

Management of Master GMP Document

Documents held electronically may be printed for use in the local work environment, for example, SOPs. The printed document should indicate a “valid date” or display other suitable warning, where this is considered necessary. Documents held electronically may also be required to be displayed or provided to third parties.

5.7 Distribution of Documents and Retrieval/Disposal of Superseded Documents

Concurrent with the issue of a revised document, the master of the superseded version must be made unavailable for use and formally archived.

Procedures must be defined to ensure that superseded copies of the revised master GMP document, which are available in the work place, are retrieved and/or destroyed.

Full accountability and traceability of documents should be considered and procedures established to verify this activity.

For paper copies, the authorized person(s) or delegate should circulate copies to relevant staff.

For a document that is available electronically, the authorized person(s) or delegate should inform relevant staff that the new or revised document is available for use. Alternatively, the person may be authorized to make the copy available for use. Confirmation of receipt of an electronic document may be required to indicate receipt and/or that training has been completed.

Training may be required for new or revised documents prior to their use and this should be documented, where applicable.

Superseded master GMP documents may need to be used for reference purposes and/or retrace previous GMP activities. In these cases, procedures for their use/retrieval must be implemented to prevent unauthorized use for current activities.

5.8 Unofficial Copies

Unofficial copies of GMP master documents may only be used for review, training or audit purposes. They must be marked as such to avoid unauthorized use.

5.9 Archiving of Master GMP Documents

Superseded master GMP documents must be archived in secure, access restricted and, where possible, purpose-built archives. Retention periods for master GMP documents must be defined to meet specific codes of practice and business needs.