

ALCOA+ Checklist

Arkivum adheres to ALCOA principles and GxP guidelines providing secure access and ability to re-use data, all whilst keeping the data complete, consistent, accurate and in its original form.



Attributable

Who acquired the data or performed an action and when?

- ✓ Rapid search and enhanced metadata to provide context and further understanding
- ✓ Immediate access to your long-term data, complete with full audit trail and chain of custody report

Legible

Can you read the data and any entries?

- ✓ Adheres to OAIS standards for preservation
- ✓ Ongoing file normalisation to ensure your data is always readable

Contemporaneous

Documented at the time of the activity.

- ✓ Original and enhanced metadata to provide context
- ✓ Full audit trail and chain of custody report

Original

A written printout or observation or a certified copy thereof.

- ✓ Original and enhanced metadata to provide context
- ✓ Original copy of the data is kept as well as a normalised copy

Accurate

No errors or editing without documented amendments.

- ✓ Documents and files are immutable in the system
- ✓ eSignatures can be implemented to document approvals

Complete

All data including any repeat or reanalysis performed on the sample.

- ✓ 100% data integrity guaranteed
- ✓ Full audit trail and chain of custody report
- ✓ Enhanced metadata to provide context

Consistent

All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence.

- ✓ Original and enhanced metadata to provide context
- ✓ Full audit trail and chain of custody report

Enduring

Not recorded on the back of envelopes, cigarette packets, sticky notes, or the sleeves of a coat but in notebooks or electronic media in the data systems of instruments.

- ✓ Our modern and modular technology stack supports emerging use cases and multiple data types from different sources including CTMS, ELN, EDC, eTMF, GxP data sources

Available

Can be accessed for review and audit or inspection over the lifetime of the record.

- ✓ Single source of truth brings silos of data together
- ✓ Our built-in exit strategy means there is no data lock-in
- ✓ You own the data at all times and hold the encryption key