Why Your Document Control System is Obsolete

By Kevin Bogert

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For many years companies have implemented document control systems that had the ability to manage the version of the document throughout their life cycle. As documents were approved the process would notify users that a new version is available and obsolete copies should be discarded. Systems limited access to the older version of document to a select few individuals in the document control department. Employees were notified that they required training on the new version. Life was good. That changed with the newer version of ISO and the issuance of the FDA's data integrity guidance document.

Electronic Document Control Definition

Most companies believe that a document control system includes functionality of a document management system with version control, audit trail, and electronic signature. It automatically manages and retains all old historic versions together with information on who changed it and why, who authorized it and who was advised of the change. It will also include periodic recall for review of selected documents without operator intervention.

The problem with this definition is that it limits the scope of a document control system to only managing the approval and control of an electronic document. The FDA considers the document throughout its lifecycle as requiring a certain level of control. This lifecycle includes approved and unapproved controlled documents as they move from creation to retirement, including their daily usage. The system should track the daily usage of the document from printing, including the number printed, until submitted back to Document Control as required to comply with data integrity requirements.

ISO Standard Requirements

The current version of the ISO standards better defined what a document control system must have to be compliant with a standard. The difference between a document control system and a document management system are shown in the table 1. The difference is how the documents are controlled external to the process that manages the approval and control of the electronic version. Document management is concerned with managing the electronic version of the document, from time of creation until retirement. Document control handles all the process of document management while controlling the external (hard copy) document.

ISO Standard	Document Management	Document Control
Review and approve documents	X	X
Provide the correct version of	X	X
Protect the identity and legibility	X	X
Identify and control the distribu-		X
Prevent the unintended or inad-		X
Preserve obsolete documents for	X	X

Table 1: ISO requirements for document control.

For those companies that are regulated by the FDA, the process is even more complex. With the issuance of the FDA's guidance document on data integrity, the definition of document control was expanded and better defined. The agency refers to data integrity as "the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).[1]" Data integrity does not end when the data is captured, either on a paper form or a computer system. It is critical throughout the cGMP data life cycle until final disposition of data after the record's retention period ends.

Both static and dynamic data are important to any cGMP organization. The FDA uses 'static' to indicate a "fixed-data record such as a paper record or an electronic image, and *dynamic* means that the record format allows interaction between the user and the record content.[2]" A document control department works primarily with static data in the form of electronic and printed documents and forms.

The primary areas of focus of the data integrity guidance are on record retention, audit trails, control of the original documents, and any blank forms or copies that were not used. The organization must ensure that additional blank forms are not printed beyond what is required to perform the task. Controls should be put in place to prevent a user from making copies of forms without a mechanism to identify the copies from the original.

Managing External Documents

There is no standard way of handling the external documents. The most common practice is to delegate the control to the user of the external document. When the document is no longer required or becomes obsolete, the user is responsible to ensure that the document is properly controlled. When forms are printed for use, the trust that the original printed form is returned as the original, not a copy. An alternative and more complex way to control the external document is using logs and control of who can print a document. Whenever a user requests a hard copy a serial number is applied to the document and tracked until it is returned. This is a manual process that requires many resources and time to properly control. Organizations are not equipped to handle such a manual process.

Most automated systems on the market can tack who printed the document. Only a limited number track the document once it is printed. Of those that do track the documents, they lack the regulatory requirement of records management, management of blank documents, ability to verify ALCOA requirements, and the inability to identify copies from the original document.

Document Control Challenge

Automated system cannot solve all your process problems no matter how the vendor configures or customizes the document control component. Individuals need to be responsible for their actions and follow documented procedures for controlling hard copy documents.

No matter what system you have implemented, you must have a policy in place to manage the external documents. It must address the regulatory requirements and good documentation practices. Employees should be trained on their regulatory responsibility of using uncontrolled documents, controlled documents, and how to handle unused or partially completed documents.

Automating the process to eliminate the forms may be your best option. Work with your vendor to see how they can help you with this process. It will help prevent your organization from having a paper process problem and provide an electronic means to capture and analyze the data real time.

About the Author

Kevin Bogert is currently a Managing Member of Azimuth Compliance Consulting, LLC.
He has more than 35 years of business experience, 30 of them in the life science industry, where he has been involved in global implementations of quality and regulatory systems. His background includes statistics, quality and regulatory systems, computer and process validation, and automation of manufacturing processes. You can reach Kevin by e-mail at kbogert@azimuthcc.com or by phone at (215) 990-9123.

[1]U.S. Food and Drug Administration. Office of Pharmaceutical Quality and the Office of Compliance in the Center for Drug Evaluation and Research. Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry, December 2018.

[2]Ibid.