

Global Pharmaceutical Firms

The **IN**side Story

Company One – A Need for Speed and Compliance

This major pharmaceutical company processes five million pages per year, primarily involving documents critical to research and FDA compliance. In order to comply with FDA regulations, records and electronic signatures must be protected and backed up in a human-readable format.

Starting with an antiquated database program for storing index information – plus a reliance on manual processing – it had become exceedingly difficult, if not impossible, to keep up with growing document volume. Project managers understood that while maintaining paper copies was mandated, paper had to be digitized much faster as part of a three-level disaster recovery plan – paper, microfilm and digital online.



Kodak Document Archive Writer

In soliciting three proposals to meet these requirements, two included the *Kodak Document Archive Writer* as part of the microfilming solution.

The company selected Document Conversion Associates, an Authorized Reseller of *Kodak Document Imaging Products*, believing their solution offered significant advantages – including the ability of the DAW to be networked. Instead of just serving one workstation, the DAW made it possible to utilize remote scanners in the network, moving digital files to the writer over the corporate IT backbone.

The company is utilizing *Kofax Ascent Capture* Software with the scanners, as well as *Kofax Ascent Scribe* plus *Kodak Imagelink Archive Writer Interface Software (AWIS)*, in conjunction with the DAWs.

Paper is sorted and scanned for conversion to PDF files required for FDA submission. These same image files are written to film and indexed all in one pass, providing easier retrieval and a high degree of accuracy.

By contrast, when paper was being filmed optically directly to film, the process required more steps; dust and dirt compromised image clarity; and indexing was not integrated with the rest of the system.

The company will create two microfilm copies on *Kodak Reference Archive Media* for each document – one for on-site use and another for vital records/disaster recovery (stored off site). The overall solution will not only move paper faster, it will also free up valuable space and end backlogs.

Approximately two months of on-site box storage will no longer be needed.

The company anticipates the benefits of this new solution will be extremely significant. The company no longer has to worry about refilming, records can be searched far more efficiently, the microfilm process is automated, and there's no more paper feeding to the device creating microfilm.

Situation

Two leading global pharmaceutical firms shared similar problems – coping with an ever-increasing archiving volume, while providing for effective disaster recovery of physical records management.

Objective

Create a highly efficient and centralized process for managing physical records that minimizes paper requirements, speeds conversion, saves space, and enables creation of a digital archive.

Solution

***Kodak Digital Science Document Archive Writers 4800 (DAWs)** which rapidly convert digital documents to analog, human-readable images stored on microfilm.*

In addition, human-readable microfilm is archival quality and there is no danger of technological obsolescence, or digital media degradation, or loss. The entire imaging/safekeeping process has been streamlined and simplified. Bottom line: steps are reduced, productivity enhanced, compliance assured, quality improved and money is saved.

Company Two – Keeping Up With Volume and Regulations

As one of the world's leading pharmaceutical firms, this company required a microfilming system that could provide disaster recovery and legal protection, as well as keep up with its ever-increasing archiving volume.

This global firm develops and markets prescription drugs, animal health products, over-the-counter drugs, and foot care/sun care products – and files an average of three to five new drug applications (NDAs) with the FDA per year. The applications are submitted via the electronic submission standard – designed to reduce review time, improve quality, and progress beyond paper.

In submitting NDAs, content comes in the form of paper and electronic documents, which have been developed in clinical field studies, chemist lab research notebooks, and other product development research documents.

Archiving these documents for easy future retrieval is a high priority, since the company's regulatory affairs department must frequently access the records to show evidence of compliance. Complicating the challenge is the projection that in five years the company's film archiving volume is projected to grow from five million to 10 million documents. Any solution would need to accommodate this anticipated archiving volume growth, while also eliminating paper and reducing labor costs.

To meet this challenge, the *Kodak* Digital Science Document Archive Writer 4800 (DAW) was selected to rapidly convert digital documents to analog, human-readable images stored on microfilm.

The DAW was chosen for its interoperability with the company's current digital system. An Authorized Reseller of *Kodak* Document Imaging Products – Image Access Corporation – wrote a program to manage the convergence of the pharmaceutical company's PDF files to microfilm using *Kodak* AWIS Software.

Over the first nine months of the installation, more than two million documents were written to microfilm – an equivalent to 600 boxes. The company managed to drive the cost down from 5 cents per image to 2.5 cents per image. Additionally, the

company's 1.7 million-document backlog was cleared in three months.

The company managed to recoup its costs during the four-month test cycle and is looking to add an additional DAW soon. The implementation has resulted in a simpler, more efficient and cost-effective way of producing film becoming a simple six-click system.

As an unattended 24/7 online installation, the company also achieved its desired staffing goals. Since the DAW groups and indexes associated images on the same piece of archive storage media, the company's regulatory affairs department has been able to simplify search and retrieval operations.

The company has made a conscious commitment to use microfilm as a backup medium for disaster recovery and protection from legal exposure.

These efforts paid off when 40,000 images literally went up in smoke. Using the microfilm – which was stored in a separate location – the company was able to selectively restore 30,000 images in three months.

