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Managing cGMP Documents Under a Document Management System (DMS)

Introduction

Most organizations can greatly benefit from utilizing a system to manage documents. In current Good Manufacturing Practice (cGMP) facilities, a validated Document Management System (DMS) is an essential tool to help a facility maintain a state of compliance. A DMS platform supports the quality management processes that allow for electronic document storage and retrieval, workflow management, and effective safeguarding against unauthorized revisions, deletion, or alteration of records. This also serves to minimize potential compliance and audit problems.

Per ISO 19475, a DMS must meet the "requirements necessary to maintain the authenticity, integrity and readability of documents managed by an electronic document management system." A DMS uses the following features to manage documents in an effective manner.

Access Permissions

A DMS should use access permissions that assign specific user roles to ensure information and document security. Some of the most common roles in a DMS are creator/revisor, reviewer, document control, training coordinator, and approver. This is especially important for cGMP facilities, where any alteration of data could result in an adverse regulatory finding for failure to maintain a DMS that conforms with GMP regulations. A DMS is also often used to restrict document access to only those needed for the performance of an individual's assigned job duties, which limits the potential for exposure of intellectual property, Patient's Personally Identifiable Information (PII), and other sensitive data. A DMS should also be configured to retrieve documents in a manner which clearly identifies versions which are effective/released, marking current documents in a manner which clearly distinguishes them from earlier versions to minimize the likelihood of mix-up.

Workflows

A workflow is a series of orderly steps that a document must follow before it can become effective and/or released, depending on the type of document. Workflows also prescribe how documents are changed. These steps may include creation, collaboration, training, and approval. A short workflow can be used for documents that require minor changes; however, documents such as a new Standard Operating Procedure (SOP) may require a more comprehensive workflow before being released for a first-time use. This is because a new procedure would require staff training as well as additional layers of approval. Other types of documents, including batch records, may only require a review-and-release workflow.

Collaboration

Throughout the control process, collaborators are assigned to work together on documents that are being developed or revised. The system keeps a complete revision history of comments, which includes revision dates and the identities of editing parties. This allows for transparency, efficiency, and adequate collaboration, as all comments will be visible to collaborators. Throughout the collaboration process, only the most current version of a document is available for general user access.

Revision Control

Document revision control plays a vital role in adhering to GMPs. The system automatically keeps track of document expiration dates and sends notifications to advise document owners when revisions are necessary. The system also supports the tracking of all controlled copies that are in effect so that, when a revision is made to a document, the users will know where to update these copies. If a document is needed for a short period of time, an uncontrolled copy may be retrieved with an expiration date automatically printed on the document to ensure its disposal after use. A DMS can manage the archiving and deletion of outdated documents.

Electronic Signatures

Critical documents may have an approval phase in the workflow which requires final review and approval from authorized parties. An electronic signature is created using personal credentials and used to sign and date documents to indicate review and approval. After all the required e-signatures are complete, the document becomes effective and is ready for general use. Once the document is approved, the system can automatically provide a signature manifest, if required.

Conclusion

Document management is often overlooked, which can lead to issues during audits and inspections. Good document management is beneficial for all facilities and especially critical for maintaining cGMP facility compliance. A DMS provides an effective way to reduce the risks of incomplete documentation, incorrect forms, forms without signatures, and inconsistent audit trails. It also ensures that documents are suitable and readily available for decision making and facility operation purposes.

References

International Standards Organization. (2021). *Document management – Minimum requirements for the storage of documents.* (ISO 19745-2021). ISO. https://www.iso.org/home.html