

Markus Roemer

GMP Series

Successful Implementation of Electronic Document Management Systems



Maas & Peither
GMP PUBLISHING



PDF Download

Excerpt from the GMP Compliance Adviser

Contents

1	Electronic Document Management Systems	
1.1	Introduction	2
1.1.1	Documentation and document management	2
1.1.2	Knowledge and information management	3
1.1.3	Project management	3
1.1.4	Training management	4
1.1.5	DMS Integration in the company	5
1.2	GMP-relevant documentation and processes	5
1.3	System landscape	8
1.3.1	Adjacent systems	9
1.4	Basic principles of a DMS	9
1.5	Example: SOP management	10
1.6	Basic Functions and Key Concepts	13
1.6.1	Defining Master Document	13
1.6.2	Electronic signatures	13
1.6.3	Check in & check out	14
1.6.4	Managing header and footer information	15
1.6.5	Miscellaneous	15
1.7	Validating a DMS	15
	Index	17
	Contributor	18

1 Electronic Document Management Systems

Markus Roemer

Here you will find answers to the following questions:

- What regulatory requirements must be considered when an electronic document management system (DMS) is implemented?
- How is the document management linked to information and knowledge management?
- How can training management or other quality-relevant processes be taken into consideration in a DMS?
- What are the basic principles and functions of the DMS and what technical aspects must be considered?
- What aspects have to be considered when a DMS is implemented? How can project management, validation and system selection be designed?
- What must be considered in determining electronic data and electronic signatures?

1.1 Introduction

This chapter is dedicated to the topic of *electronic document management systems (DMS) in the GMP-regulated environment*. The basic legal and technical demands made on such systems will be introduced here and there will be a description of how such a system can be selected, designed, implemented, validated and used. The abbreviation DMS used here refers to electronic IT solutions for document management. Sometimes other abbreviations such as EDMS or eDMS are also used.

Consideration of the regulatory requirements pursuant to the EU GMP Guide is a matter of great significance and vital importance as the basis for developing and using a document management system. In this context, Chapter 4: Documentation and Annex 11 Computerised Systems, both of which were revised in 2011, are particularly relevant. The US-FDA 21 CFR Part 211 – Subpart J – Records and Reports – is analogously relevant for the American market.

A primary objective of electronic document management systems is to support the processes of the Quality Management System. In addition, such systems can generate measurable parameters for the *Process Performance and Product Quality Monitoring System* introduced in the ICH Guideline Q10. An additional advantage can reside in the support of multilingual usage (user interfaces), and the administration of documents in different languages.

Due to the complexity of the topic and the large number of possible concepts for realization, it is not possible to describe a universally valid approach for planning and implementing a document management system. Therefore, this chapter will be an attempt to explain various aspects and key concepts that must be considered when a validated document management system is to be implemented, and to illustrate the close interrelationships with other systems.

1.1.1 Documentation and document management

It is true that managing documentation in conjunction with the universally valid Good Documentation Practice is important when the term “documentation” is being handled. However, it is also important to study the process landscape and the flow of information from which this documentation is born.

There are several different **process interrelationships** such as those among an operating procedure (SOP) or operating instruction, confirmation of training, the batch record and certificate of analysis (records), relevant process parameters (logbook entries or monitoring reports), an occurring notification of deviation with a request for change and a semi-annual trend analysis for a Quality Review Report.

In Chapter 4: Documentation of the EU GMP Guide, a distinction is made between paper-based and electronic systems; so-called **hybrid systems** are also possible, meaning a mixture of electronic systems and paper printouts (for instance, those bearing a handwritten signature). The planned layout of

a document management system generally has an impact on the implementation strategy and possible project phases.

The objective of converting all documentation within a company to electronic systems is certainly very ambitious, as a full conversion may not be entirely possible or even desirable. However, the advantages, profitability and added value for the company are at their greatest if a broader range of goals is set for implementing the documentation.

The following example illustrates this: If the focus is placed entirely on the process and/or the "Deviation Notification" document and this is to be transferred into an electronic system without considering the inter-relationships with other processes or documents (such as SOP's, requests for changes, master data of material, personnel, systems and equipment), then the advantages or profitability of the system in electronic form will more likely be marginal. Manually converting or transferring data or information is unavoidable in this case, but it entails a high risk of transfer errors.

1.1.2 Knowledge and information management

Document management can be a major component of **knowledge management** in a company. Thus, it constitutes the conscious, consolidated handling of knowledge and/or information even in the face of an uncontrolled glut of information. In today's information society with its many possibilities, knowledge is only worthwhile if its use within a company is entirely focused. These thoughts and facets should also find entrance into the implementation strategy for a document management system. In one example, a system is set up for an automatic e-mail notification to be sent to the Qualified Person or the like when a document has been assessed or read. However, in reality the person in question receives 150 confirmation e-mails every day, with the result that this objective fails completely.

Having to filter out truly critical information that requires action and of course being exposed to the excessive stress caused by the flood of information as well as the state of resignation that results from it are all very negative consequences of this situation. Therefore, *the risk-based filtering of information* and knowledge as well as its early distribution and communication has high priority within a project. Moreover, the practicability of electronic solutions must be included in this treatment, meaning that not all possibilities that are technically feasible would actually be completely advantageous in practice.

This also affects *communication models and paths*, which must be assessed and sustainably interpreted. The flow of information and the knowledge of processes are part of the project content of a document management system. This is not only necessary for the technical layout or configuration of such systems, but also for acceptance by later user groups.

1.1.3 Project management

Analytical evaluation and conceptual orientation generally represent a significant segment of a comprehensive implementation project for a document management system, which perhaps would be better referred to as a strategic program with various subprojects. Evaluating the individual topics or areas at an early date as comprehensively as possible offers advantages and helps prevent "blocking" a functional or technical expansion in later phases or implementation steps.

A planned DMS project realisation can be approached from various different angles, for example, from that of:

- process descriptions (production, auxiliary and quality processes) in planning for the present and the future
- available document management systems (market analysis)
- analysis and compilation of actual documentation created in the company (records-based approach)

The scope of the project and the planning for the selection and deployment of a document management system should be based on known standards for project management. Already existing systems can also be analysed under the following conditions. Due to the **process interrelationships** mentioned above, a step-by-step conversion generally makes sense up until the point at which the defined GMP documentation is available in electronic form.

The transformation of paper-based processes to electronic solutions and/or systems that should also contain an operative growth of value can be challenging to a company and may require a transitional phase. What is involved here is not merely a technical or process-related change, but above all it involves the users (internal and external) who actively or perhaps only indirectly participate in the processes.

Examples of additional **fields of application** that may be directly or indirectly anchored in a DMS project are:

- pharmacovigilance systems/drug safety system (or databases/IT portals)
- electronic filing of approval documents (eCTD: *electronic Common Technical Document* pursuant to ICH M2),
- managing the texts of package leaflets and other subjects (strongly dependent on the field covered by a company)
- managing labels with *Labelling Requirements*
- managing and validating spreadsheet calculation programs (file-based contents can be better controlled and protected in a DMS).
- electronic library (current rules, guidelines, abbreviations, etc.)

The expectations placed on a document management system can vary greatly within the company, depending on how the organisational structures and product and service performance are designed. Therefore, it can make sense to conduct an analysis or appropriate workshops with the aid of surveys or interviews within the company. It is of fundamental importance at the beginning of a project to determine the functional and strategic (tactical) scope of the project in a document management system, in order that this scope may be analysed and defined as precisely as possible. The project targets must be realistic. If necessary, it must be possible to assign the goals to different project phases within a long-term strategy program.

1.1.4 Training management

Document management systems are often believed to reside exclusively within the range of **SOP management**. Here, too, an example shows that there is a strong **process interrelationship** between SOP's and operating instructions on the one hand, and training management on the other. The training management in turn is based on individual job and function descriptions that are shown in an org chart (roles, responsibilities, reporting hierarchies and information paths). They show how the functional and organisational communication levels are set up, which in turn are referenced onto the numerous main and auxiliary processes in a company from which the documents and (process and quality) logs and records actually come into being.

The training and SOP contents are very closely related thematically; another factor for the training management is that the reader can confirm, for instance with an electronic signature, that the SOP has been read; the reader can comment on the content of the SOP or send an e-mail with a question to the author.

Another point in favour of training management is the planning for training in the classic classroom form (instructor and participants). The usual preparation often involves SOP content in a presentation file that is copied for better understanding and then presented. In this field as well an electronic DMS can offer substantial advantages of various sorts.

Sample structure, giving simplified document numbers (without version numbers)		
Level 1	Standard operating procedure (Process description)	Standard Operating Procedure "Change Control" SOP 1234
Level 2	Operating procedure (Concrete processing instruction)	Operating procedure "Change Control" OP 1234 (can also be part of the SOP 1234)
Level 3	Form (Template/worksheet)	Change request (template) Form 1234
Level 4	Form (Filled in form)	Change request (concrete application case) CR 001

Figure 4 Documentation structure with change control as an example

Figure 5 shows an example of the connections between process landscapes, operating procedures and processing instructions and the records resulting from them.

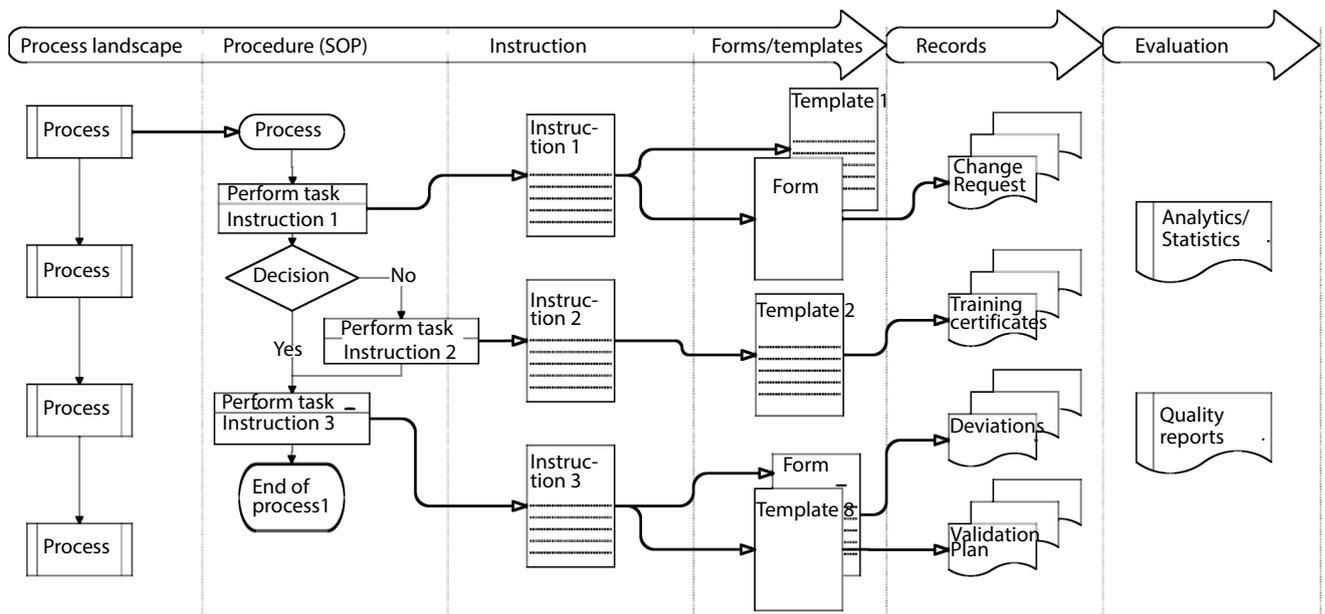


Figure 5 Documents and records

This basic subdivision of documents can also be found in the series of standards **DIN EN ISO 9001:2008** Quality management systems – Requirements. A distinction is made here between the so-called *documents* (document templates) and *records* (documents of proof). The tasks and requirements related to controlling documents and records are shown as a summary in figure 6.

In the analytical approach the relevant processes in which data and/or documents occur as records based on documented specifications must be recorded and evaluated. The result is the desired functional scope of the document management system, and compliance with regulatory requirements is thus ensured.

The viability of the system with the required retention periods for GMP documentation must also be assessed. However, for this subject long-term archiving concepts are either in place or must be developed, taking into account the system hardware and software (data formats, applications) and appropriate methods.

1.6.2 Electronic signatures

Dealing with a document management system will inevitably lead to the topic of **electronic signatures**, which can and should replace handwritten signatures. Starting from Annex 11 of the EU GMP Guide it is possible to discern three stages, which are given in figure 7.

Documentation type and signatures according to Annex 11 of the EU GMP Guide

1. paper-based documentation and handwritten signature
2. electronic documentation and handwritten signature (hybrid form)
3. electronic documentation und electronic signature

Figure 7 Documentation type and signatures

Concerning these three stages, there can be interfaces here, too, between the processes in which the batch record has been handled and released completely electronically, but the batch record refers to a notification of deviation or an analytical lab report belonging to the above-given stage 1 or stage 2. In this case, in practice these documents of stage 1 or 2 are returned to the electronic environment via a document scanner, i.e. they are electronically read in on the basis of a verifiable operating procedure. This method is also applicable if someone receives documentation from external suppliers and wants to make it electronically available. This approach may prove to be inadequate if there is a question about the true master document, which is actually provided on paper in the original and therefore should have been archived. In order to determine the proper procedure for scenarios of this nature a risk-based consideration should be made for each type of documentation.

The **representation** of the electronic signature on the paper is truly a challenge, or it must be more narrowly interpreted. Some implementations show a scan of the handwritten signature of the person or the name printed with a cursive font, or optionally with a reference to a cryptic hash value of the encoding or the like. Any of these solutions, or similar approaches would be very unfavourable and the scanned signature must even be assessed as being critical. In fact, the authenticity of the signature can only be examined in the electronic system itself, where in contrast to a handwritten signature, however, the electronic signature must be assessed as being of very high quality. The unique relationship of the three given types of information (document number, version, document status) actually makes rendering the signature superfluous. Through the system, it must be guaranteed that the "released" status can only be achieved and thus a printout can only be made if the signatures have been properly executed.

1.6.3 Check in & check out

The so-called **check in & check out** of documents and/or files is also typically one of the basic functions of document management systems that need to be explained. This function can also be related to the management of version-controlled templates.

The creation of a new SOP as a document is given here is an example:

- A version-controlled SOP template (blank) is readied in the DMS. It is selected and used for creating the SOP. The DMS can automatically invoke the metadata (title, scope, etc.) or create them itself (document number, version, etc.).
- The DMS creates a new SOP document from this template.
- The operator checks out the SOP for editing. During this time, the SOP is locked for other users and a local copy is made available to the operator for editing.
- The operator now creates the SOP. After the contents have been completed, the SOP is checked in again. The examination and release cycle can begin.
- As soon as the examination and release cycle has been successfully completed, the document is distributed and becomes available.

Index

D

document management system 2

- adjacent systems 9
- application 4
- basic principles 9
- check in & check out 14
- electronic form 10
- electronic signature 13
- external access 15
- front-end study 8
- GMP-relevant documentation 5
- host variant 8
- hybrid systems 2
- implementation strategy 8
- integration 5
- knowledge management 3
- licensing model 8
- master document 13
- metadata 11
- presentation of information 11
- process interrelationships 2
- project management 3
- requirements 5
- SOP management 4
- SOP management, example 10
- system landscape 8
- training management 4
- validation 15
- workflow engine 9

documentation

- DIN EN ISO 9001 7

E

electronic document

- copy 13
- master document 13
- paper printout 12

electronic form 10

electronic signature

- document management system 13
- representation 14

K

knowledge management 3

M

metadata

- definition 11

Contributor

Markus Roemer
markus.roemer@comes-services.com

Consultant
comes compliance services, Ravensburg

Markus Roemer works as an independent consultant for comes compliance services in Ravensburg, Germany. He deals with a wide variety of topics, including validation of computerised systems, auditing, quality management, project management and compliance management. He has acted since 2008 as ISPE Ambassador for the Germany/Austria/Switzerland Affiliate.



After completing his studies in engineering, Mr. Roemer began his career as a team member in computer validation at Vetter Pharma-Fertigung in Ravensburg. After changing to the MES system provider Propack Data GmbH in Karlsruhe, he served there as Quality Manager for EBR projects.

In 2003, Mr. Roemer moved on to become Senior Validation Consultant for Invensys Validation Technologies in Montreal, Canada. He also accompanied global IT and validation projects abroad, following which he applied his global experience with customers and suppliers in his capacity as Head of Compliance Services and Quality Management at Systec & Services.