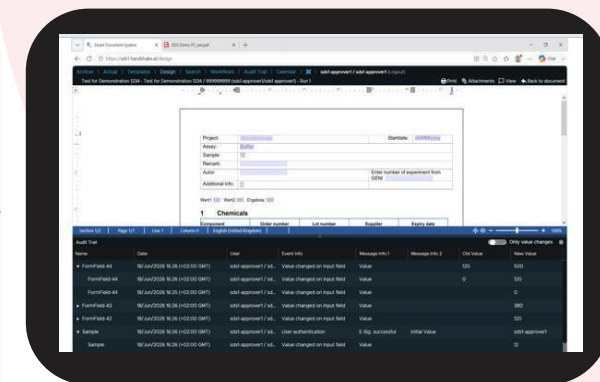
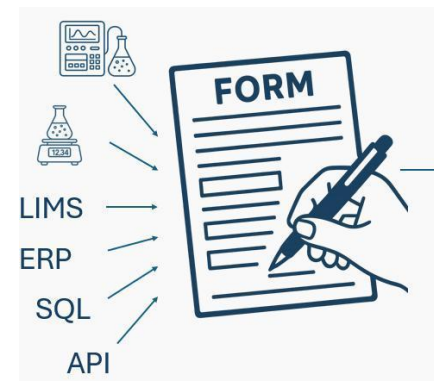


Speed. Delivery. Success. Planned for 4 years – delivered in 14 months.

Review time reduced by up to 95%



How a globally operating US pharmaceutical corporation replaced paper-based GxP forms with a unified digital documentation infrastructure – across 50+ production sites.

Industry: Big Pharma · 50+ production sites worldwide · ~25,000 users

The situation before handshake:

Paper everywhere and growing digital regulatory pressure

- 1 Structure created in Office applications
- 2 Reviewed & approved on paper
- 3 Stored in a static DMS
- 4 Printed out for production
- 5 Filled in, printed and checked – entirely by hand

Under GxP and 21 CFR Part 11, every step meant manual effort, transport routes and high review effort.

The company did not want an isolated solution for Master Batch Records.

The customer needed a forms platform for the entire organization and for different departments and their needs.

Review reduced by up to 95%

No paper. One source. At every site.

Reviewers only see exceptions and deviations.

Automated plausibility checks ensure that reviewers only see values outside defined limits – that reduces review time by up to **95%**, regardless of site and in real time.

Data threefold and consistent in the system.

Every form exists as a document, database structure and audit trail – always in sync. Manipulation is reliably detectable.

Digital, consistent data usable everywhere.

Data from people, equipment and systems (ERP/LIMS) converge at the point of origin – a consistent, AI-ready data layer across departments.

It all began with *Smart Document System*© (SDS)

The journey: two sites, then the world

1

First pilot

The pilot site (Europe)

First Smart Audit Trail©, two years later Smart LogBook©, then **Smart Document System©** for the forms landscape. Users created and refined their forms themselves – in an editor modeled on Office applications.

The site went fully digital – and attracted global attention.

2

Second site

900 forms become 60 blocks

The Document Library turned recurring form elements into modular building blocks: 900 forms consolidated into ~60 standardized form blocks.

Evaluation in September, contract in December, go-live at the end of February.

3

Global decision

Business case approved

KPI-based site evaluation with Global Quality and IT. The decision: three cloud instances:

Asia, Europe & America.

4

Global rollout

Ready in 14 months

The license agreement provided for four years. First lifecycle update two months later – first the test environment, then smoothly live.

The infrastructure was globally ready after 14 months.

Results at a glance

Up to **95% less**

Review time in the
approval process

14 months

to global readiness –
instead of: 4 years planned

50+ sites

Production sites
connected

~25,000 users

active users, from
production to validation

**900 forms →
60 blocks**

900 forms reviewed & consolidated into
60 standardized form blocks

\$ Millions

in savings, confirmed
by management

Our customer says:

“Before: paper. After: a consistent data foundation – that is the decisive difference that boosts productivity.”

Technology / Innovation Director / QSEO Transformation · globally operating US pharma corporation

Savings in the millions – confirmed by management.

Next steps

Conclusion: One Source of Truth – Data by Design-Data by Design – your data foundation for efficient AI projects. Significantly faster reviews. Data-based ad hoc reporting capability for customers and suppliers. Complete audit trail. GDPR-compliant by design.

This approach applies to every **highly regulated, documentation-intensive industry**

- Pharma & Biotech
- Chemicals and cosmetics
- Food and beverages
- Medical technology
- Oil & gas
- Energy & water/wastewater
- Aerospace & defense

Send us your industry and a short initial inquiry to:

marco.albinus@handshake.at **Marco Albinus - Head of Sales, Marketing & Global Partnerships**

C O N T A C T handshake Consulting GmbH · marco.albinus@handshake.at · www.handshake.at