

## Basic Principles of a DMS



*by Markus Roemer*

Document management systems are basically equipped with a sort of functional workflow engine that enables processes to be collaboratively defined, controlled and monitored. In the simplest case this workflow is used on the status levels of creating, examining and releasing specification documents.

- development of the document up to completion
- passing document on for examination – document is locked
- examination of the document:
  - accepted: forward to Release
  - rejected: return to author
- release of the document:
  - accepted: document released
  - rejected: return to author and/or reviewer

The “document” data object passes through different states that are altered on a cyclical or iterative basis following automatic or manual decisions.

Possible statuses for the document in this example could be:

- processing/development in progress
- currently under review
- review failed
- review successful – forward to release / approval
- currently in release cycle
- approval rejected – back to author
- approval rejected – back to reviewer
- document released/approved

These individual status conditions are typically given version numbers and can have additional status information associated with them, for example if corresponding target dates are set for a cycle.

Since ideally the system is intended to manage not only documented procedures (SOPs), but also records available as templates and forms, this "workflow engine" is sometimes offered in a configurable form for the documentation processes. In this case, the complexity increases significantly if a form (record) is to be provided with different sequences, levels, statuses and states.

There are two basic possibilities for implementing **electronic forms**:

- Handling the forms as a document as in the document process: The different status levels must partly be either paper-based or strictly sequential in the DMS itself. If applicable, the contents as well would no longer be data objects, but rather text content of documents.
  - Example: A new text file is generated from the original, and filled in electronically. This record (filled in text file) is then re-entered into the DMS.
- Creation of separate workflows for the particular processes using an electronic form: The creation or definition of these workflows could be relatively complex or initially time-consuming.
  - Example: The process runs autonomously for the user in a sequence of input masks.

Nevertheless, the second possibility offers greater advantages. Converting a form on a one-to-one basis, meaning transforming a paper-based form into an electronic version is not practicable in terms of usability and applicability (e.g. statistics).

The following example illustrates this:

The documentation for the quality system of "Deviation Management" should also be covered in the DMS. This means that deviation notifications will be created electronically and documentation of the entire deviation processing will also take place in the DMS right up to the concluding report. In the first variant, the deviation documents were created in a word processing program and deposited in the DMS. If it becomes necessary at a later date to access the data of the deviation management, for instance, as part of trending or to create the PQR, the problem is that data in the form of text content of documents is not directly accessible for a statistical evaluation. Therefore the data would have to be converted manually, the same way as if the documentation were paper-based. The situation is different if the data is entered into an input mask and filed as data objects in the system. In this case, for example, in a trending process there could be a search for the number of deviations occurring within a certain period of time, or the deviations relating to a specific product could be called up for a PQR.

This example also clearly shows how important it is to put some thought into the interrelationships with other processes and the desired availability of data for these processes in order to efficiently use document management systems.

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