

Standardized Document Management

Standardized electronic document management systems (EDMS) help pharmaceutical companies to lower costs by up to 30 %. The implementation, however, raises two major challenges: the technical and organizational standardization of legacy structures evolved over many years; and, as the case may be, the integration of corporate entities acquired through mergers.

The trend towards consolidation continues unabated in the life science industries. In this climate, inefficient internal document management processes represent opportunities for tremendous improvement potential. For many years, the approach has been to install highly specialized systems for handling the incredible volume of documents and their variants, which are being created during pre-clinical and clinical phases, marketing approval, production, quality assurance. However, the current rate of market changes impacting processes and business areas and the effect of corporate mergers has led to huge and ever increasing EDMS adaptation costs. Nowadays it has been shown that standardized systems are more in line with those realities. They have established themselves as a more flexible and cost-effective alternative. Through the use of a standardized EDMS, regulations imposed by public agencies as well as any legal and regulatory guidelines and standards can be more easily managed and complied with. Even complex dossier structures can be maintained more securely and at higher quality, while reducing expenditures at the same time.

Standardization of Document Management

The starting point for such standardization is a model of the »Drug Information Association« (the DIA EDM Reference

Model), which has become a standard for the newer software systems. The DIA model clearly specifies the important elements of a DMS, including document structure, document type, basic attribute concept, document storage and folder structures. Basic process requirements in the areas of regulatory affairs and manufacturing are defined in terms of document life cycles along with appropriate optional and mandatory process states as well as essential verification and approval processes. For the management of controlled documents (e.g. SOPs) or for document orientated cross functional business processes, a standardized approach of this kind typically opens up many new opportunities for efficiency improvements. Outdated structures and procedures, evolved over the years, and the diverging interests of different business functions have been the rule for too long. The implementation of a standardized DMS, in contrast, will positively impact organization, processes and structures towards reasonable, predefined standards. The DMS thereby provides a chance to streamline workflows and to make better use of IT assisted processes.

The implementing of such standardized systems in pharmaceutical enterprises typically raises two main challenges: the technical and organizational standardization of structures, which have grown over many years; the integration of different business entities acquired through corporate mergers.



Standardized DMS have proven to be more efficient in the management of huge volumes of documents and their variants, which occur during pre-clinical and clinical phases, admission, production, marketing and quality assurance.

Underestimating the Challenges

When harmonizing internal processes or migrating from an old DMS to a new standardized system, it is of course not enough to simply install a new application. In a document management landscape, which has evolved over many years, one must be prepared to encounter fundamental deficiencies regarding the integrity and completeness of its data and its structure. The main causes tend to be non-compliant data management and the many inconsistencies inherited from company acquisitions and mergers. Old structures of this kind, with their varying quality of data integrity and classification, are unfortunately often deeply rooted within the organization.

Example 1: When launching a new product variant, the attributes active ingredient, trade name and dosage form are added to the documentation. The problem: the original product name remains unchanged and all older documents do not contain the new attributes. For cost reasons, the required correction was deferred.

Example 2: A change in the enterprise structure during a growth phase led to the decision to record location in addition to study ID in the attributes. This information, however, is not available in prior study documents. Time constraints did not allow correcting this.

The implementation of a standardized DMS requires the migration of documents from the old to the new system. The fact that each of these older systems carries its own legacy of insufficient data quality and structure has to be taken into consideration. »Most companies tend to underestimate the required cleanup effort. It nearly always ends up being more than double than what was originally expected«, reports a DMS expert for life sciences at fme AG, an information management specialist. This can be illustrated by the example of trying to consolidate scientific literature from different libraries. Inventories of millions of books on many subjects have grown over the years and been catalogued by different librarians according to individual preferences. When moving all of these books to a new library, first priority is given to their transport, while the reorganization and consolidation of the library register is being neglected. This omission quickly proves to be problematic. With every new book added, the new library becomes more difficult and cumbersome to use. Only the timely and intelligent re-structuring of the library register will guarantee its efficient use. Such an effort though, requires competent document management experts with extensive experience in projects of this nature.

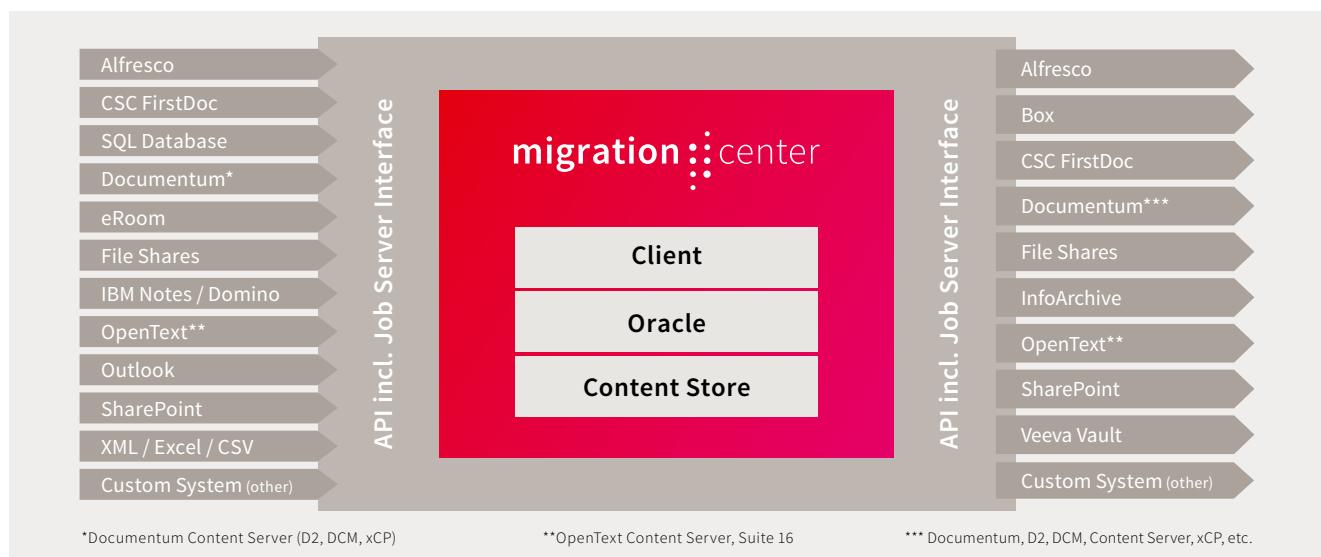
The Right Organizational and Technical Solution

When attempting to complete missing data elements, it is necessary to create transformation tables and correction



For the support of life science industry processes, standardized DMS make use of the DIA EDM Reference Model.

rules for the purpose. These rules define how missing data elements are to be derived from existing data sources. Document attributes and access rights are then automatically added during the actual migration. The elaboration of intelligent transformation rules, however, requires the participation of company internal experts who are familiar with the details of the old data structures. The availability of such individuals often represents a bottleneck. If not resolved, it can quickly lead to errors and schedule slippages for the entire project. Especially senior management has a tendency to underestimate this problem. Besides taking into account the particularities of legacy systems, the diverging interests of different departments need to be harmonized. Regular workshops of adequate informational depths help to provide sufficient insight and understanding for all concerned. This should accompany the planning and concept phases and be used to continuously re-examine and verify the chosen solution approaches. The secret of a successful migration, according to fme's migration expert, lies in knowing the right course of action to be taken and in the use of competent migration consultants who are experienced with all the relevant technical and organizational ramifications. They need to be experienced in conducting effective interviews with departmental staff, in the creation of the required rules and be able to make good use of the internal experts for reviewing and verifying first migration results.



Migrating legacy documents and other file system content with the help of thousands of transformation rules does require suitable migration software to manage it.

During the course of the project, many thousands of rules may be created. To keep them manageable, they have to be organized into separate rule sets. The rule-based migration of documents and files requires appropriate software tools, and before applying such transformation rules they of course need to be thoroughly tested and simulated. To this effect a validation concept has to be elaborated in collaboration with representatives of the user departments and then implemented at the process level. The actual technical execution thereafter is simply a question of diligent effort.



After 6 to 10 years of operation of a DMS, the quality issues of its legacy data can no longer be overlooked. Continuing to operate divergent, inconsistent systems for several more years will only cause disadvantages substantially greater than the cost of migrating to a unified, consistent system.

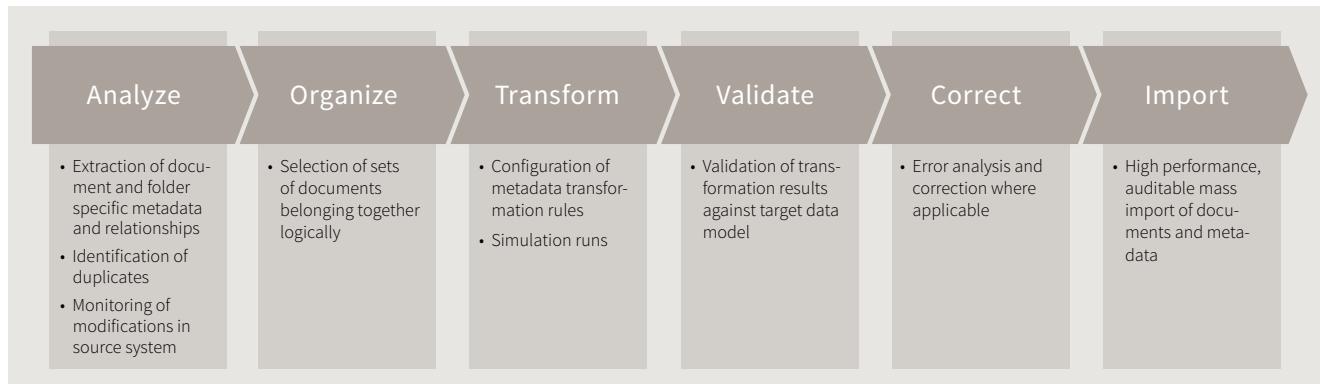
The Right Time for Consolidation

When has the time come for the consolidation of a document landscape? Apart from the collective know-how of staff members, in a pharmaceutical company it is documents that comprise the main means of maintaining enterprise knowledge. Leading corporations of the industry are aware of this. They invest on a regular basis not only in new EDMS technology but also in the re-ordering of their electronic data content. Yet, in view of frequent changes in the industry, many companies still hesitate to commit investments in their documentation systems. Most systems will develop significant quality issues over time, typically after 6 to 10 years at the latest. Clearly, by then earlier investments have been fully amortized. There is no point in waiting any longer, as it will only aggravate the aging problems of existing systems. »Quality problems with legacy data become clearly evident after that length of time. Operating separate, inconsistent systems for much longer will cause long-term disadvantages which are substantially greater than the cost of migrating to a single, consolidated system«, say fme Life Sciences experts. The effort of working with this kind of data on a daily basis tends to rise disproportionately with the number of years. Pushing the use of such a system further out for many more years will also significantly raise the final inevitable migration costs.

Double Digit Savings

During the last five years, the four largest German pharmaceuticals players have completed or are in the final phase of completing such a migration. In some cases the decision was triggered by corporate acquisitions leaving them with up to seven different legacy systems and several millions of documents to be migrated. In other instances, an individual solution had to be replaced. Several years went into the conception and implementation of these migrations, but have proven to be well worth the effort. In the long run such investments always pay off. Especially when considering the increased efficiencies in the user departments, particularly notable in research and development.

Companies willing to change over to a standardized EDMS have a chance to gain real competitive advantages. It places them in the pole position, so to speak, for the challenging years ahead. The joint usage of a central EDMS in clinical research and drug regulatory affairs significantly reduces the administrative overhead during document capture and document search. Not to forget the diminished document control overhead. Experience also shows that double digit reductions in operational and support costs of such a standardized application are not uncommon.



A document management landscape, which typically evolved over many years, will most likely contain basic deficiencies in the integrity and completeness of its data and storage structures.

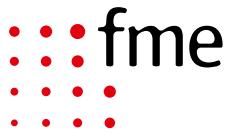
The Significance of Standard Software for the Migration

On a technical level, specialized software, such as fme's migration center, is nowadays being used to assist in the execution of such migration efforts. Activities, which a decade ago still required self-developed scripts, can now be carried out at a fraction of the earlier development costs. Validation of individually programmed scripts is no longer applicable. Transformation rules can now be formulated as part of the configuration and verified during simulation runs.

The automated data analysis of the source content has proven to be of great help. So has the procedural model imposed by the software tool. And automated verification runs have significantly reduced testing efforts. Not to forget the ongoing recording of a complete migration audit trail, an essential element for projects in regulatory environments.



Migration Phases



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10 Best practice rules for migrating to a standardized DMS

1. After 6 to 10 years, all document management systems develop notable quality problems. There is no point in waiting any longer with the implementation of a standardized electronic document management system (EDMS).
2. Industry standards, such as the EDM Reference Model of the »Drug Information Association« (DIA) have considerably evolved in recent years. The concepts contained in these standards are the fruit of practical experiences with such systems and of great help in the conception and changeover to such a DMS.
3. The timely and well thought out re-structuring of source data from legacy systems is a prerequisite for obtaining the full benefit of the new EDMS.
4. Prior to any changeover it is advisable to critically evaluate which legacy issues regarding data and structure quality need to be cleaned up.
5. DMS migration projects are easy to underestimate. It is therefore recommended to take advantage of the advice and support of specialists who are well versed and experienced in comparable projects.
6. The availability and active contribution of the company internal experts is one of the key success factors for a migration project, since they are the only ones intimately familiar with legacy data structures.
7. Prerequisite for a successful migration is knowing which method is best suited for the case in question and how to establish an effective migration team. It should be composed of committed internal members backed by external migration consultants who are well experienced in all organizational and technical ramifications.
8. During the course of such a project, extensive rule sets will be created, designed to assure the correct transformation and loading of documents into the new system. Some may contain thousands of rules. To keep all this manageable requires considerable migration know-how.
9. The secure and efficient migration of documents and other file system content does require a suitable software tool, which assures documents to be migrated accurately and under observance of all relevant validation requirements.
10. Essential elements for a solid and reliable validation are robust logging, data validation prior to import, content integrity evaluation, error recognition, error logging and the complete auditability of the migration.