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Conquering the Last Paper Mountain — The Impending Extinction of Paper Master Records

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IN THIS PERSPECTIVE

This IDC Health Insights Perspective highlights leading efforts to eliminate the creation of paper versions of the master documents created during drug development. Building on leading efforts by a consortium of major German life science companies, the need for paper master documents has been refuted, a fading practice further reinforced by the rapid transition to electronic submissions expected over the next few years. For those paper documents already in place, there is discussion as to whether there is sufficient value in conversion to electronic master documents or whether documents should remain in place until regulatory holding requirements expire. As the last bastion of massive quantities of paper, the elimination of paper master documents finalizes the shift away from paper and helps to advance effective pragmatic information management processes out of the 20thcentury.

This Perspective is based on independent IDC research, a QUMAS Webinar on the topic (see **www.qumas.com/webinars/sounds-of-compliance-two.asp**), and direct discussions with a leading industry manager implementing the change at a major multinational pharmaceutical company.

Situation Overview

Historically, all life science companies created master copies of all of their regulated documents that were physically archived for (and beyond) the life of the product in the marketplace. This master copy was typically sent offsite to a storage facility like Iron Mountain and could fill as much as two or more full-sized semitrailers at a cost of hundreds to thousands of dollars per year for 20 years or more. These master documents were presumably to be available should regulatory agencies request them and would need to be accessed and subsequently delivered to agencies on demand. In real life, master document retrieval rarely occurs and, with current expectations for electronic submissions, no longer makes sense.

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Regulated Document Holding Requirements

Looking at drug document retention requirements in the United States, a review of the FDA's GxP and 21 CFR Part 11 rules unveils that for most drug-related documents, records should be retained for as long as 30 years after the respective key associated drug event (e.g., marketing application approval, product expiration date, or study termination.) For recently completed preclinical study reports that were included in a new drug application (that would typically be submitted 6–8 years in the future), the reports will likely need to be retained for at least 8–10 years before they can be destroyed. As additional study reports are generated to extend approved drug indications, quality and manufacturing documents produced for each new drug lot, and unsuccessful new drug programs terminated, each of these creates records that must be retained for specific, well-defined periods (typically measured in years).

A primary reason for retaining paper master records has been concern in the United States (and elsewhere) that regulatory agencies have the ability to request submitted documents should any questions arise. Historically, master paper documents with original signatures have been considered "the" master record, requiring retention and safe storage. As the United States and Europe have moved to encourage and eventually require submissions electronically, the concept of what document is truly the master document is changing. With the advent of electronic signatures, even the notion of original signatures is changing.

Changing the Status Quo

A consortium of German life science companies came together to determine whether it was possible to eliminate paper as the master record for GxP documents (i.e., virtually all regulated documents within the companies). Initial efforts focused on detailed review of document-related regulatory requirements and direct discussions with regulatory agencies to determine whether explicit requirements for paper records are present. Having found none, the consortium compiled and published a white paper of their findings (Ref.: Pharm. Ind. 69, Nr. 7, 791-794 [2007]) with the expectation that regulatory agencies would issue a response if the insights from the white paper conflicted with regulatory regulations and policies. No response was forthcoming. With this passive affirmation in hand as well as complete corporate support, some companies have proceeded to implement policies with the goal of eliminating paper master records first in Germany, then at the corporate level, and finally across the organization globally.

As with any organizational changes, there exists considerable resistance to change. Early revisions to corporate standard operating procedures (SOPs) specified elimination of paper records unless there

were regulatory statements against doing so. While none have been found, this provision empowered many within the organization to maintain the status quo. With no regulatory statements found after diligent searching, it was decided that the provision should be removed and the organization driven forward. Although still a work in progress, companies are achieving significant progress in moving beyond paper master records and expect to save considerable time and money over the long term, improve operational efficiencies, and reduce paper recordkeeping across the organization.

To Convert or Not to Convert

With a plan in place to eliminate paper master records moving forward, the question of what to do with the miles and miles of documents already in storage was discussed. With master document holding requirements of 25 years or more, comprehensive return on investment (ROI) discussions drove decisions as to whether to convert existing paper records into electronic form. For documents with anticipated retention periods of 10 years or less, it was clear that the cost of conversion exceeds the potential benefits. In addition, potential concerns regarding the status of these old records (e.g., paper/ink decay, rodent damage) drove the decision to not unearth potential older problems that are not meaningful.

For newer paper master documents (e.g., documents in storage less than five years), the ROI for converting these documents made better sense. Working with QUMAS, at least one of the companies has implemented the company's Enterprise Scanning and DocCompliance solutions as the preferred approach to scanning and conversion of paper master documents into electronic versions and the subsequent destruction of paper documents.

Essential Guidance

A Future Without Paper

The legacy of paper-based master regulatory documents is a pervasive issue across the life science industry today. A conservative industry by nature, life science companies have had the luxury of redundant paper records with the support of high profitability margins. With the impending loss of patent protection for major blockbuster drugs, those margins will no longer be available to support inefficient processes. With all facets of the life science business under high scrutiny to improve operational efficiencies, elimination of paper master records should be an early consideration.

Based on the leading efforts in Germany, it is clear that there are no regulatory requirements to maintain paper-based master records for regulated documents. While there will be considerable resistance to organizational change in the elimination of paper records, companies

looking to improve operational efficiencies need to drive the adoption of electronic documents in place of their historic paper counterparts moving forward. In doing so, companies can expect to eliminate redundant efforts that affect virtually every individual within their organizations. These turbulent times are an opportunity for companies to streamline processes while concurrently taking on the mantle of green processes that help the environment. For life science companies worldwide, the decision to eliminate paper master records should be a clear one.

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Related Research

- *Changing Strategies: Progress in Pre-Competitive Pharma Collaboration* (Health Industry Insights #HI219781, August 2009)
- *Fording the Economic Crisis: Strategies for Life Science IT Vendors to Survive and Succeed* (Health Industry Insights #HI216453, February 2009)
- *U.S. Life Science 2009 Top 10 Predictions* (Health Industry Insights #HI216217, January 2009)
- Heinrich, Christine, Mario Hertlein, Stefan Krull, Thomas Linz, Ulrich-Andreas Opitz, Joerg Schwamberger, and Frauke Woltmann, *Elektronische Archivierung von Papierdokumenten,* Pharm. Ind. 69, Nr. 7, 791-794 (2007)