

Digital Archiving in the Pharmaceutical Industry

While relatively new as a retention method in the drug industry, e-archiving of records is a must-do to best ensure the health of patients and the industry

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In the highly regulated world of drug manufacturers, preserving records is a critical requirement for business continuity. So far, paper has been considered the only official documentation format, and microfilm has provided a low-cost – but low-tech – backup solution that is stable over time and essentially technology-independent. For the past two decades, however, all areas of pharmaceutical development have been generating electronic records. The accumulation of electronic source data and the evolution of electronic documents toward more dynamic forms that can combine written text, bookmarks, hyperlinks, and multimedia features create the need for digital archives and electronic signatures to preserve the integrity of originals.

In 1997, *the Code of Federal Regulations* (CFR), the chief U.S. source for listing regulatory requirements, set the U.S. Food and Drug Administration's basic rules for the validation of electronic records and electronic signatures (21

CFR part 11). Although archiving electronic records is clearly stipulated in 21 CFR part 11, only lately has the question of the long-term preservation of and access to digital assets arisen among drug makers.

Data and Documents

In addition to the traditional administrative information on employees, payroll information, network access, and e-mail, pharmaceutical companies retain a large number of records pertaining to their research and develop-

ment activities: laboratory notebook data from pre-clinical research, case report forms and trial master files from clinical research activities – as well as large databases of raw and surrogate clinical data. To these, one has to add a variety of other data sets on standard operating procedures, training, systems validation, systems access records, and more. All this information is crucial to business either from a knowledge management or a regulatory-compliance point of view.

The duration of retention for pharmaceutical records has been the object of great debate among specialists from different areas. To various parties, the picture looks different. Regulatory requirements in the United States define a two-year post-approval retention period for all the documentation supporting the filing for a new drug approval (NDA). New submissions, of course, re-set the clock. In the European Union, the retention period is 15 years from generation of a record. But regula-

At the Core

This article

- ▶ Explores the increasing need to store records electronically
- ▶ Outlines the advantages and challenges of a digital archive system
- ▶ Offers a checklist to create a digital archives program

tory requirements are not the only reason for records retention. Patent disputes, legal actions from patients and, of course, knowledge management can dictate a whole new set of rules for documents and data retention. So far, the simplest way many pharmaceutical companies have found for dealing with the complexity of the situation has been to retain paper copies of everything indefinitely.

In most cases, e-documents were viewed as interim manifestations of a final hard copy or, at best, as backups for those hard copies. Storage and preservation of e-records has remained off the radar screen of most pharmaceutical organizations.

Databases have been around much longer than e-documents, but this only seems to translate to a longer and more painful history of records lost, IT incompatibilities, and other unpleasant surprises. There are countless examples of databases lost only months after they were created.

The (e) Document Management Landscape

The pharmaceutical industry has been generating official electronic documents for more than a decade – the most prominent being e-NDAs. Laboratory instruments, diagnostic devices, electronic data capture tools, electronic patient diaries, and electronic data transfers from external partners are all generating source data that need to be archived. Many companies, including those in the biotechnical areas, have implemented elaborate and costly electronic document management systems. In the pharmaceutical industry, no robust e-archiving solution has emerged, however. Paper ironically remains the “gold-standard” archiving format.

This state of affairs can be explained for a number of reasons.

- The pharmaceutical sector does not view archiving as being on the critical path to new drug approval.
- Legacy archives contain mainly

paper and simply adding to that requires little effort.

- Archiving is sometimes confused with disaster recovery.
- Finally, archiving is a difficult, low-visibility task that no one is willing to take up as an extra chore.

The industry is now dealing with a whole new group of original, born-digital records that need to be preserved and accessed over time in a way that preserves content as well as their dynamic features.

Is e-archiving really needed in the pharmaceutical industry? The answer is “yes” and for good reasons. Regulations require archiving of original documents. As long as paper copies with wet-ink signatures were the originals, there was no question about what to archive, but today “originals” include a multitude of digital files generated by numerous devices and applications in the life cycle of a drug. The industry is now dealing with a whole new group of original, born-digital records that need to be preserved and accessed over time

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A Digital Archive

Until the mid-90s the situation was relatively simple: Electronic documents did not need to be retained, and electronic data could not be adequately preserved according to the prevailing standards. However, the reasons noted above – together with space and time management issues – pushed several organizations to retain electronic records. Thus, they become living experiments for digital archiving, revealing the advantages and challenges of this new retention method.

Advantages

The advantages of a digital archive in the pharmaceutical sector cover four areas: accessibility, selectivity, fidelity, and compliance.

Accessibility and Selectivity

Accessibility and selectivity are best illustrated in retrieval and disposal operations. The ultimate goal of effective records management is fast, easy, and accurate retrieval. As knowledge-based organizations, pharmaceutical companies have a constant need to access records in their archives and distribute them to a variety of internal and external agents. Selective disposal based on retention schedules is a standard part of a good cradle-to-grave records retention process. A well-organized digital repository allows both operations to be completed with minimal human intervention.

Fidelity

Preserving the “look and feel” of original records is a key element of good records preservation, and it is one of the key elements of 21 CFR part 11. Paper copies, microfiche, or scanned images can not reproduce all the dynamic features of the electronically generated records. Only a digital archive can preserve those and constitute a faithful version of the original.

Compliance

21 CFR part 11 sets forth the basic rules for electronic records and electronic signatures in the United States, and for several years, government agencies and industry representatives have worked to clarify the impact of this regulation on the use of technology in the production and retention of electronic records. Simply put, electronic records must be retained in electronic repositories, and those repositories must be compliant with 21 CFR part 11. Additionally, in 1998, Congress enacted the Government Paperwork Elimination Act (GPEA), which requires federal agencies to accept electronic records and signatures in satisfaction of programmatic requirements. It is clear that digital archiving is a key compliance issue and should always be part of the assessment (and remediation) plans for systems generating electronic records.

Challenges

Digital archiving, however, continues to face some serious challenges. As Terry Kuny of the National Library of Canada suggested in 1998:

“As we move into the electronic era of digital objects, it is important to know that there are new barbarians at the gate and that we are moving into an era where much of what we know today, much of what is coded and written electronically, will be lost forever. We are, to my mind, living in the midst of digital Dark Ages; consequently, much as monks of times past, it falls to librarians and archivists to hold to the tradition which reveres history and the published heritage of our times.”

Electronic Versus Physical Archives

Digital archives face specific challenges linked to physical storage media as well as hardware and software longevity. In reality, every method of recording information, whether on paper, stone, or photographic film, has a limited resistance to time. The value of any information is dependent on the ability to decode it after a long storage period. The difference with digital archives is that these limits are

ignored because of the addition of complex and versatile technology to the overall equation. In pharmaceutical organizations, a high level of confidence in the longevity of our archives is needed because not only the whole business depends on the information contained but also the health and well being of the patients using pharmaceuticals.

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The Solutions

Several types of solutions have been suggested over time for dealing with long-term preservation of digital records. Those can be classified into two categories: the simple and the complex. Among the simple solutions are keeping all data “live” in the production database and using a time capsule to maintain all obsolete hardware and software to allow for access of legacy data. The simplest and, not surprisingly one that is being

used quite often, is the “live data” solution. The dramatic reduction of disk memory cost makes this an easy and affordable solution. Unfortunately, both approaches are limited in time and cannot legitimately claim to be archives.

Among the more complex solutions are emulators and multiple migrations. The former has proven to be beyond technical feasibility, at least for proprietary software. The latter, migration, needs to be carefully planned and rigorously executed to stand a chance to succeed. In any case, a dual approach has the best chance to succeed. This would mean choosing an archive format that may lack some of the functional features of the native format but complies with standards for long-term retention. TIFF, PDF and XML are good candidates depending on the nature and purpose of the archives. Archival copies of records could be produced at specific points of the record life cycle (e.g., sign-off) and routed for storage according to the retention policy. Migration of these records to newer media as time passes should be planned and executed by professional archivists.

A Digital Archiving Checklist

What should document and records managers in pharmaceutical companies do today to best preserve the digital assets in their custody? Below is a checklist that can be helpful as a starting point.

- Define records retention policy. This is clearly the number one requirement and the cornerstone for any solution.
- Include archiving, retrieval, and disposal in the records workflow when building data and document management systems.
- Choose the file format for archival material as early as possible. The less elaborate its features, the easier it will be to preserve and migrate.
- Choose a robust redundancy method to ensure the ability to retrieve records even after a disaster or other

major adverse event.

- Carefully choose the storage medium and test the migration method to ensure accuracy of the copies.
- For short periods of retention, storing hardware and software can be a smart strategy.
- In parallel, monitor software backward compatibility to determine when the time comes for migration.
- Test record retrieval to ensure it works properly after migration to a new medium.
- Prepare for the unexpected.

Now the question is “who is going to do all those things?” The records management department (assuming there is one in the company)? Information technology? The functional areas who are owners of the records? Quality assurance? A dedicated archivist? Somebody else? It seems that digital archiving is a sufficiently complex operation that is well outside the core competencies of pharmaceutical companies. Consequently, it appears reasonable to entrust it to specialized archivists that can focus on all the above and many other secondary issues.

No Turning Back

In the pharmaceutical industry, perhaps more than anywhere else, documents are the most valuable assets. Not only business and wealth – but the very health and well being of patients – depend on the integrity of files. Drug registration and marketing approval is based on the information provided to the health authorities in the form of paper or electronic documents. The adequacy and the quality of pharmaceutical products are attested in the documentation produced and retained. So are the continuous monitoring and the assurance that the industry always will consider the safety of the people who trust the medicines above all.

As the world moves deeper into the digital era, it is clear that digital archiving

is a requirement and a need for pharmaceutical corporations. Technology solves familiar problems and creates

unfamiliar ones. Nevertheless, the silent revolution is moving on and there is no turning back. ■

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