



## Veeva eTMF: Certified Copy Guideline

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### 1. PURPOSE

The purpose of this guideline is to describe the creation of certified copies of paper and other non-electronic media records for the purpose of retention in electronic format in an electronic repository.

### 2. SCOPE

This policy applies to GxP controlled documents supporting legal, financial, nonclinical, clinical, manufacturing, pharmacovigilance operations, and regulatory submissions.

### 3. DEFINITIONS

**Certified Copy** – A copy of an original or source record that has been verified as an exact copy of the original and is intended to permanently replace the original.

**Controlled Documents** – Documents which require approval and retention.

**Essential Documents** – Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

**GxP** – Good “x” Practice. “x” stands for the various fields.



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## 4. RESPONSIBILITIES

Role	Responsibilities
Document Owner	Certifies the copy from the original
Guideline Owner	Owns this guideline and assures it meets global regulatory expectations

## 5. POLICY

### 5.1. Certification Process Requirements

- 5.1.1. A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

### 5.2. Certified Copy Creation Within a Validated Electronic Repository

- 5.2.1. Document Owner is to scan/image the original, source record and upload the draft electronic document to the appropriate document repository in accordance with any/all applicable requirements belonging to said repository.

- 5.2.2. Document Owner is to begin the Certified Copy Review workflow.

- 5.2.2.1. Document Owner is to review the original, source record and ensure that the draft electronic document appears exactly as the original, source document. Verification must include confirmation that the draft electronic document is attributable, legible, contemporaneous, original, accurate, and complete including all document content, headers, footers, and pagination.

- 5.2.3. Upon review, Document Owner is to provide a workflow verdict to certify or reject the draft electronic document in addition to any applicable comments.

- 5.2.3.1. If the draft electronic document does not meet the verification requirements to be a certified copy, Document Owner is responsible for the creation of a new version of the draft electronic document. This process will continue until a draft electronic document is verified as a certified copy against the original, source document.

- 5.2.3.2. If content is incomplete or missing in the original, source document (i.e. all signatures, noted attachments), Document Owner is to provide a description of the erroneous or incomplete source record as a comment with the workflow verdict.

- 5.2.4. Upon certification, Document Owner is responsible for ensuring that evidence of the certification process is maintained as document metadata.

### 5.3. Retention and Disposition

- 5.3.1. Following verification, all certified copies will be maintained for a period of time identified by study-specific protocol, policy, or contract, institutional or regulatory



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regulation, and/or VCU's Record Retention Schedule for whichever period is longest.

5.3.2. Following verification, all original, source documents may be disposed of in line with:

5.3.2.1. Record Retention Policy for Veeva

5.3.2.2. [Records Management Policy](#)

5.3.2.3. [Research Data Ownership, Retention, Access, and Security Policy](#).

## 6. REFERENCES

- 21 CFR Part 11
- ICH-GCP E6(R2)
- Record Retention Policy for Veeva
- Records Management Policy
- Research Data Ownership, Retention, Access, and Security Policy

## CONTACT

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## DOCUMENT HISTORY

Version	Effective Date	Brief Description of Change
1.0	01/05/2023	Initial Version