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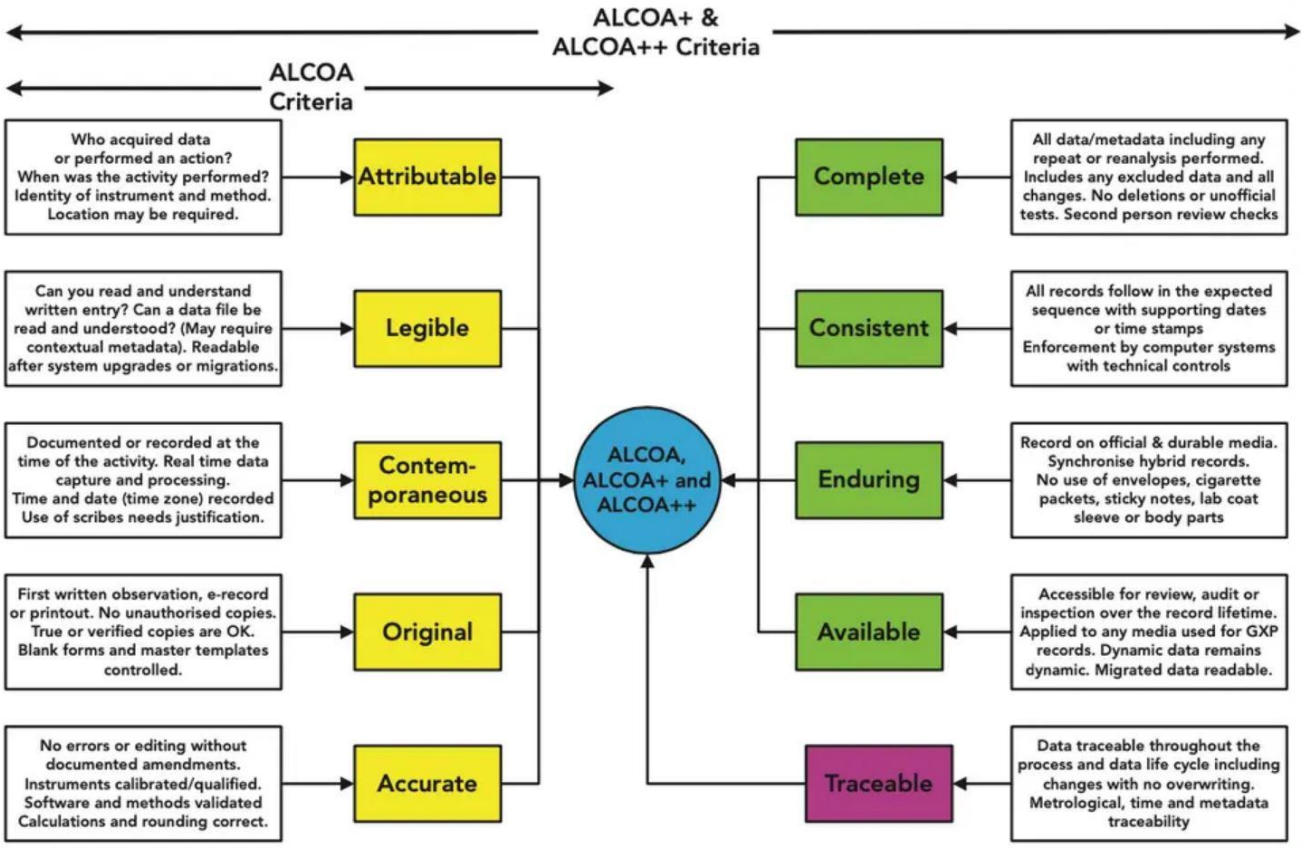
Data Integrity - The meaning of ALCOA++



Since data integrity has become a "hot topic" in the pharmaceutical industry, ALCOA+ is cited as the ultimate reference. Still, the meaning and consequences of this acronym should be clearly understood to avoid mistakes and abbreviations.

Keep in mind that the ALCOA+ criteria, like the general data integrity requirements, cover paper-based, electronic and hybrid records equally.

The following interpretation should be taken into account:

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Attributable

Who recorded the data, when and how, or carried out the action?
Where - which system, which device, which sensor, etc. - does the data come from?

Legible and intelligible

Can you read and understand the data?

- Legible handwritten records
- Understandable records, especially (but not limited) to audit trail entries.

Contemporaneous

Are data, observations and activities recorded in a timely manner?

For paper records:

- The observation must be logged at the time of observation.
- The activity must be logged at the time of execution.
- It is particularly difficult and ultimately impossible to control this requirement during the second person review because "paper is patient"!

In the case of electronic records generated by a computer system, the system architecture must be carefully checked to ensure that the data is actually time-stamped (including the time zone, if applicable) at the time the data was recorded or created, and not afterwards they stood in a queue for an indefinite amount of time.

Original

This requirement is particularly versatile because it covers very different contexts.
For paper records:

- The data must be recorded directly on a controlled blank paper form.
- It must be possible to distinguish accurately between the original and a copy.
- If a paper or electronic copy is required, a formal procedure must be followed to produce that copy. This requirement is particularly important where paper records are to be scanned and/or transmitted for storage or as a PDF document. This procedure must ensure that the copy has been formally verified; i.e. This means that the copy is a genuine copy or a certified copy.

For copied electronic data: all essential metadata and the original record format [WHO].

- Care must be taken to ensure that the GxP relevant electronic data is accurately and completely identified and that it is the subject of the copying process.
- Especially in the case of electronic data records, this requirement comes very close to the "completeness of the data".

Accurate

In connection with data integrity, it is necessary to fully translate the English term "accurate", since it means both the correctness and the accuracy of the data.
Only accurate (e.g. calibrated) and controlled data sources may be used. No error correction or editing without documented changes, i. H.:

- AOn paper: application of good documentation practice in case of correction.
- If electronic data needs to be changed, this must be documented by audit trail entries. Access to the electronic data must be controlled.

For paper records, the process for collecting the data must be clearly defined and the data recorded accordingly, including the expected data format (e.g. date) and precision (e.g. number of decimal places). The identification of the data source must be clearly documented.
For data collected from a computer system, the checks at initial qualification and later at changes or repairs must ensure that the data comes from the correct source and has been correctly processed (e.g. linearization, normalization, conversion, etc.).

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Complete

All data is present (no omission, no deletion), including source data, metadata, etc.

- Selective reporting corresponds to a falsification of the data.

If electronic data is to be printed out on paper or as a PDF, it must be ensured that the printout contains the complete data with the required accuracy.

- This requirement affects both the initial qualification activities and the second person review activities during the operational phase (see also "Accurate and Correct Data").

Consistent

The records are in the expected (chronological) order and are time-stamped (including the date).

- The time stamps are consistent and refer to a common reference (time server).
- If data must be recorded manually, the operator must read and record the time from a qualified time source.

Enduring

Data must not be recorded on the back of envelopes, sticky notes, etc., but directly on the controlled media provided for this purpose (see also "Original data").

- The use of thermal paper for device printers should be avoided.

Electronic data must be stored on controlled and robust electronic media; i.e. H.:

- CD-ROM, DVD-ROM, uncontrolled USB storage media cannot be considered GxP compliant and robust.

Available

Is it possible to access the data throughout its required retention period for reviews, audits or inspections? Even after the end of the contract in the case of outsourced activities?
The data must be recorded and kept on controlled paper forms or on controlled electronic media.

A notice:
The availability of GxP-relevant data (possibly critical to patient safety) stored in a cloud could cause significant problems in the event of a short- or long-term failure of the cloud provider.
The ALCOA+ criteria must always be viewed in context. Furthermore, a "single term" can encompass a complex reality and multifaceted interpretation that must be considered in its fullest extent.
It must not be forgotten that data integrity requirements are as old as GMP/GxP requirements; consequently, GxP compliance cannot be achieved without ensuring and enforcing data integrity.
Adequate implementation of the ALCOA+ criteria is a prerequisite for being able to rely on the data generated, processed and reported.

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Published: 05.31.2021
https://www.gmp-compliance.org/gmp-news/alcoa-what-does-it-mean

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Traceable

- Daten sollten während deren gesamten Lebenszyklus rückverfolgbar sein.
  Eventuelle Änderungen an den Daten, am Kontext oder an den Metadaten sollten nachvollziehbar sein, den ursprünglichen Informationsgehalt nicht verschleiern/verändern und bei Bedarf erläutert werden. Änderungen sollten als Teil der Metadaten dokumentiert werden (z. B. Audit Trail)(15).
- Zeitstempel, die auf eine vertrauenswürdige Zeitquelle zurückführbar sind (siehe „Accurate - Genau und korrekt“ und „Consistent - Konsistent“)
- Zeitgleiche und konsistente Aktivitäten, die auf vertrauenswürdigen Zeitstempeln zurückgeführt werden
- Metrologische Standards und verwendete Geräte, die auf internationale Standards rückführbar sind (siehe „Accurate - Genau und korrekt“)
- Analytische Referenzstandards und andere Kalibrierungsstandards, die von einer vertrauenswürdigen Quelle stammen (siehe „Accurate - Genau und korrekt“)
- Fähigkeit, eine Aktivität und die der Arbeit zugeordnete Person bis zu ihren Schulungsunterlagen zurückzuverfolgen.

Publiziert: April 1, 2022
R.D. McDowall
Spectroscopy, April 2022, Volume 37, Issue 4
https://doi.org/10.56530/spectroscopy.up8185n1

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20.05.2023
ODM/U.Kundert