

# Global Deployment of Training Manager Software for a Top 5 Generic Pharmaceutical Company

Discover how our Training Manager Software orchestrated a seamless global deployment strategy, revolutionizing their training processes.

## Client Introduction

Our client stands as one of the top 5 global generic pharmaceutical companies, boasting a presence in over 20 manufacturing facilities across the United States, Europe, and Asia.

Within the pharmaceutical sector, where adherence to Standard Operating Procedures (SOPs) governs all facets of operation, this client holds a prominent position. SOPs are the lifeblood of pharmaceutical companies, necessitating meticulous data management and immediate access to training-related information.

## Pharmaceutical industry and importance of training

The pharmaceutical industry is subjected to rigorous regulation and frequent audits by esteemed bodies like the US Food and Drug Administration (US FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA). A central focus of these regulatory agencies and client audits is personnel training on SOPs and compliance with these procedures. Any lapse in training adherence can trigger Form 483 findings, highlighting potential regulatory issues with significant repercussions for the company's financial bottom line.

Within this environment, all pharmaceutical company personnel must undergo extensive training. Junior-level employees are required to follow an average of 50-200 SOPs, while senior management may grapple with as many as 300-400 SOPs. Additionally, employees must successfully complete assessments at various stages to qualify for work on specific products.



## Key Challenges



### Data Deluge and Management Overload

The client faced the daunting task of managing an avalanche of training data, from allocation to data management and presentation during audits.



### Lack of Process Uniformity

Inconsistent training processes, divergent data collection methods, and dissimilar data representation across multiple sites led to repetitive observations in various locations.



### Data Integrity Concerns

Excel's limitations, including the lack of a reliable audit trail and vulnerability to tampering, raised concerns about data integrity. Regulatory bodies questioned the authenticity of Excel data, casting doubts on its reliability.



### Unproductive Time Allocation

A substantial amount of non-productive time was dedicated to training assignments, training management, and assessments, accumulating to a significant yearly total.



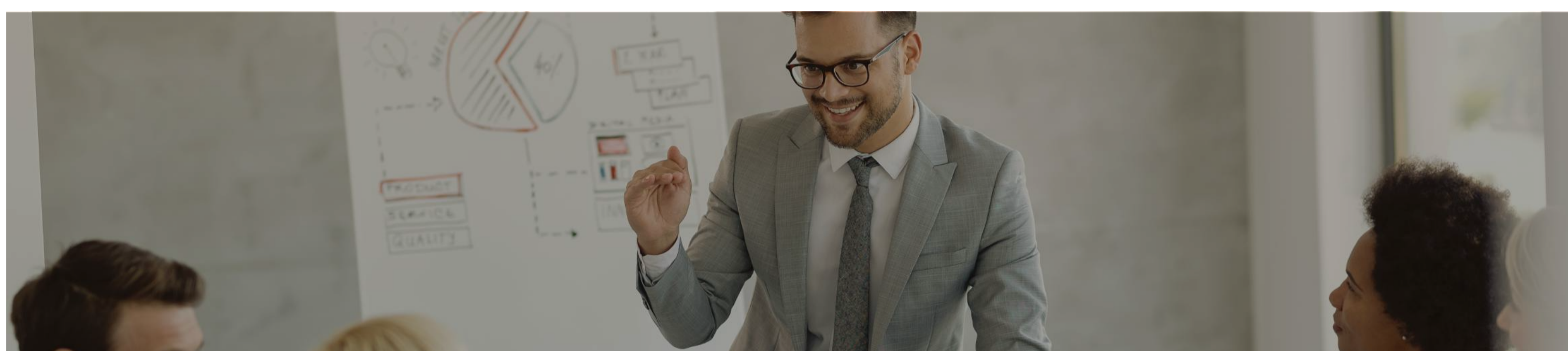
### Auditor-Readiness

Regulatory agencies demanded immediate access to comprehensive training data during audits. The use of Excel or physical documents created obstacles in promptly providing requested information.



### Multi-System Management

Overseeing multiple IT applications and vendors across various locations posed significant challenges for the IT department. Additionally, maintaining system validation at diverse locations proved to be an arduous task.



## Solution

To address these formidable challenges, the client adopted the DBS Training Manager, a solution built on CFR 21 Part 11 compliant architecture and classified as a GAMP Category 4 solution. The Training Manager, tailored for the pharmaceutical industry, streamlined training processes by automating assignments, reminders, follow-ups, and escalations. Key features included:

- ▶ Automated training control and management
- ▶ Multiple training modes
- ▶ Document effectiveness control
- ▶ Online exams and automated assessments

The implementation began at a major manufacturing plant and was subsequently scaled rapidly across multiple client locations, following the initial phase that entailed a comprehensive analysis of the Indian manufacturing facility's specific requirements, ensuring thorough digitization and verification of all paperwork. In the second phase, the software was successfully implemented across four sites within a month.

## Results

The on-premises training management solution delivered a turnkey GAMP Category 4 solution for efficient training management. The software significantly transformed the training process, enabling employees to allocate their time more productively. This automated and robust system ensured timely training completion with real-time data updates.

## Key Outcomes



### Process Standardization

The centralized software standardized training processes across multiple locations.



### Data Integrity

Compliance with 21 CFR Part 11 ensure data integrity with extensive audit trails.



### Unproductive Time

Training assignment automation and online assessments reduced training-related time expenditure by over 60%.



### Auditor-Readiness

Training data became instantly accessible, simplifying audits.



### Multi-System Management

Centralized Training Manager eliminated the need to manage various training systems and vendors across locations.

## Key Highlights

- ▶ More than 10,000 active users daily
- ▶ Successfully passed over 100 regulatory and customer audits with zero non-compliance
- ▶ Uptime exceeding 99% for the past 7 year

## Conclusion

The implementation of the Training Manager resulted in over 60% time savings in the entire training process and streamlined training procedures across multiple geographies, ensuring zero non-compliance.

## Testimonials

DBS has been our SAP global infrastructure and AWS support partner for more than 5 years. One of our most seamless SAP project has been migration to cloud which was planned and managed by the DBS team. Their support team is proactive and ensures our SAP runs flawlessly and whenever support is required they are available

- Kunal Shah  
Executive Director, AIA Engineering Limited

Discus Business Solutions successfully helped us migrate our on-premises SAP databases to AWS. After careful planning, the migration was carried out without any disturbance to our business processes. The day-to-day management of SAP is also in good hands at Discus Business Solutions.

- de Jong, Jeroen  
IT/QA Head

Discus Business Solutions manages our IT landscape which includes SAP, infrastructure, software and user support. Pharma being a very regulated industry we wanted a partner who can understands our business, compliance & end user requirements. They have been our partner since 2 years, they have been managing our day to day IT operations. With their IT support we are assured that if there is any issues than it will be resolved in a timely manner with proper RCA keeping long term approach in mind

- Kunal Shah  
Executive Director, AIA Engineering Limited

