ARCHIVING
KEEPING YOUR RESEARCH SECURE AND COMPLIANT
Introduction to Archiving

Because research records and materials are vital to drug development programs, it is fundamental that they be properly stored in a GLP-compliant archive facility that enables reliable and rapid retrieval.
Why is archiving needed?

In addition to meeting regulatory requirements for GLP compliance, archiving ensures that your data remains in a safe, secure location that can be retrieved when you need it most.

Regulatory compliance

The FDA, EPA, and OECD have specific GLP guidelines requiring the archival of study materials¹

¹21 CFR §58.51, 40 CFR §160.51, 40 CFR §792.51, ENV/MC/CHEM(98)17, 3.4

Preservation

Eliminates the risk of accidental or malicious destruction, protecting business interests and intellectual property and can be recalled for study reconstruction or legal defense.
What needs to be archived?

Basically, whatever is needed to reconstruct a study, including both paper and electronic records, needs to be archived:

- Raw data (first capture of original data)
- Documentation
- Protocols
- Specimens
- Samples
- Interim reports
- Final reports
- Facility records

These can take multiple forms, including electronic media, paper records/reports, pathology samples, slides, and medical records.
Who is responsible, and when?

The Study Director ensures that...

**FDA and EPA**

“all raw data, documentation, protocols, specimens, and final reports are transferred to the archives **during or at the close of the study**”

FDA – 21 CFR §58.33(f)
EPA – 40 CFR §160.33(f) and 40 CFR §792.33(f)

**OECD**

“**after completion** (including termination) of the study, the study plan, the final report, raw data and supporting material are archived”

ENV/MC/CHEM(98)17, 1.2(i)
How long do records need to be archived?

According to the FDA\(^2\), records must be retained:

- At least 2 years following application for a research or marketing permit were submitted
- At least 5 years following the results of the nonclinical laboratory study are submitted
- In all other situations, at least 2 years from the date of study completion, termination, or discontinuation

\(^2\text{(21 CFR §58.195)}\)
Where should records be archived?

Archive facilities should be secure, limiting outside access\(^3\) and constructed so that archived materials are protected from “untimely deterioration.”\(^4\) An ideal facility provides:

- Separate storage areas controlled by dedicated, redundant HVAC
- Temperature-controlled storage units, including low and ultra-low freezers
- Fire barriers between vaults
- Limited and controlled keycard access
- Off-site alarm monitoring in addition to audible alarms
- Indexing
- GLP archivist control

\(^{2}\)21 CFR §58.195
\(^{3}\)ENV/MC/CHEM(98)17, 3.4
Common Regulatory Findings

Time and again, auditors request study materials and find recurring issues that could have been prevented by proper archiving:

- No centralized storage area allowing for the orderly storage and expedient retrieval of records, data, and specimens. (21 CFR §58.190b/e)
- No “individual responsible for archiving all required records, raw data, and specimens.” (21 CFR §58.51 and 21 CFR §58.190c)
- Records requested by the auditor could not be retrieved. (21 CFR §58.190b)
- Materials were not archived during or at the close of the study. (21 CFR §58.33f and 21 CFR §58.190a/b)
- Unauthorized access to the archive. (21 CFR §58.190d)
Vendor Selection Checklist

Who can you trust with your data? Consider the following when selecting an archiving provider:

**Staff**
Is the archiving staff trained, and can they comply with GLP regulations?

**Organization**
Will your records be indexed in a way that facilitates retrieval when you need them?

**Protection**
How are records protected against unauthorized access/alteration?

**Facility**
Can it withstand conditions that could damage physical and/or electronic records?

**Permits**
Do they have the clearance necessary to transport, import, and export research materials immediately?