GLOBAL PHARMA COMPANY TRANSFORMS TO A PAPERLESS ENTERPRISE WITH SYNTEL

BUSINESS GOALS

A large Japanese pharmaceutical company wanted to eliminate their dependence on paper-based Trial Master File (TMF) documentation, while standardizing processes and upgrading their technology environment.

BUSINESS BENEFITS

- FASTER SUBMISSION OF DOCUMENTS TO REGULATORY AUTHORITIES
- 100% COVERAGE FOR DOCUMENT QUALITY CHECKS TO ENSURE REGULATORY COMPLIANCE
- 23% INCREASE IN PRODUCTIVITY BY REDUCING MANUAL EFFORTS WITH CENTRALIZED QC
- 20% YEAR-OVER-YEAR COST REDUCTION BY MOVING OPERATIONS TO LOW COST GEOGRAPHIES
- REDUCED DUPLICATION BY 5%
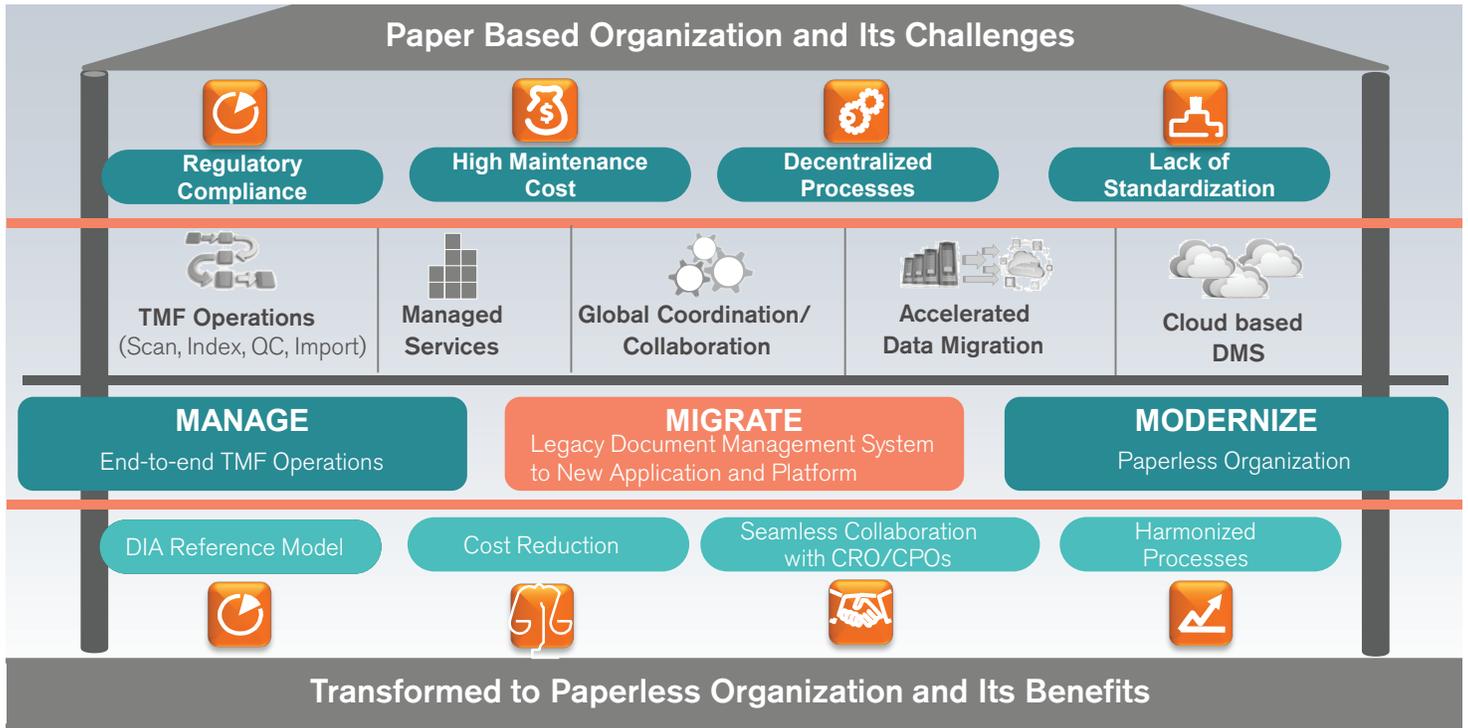- DOCUMENTS ARE ALWAYS IN AUDIT AND INSPECTION-READY STATE

CHALLENGES

The client needed to manage a huge volume of paper-based clinical documents, 80% of which were sourced from Europe and the U.S., while the other 20% came from other global locations. Coordinating the receipt and standardization of paper documents from suppliers and partners around the world was a big challenge, and performing quality checks on paper TMF documentation was very time consuming.

They were looking for a change management solution that would adhere to global regulations and help them quickly produce the required documentation in an audit and inspection-ready state.

SYNTEL'S SOLUTION

- Built regional **common access centers (CAC)** to coordinate with **contract research organizations (CROs)**, collect paper documentation from all global locations, and handle digitization and indexing

- Developed an **electronic document management system (eDMS)** to receive digitized documents for quality checks (QC) before uploading to a central repository

- Built a centralized offshore team to perform quality checks to make documents audit and inspection ready

Paper Based Organization and Its Challenges

Regulatory Compliance	High Maintenance Cost	Decentralized Processes	Lack of Standardization

TMF Operations (Scan, Index, QC, Import)	Managed Services	Global Coordination/ Collaboration	Accelerated Data Migration	Cloud based DMS

MANAGE
End-to-end TMF Operations

MIGRATE
Legacy Document Management System to New Application and Platform

MODERNIZE
Paperless Organization

DIA Reference Model	Cost Reduction	Seamless Collaboration with CRO/CPOs	Harmonized Processes

Transformed to Paperless Organization and Its Benefits

About Syntel

Syntel (Nasdaq:SYNT) is a leading global provider of integrated information technology and knowledge process services. Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Syntel's digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Syntel's "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

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