Key Aspects of Data Integrity: ALCOA+

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1. Origin of ALCOA
2. Definition of Records and Data Types (physical and electronical)
3. ALCOA+ Basis to support Data Integrity
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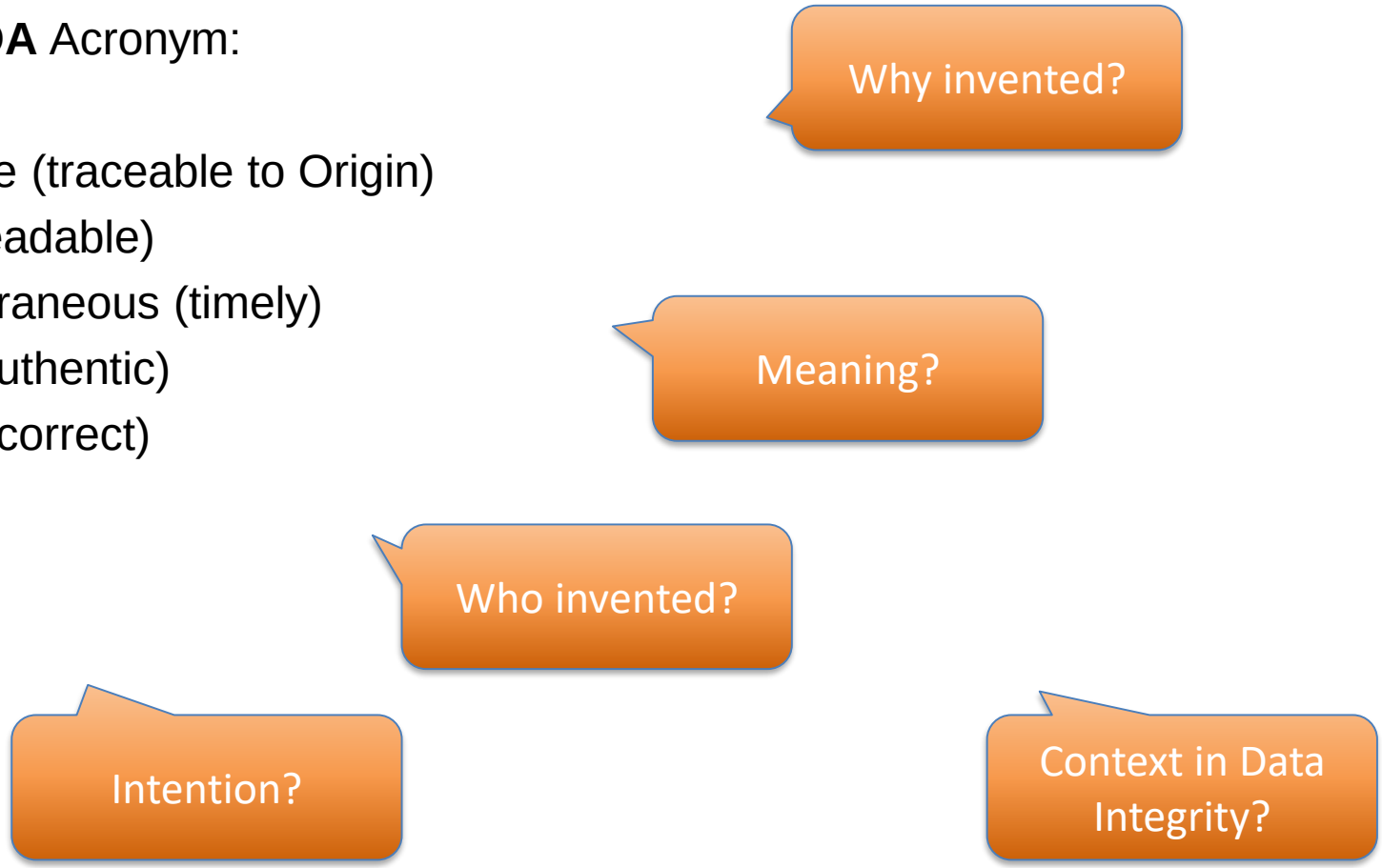
ALCOA Acronym

The **ALCOA** Acronym:

Attributable (traceable to Origin)
Legible (readable)
Contemporaneous (timely)
Original (authentic)
Accurate (correct)



Origin of the ALCOA Acronym

"… The **ALCOA acronym** was first coined by me (remark: **Stan W. Woollen**) while serving in FDA's Office of Enforcement back in the **early 1990's**. …

… One of the techniques I used was to come up with acronyms that I could easily remember to help me organize my presentations. This is where the acronym ALCOA came in. Admittedly, this acronym was easy for me to remember, because Alcoa Inc. was a commonly known company name. On the other hand, the ALCOA acronym was not known in the context of data quality.

… However, in preparing slides for one presentation, I **ran out of space on a slide, and just inserted the acronym ALCOA** as a bullet-point reminder to myself. I don't remember exactly when, or in which presentation I first used the actual ALCOA acronym. However, I do remember the consternation of at least one member of the audience, who in trying to later decipher the "government jargon" in my slide, asked what ALCOA stood for. … Consequently, the acronym eventually became known in the QA community to such an extent; I could use the ALCOA acronym alone on my slides as a concise and lazy way to discuss the elements of data quality." (1)

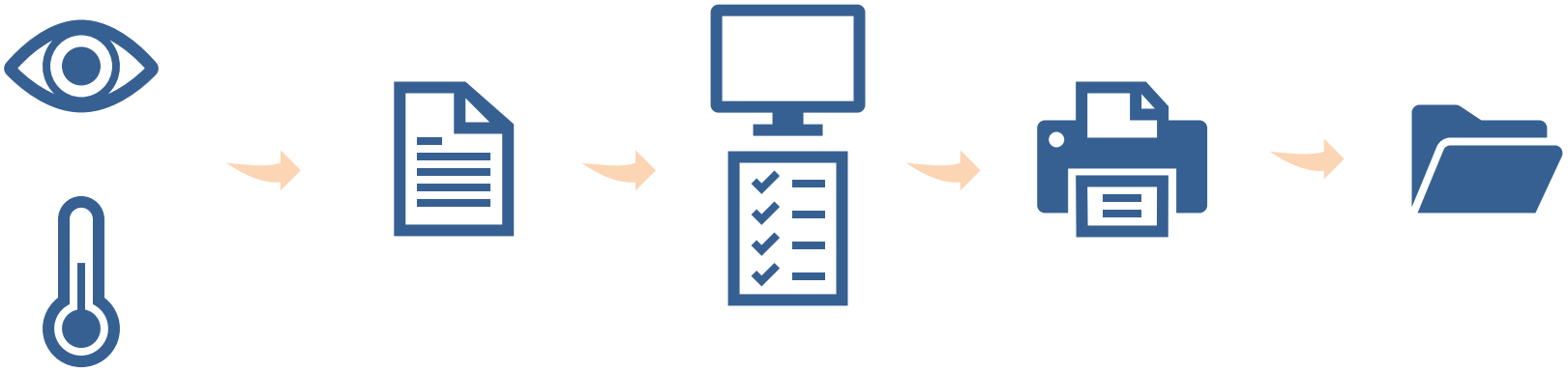
Origin of ALCOA in GMP Regulations

Again Stan E. Woollen:

"… Although the cGMPs articulate a number of the expectations for data quality, the **GLP regulations**, in my opinion, **are the first** FDA regulations which bring the ALCOA elements of data quality together in a comprehensive fashion. … particularly 21 CFR 58.130(e) which articulates virtually all the elements of ALCOA." (1)

First of all it's all about Information and its Documentation (=Data):

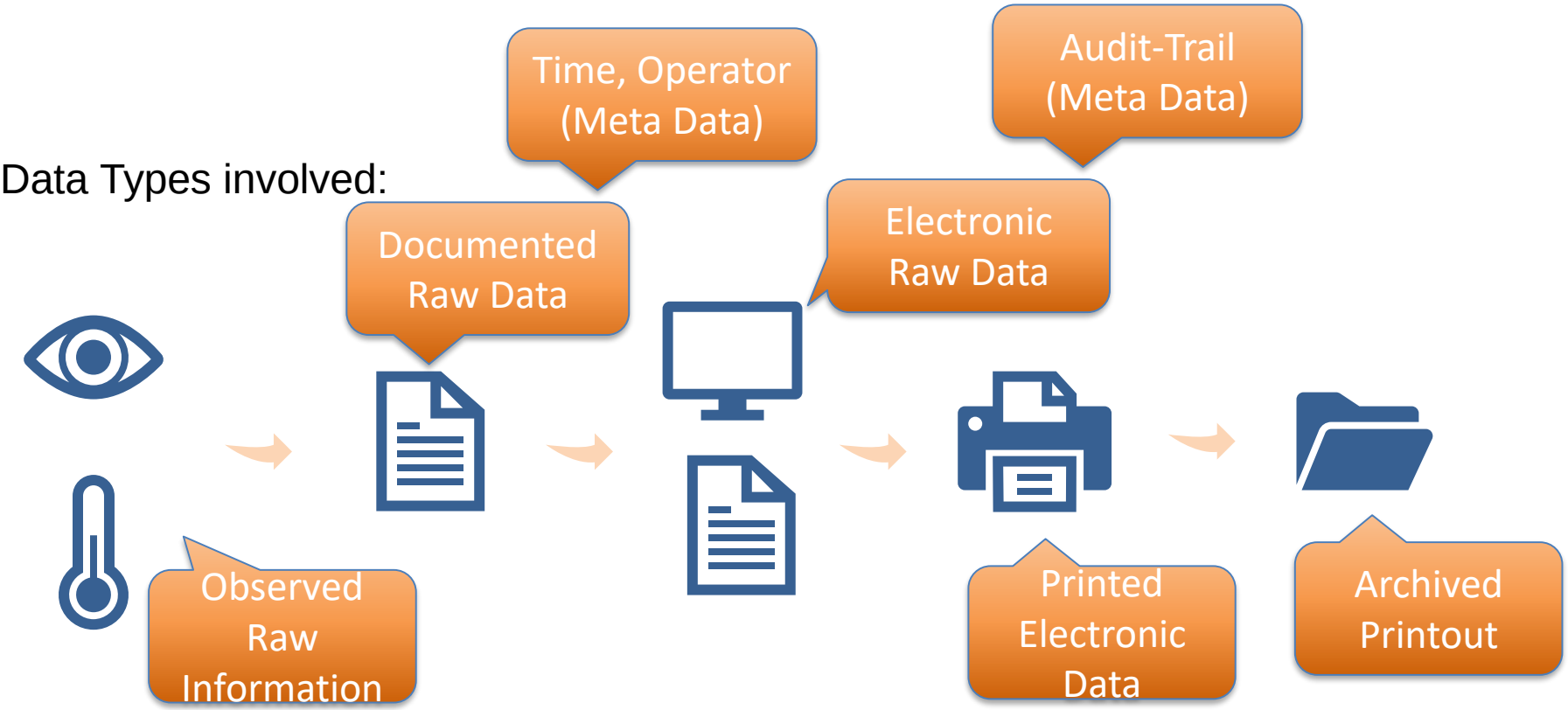
Data Flow from Origin to Records to Intended Use:



Observation of Temperature
=> Documentation
=> Batch Record
=> Printout
=> Filing

Data Types

Data Types involved:



Observation of Temperature

=> Documentation

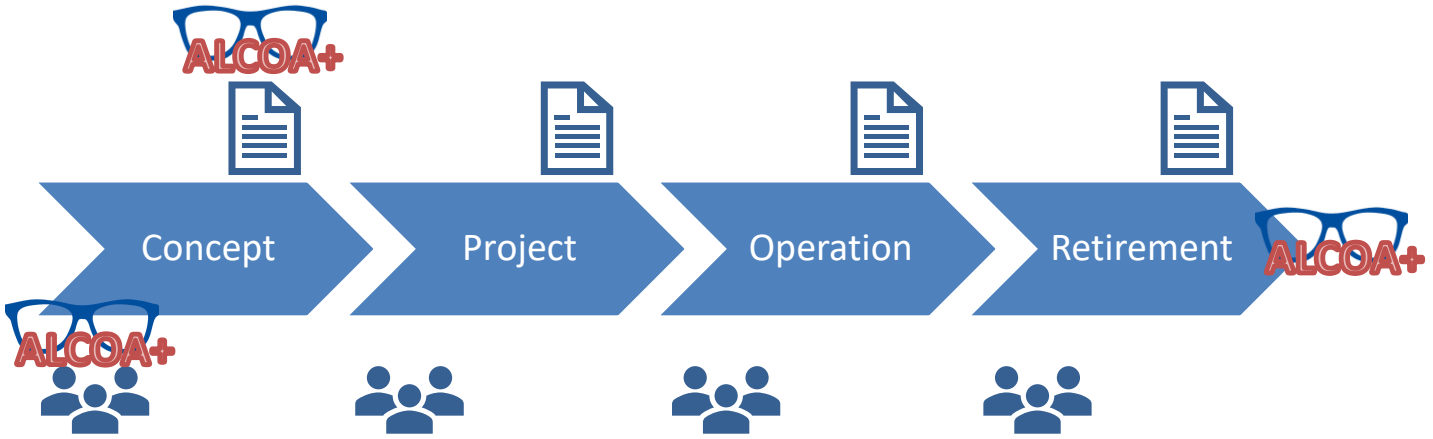
=> Batch Record

=> Printout => Filing

System Lifecycle:

Requirements, Functions, Decisions, Documents, …

View through “ALCOA-glasses”:



Data Integrity:

- Always view through „ALCOA-Glasses“
- ALCOA supports every decision and Good Documentation Practise
- Data Integrity = **ALCOA principles over complete Lifecycle**

Again Stan:

"The first **"A"** in ALCOA stands for **Attributable**. Simply put, FDA expects **data to be linked to its source**. It should be attributable to the individual who observed and recorded the data, as well as traceable to the source of the data itself. (e.g. study, system, analytical run, etc.) The applicable GLP requirements pertaining to attribution of data are found in 21 CFR 58.130 (c) and (e).

The requirement for attribution of data to the individual who collected it is found in 58.130 (e). According to the regulation, *"All data entries shall be dated on the date of entry and* ***signed or initialled by the person entering the data****".* The same is true for automated data. The regulation states, ". . . *In automated data collection systems, the* ***individual responsible for direct data input shall be identified at the time of data input***. . ." Not only does this concept of attribution apply to the collection of original data but also to any changes made to the data. Changes made to data must be signed and dated by the individual making the changes." (1)

ALCOA

Principle	Data Expectation [2]
Attributable	• Attributable to the person or system generating the data • Identify the person or system performing an activity that creates or modifies data • Linked to the source of the data

Principle	Meaning/Implications
Attributable	• No Data without Signature or Signum • Access Control, Logbooks • Header on Reports, Reference to Systems

"The **"L"** in ALCOA stands for **Legible**. Quality data must also be legible if it is to be considered fit for use. The concept of **legibility means that data are readable**. This of course implies that data must be recorded permanently in a durable medium (e.g. pen and ink on paper). 21 CFR 58.130(e) addresses this directly by requiring that, *"data shall be recorded directly, promptly, and **legibly** in ink*". The concept of legibility of data also extends to changes made to data. For example, 58.130(e) requires that changes be made so as not to obscure the original entry, thereby maintaining its legibility.

The requirements for legibility of electronic data … However, the underlying concept of legibility/readability is the same. If one consults FDA's Electronic Record; Electronic Signature rule (21 CFR 11), many of the traditional ALCOA data quality elements are addressed. For example, with respect to legibility of data, 21 CFR 11.10 (b) requires that compliant electronic systems have, *"The ability to generate accurate and complete copies of **records in both human readable and electronic form** suitable for inspection, review, and copying by the agency."* This requirement clearly establishes the expectation that electronic data must be readable (i.e. legible)." (1)

Principle	Data Expectation [2]
Legible	• Readable and permanent • Accessible throughout the data life cycle • Original data and any subsequent modifications are not obscured

Principle	Meaning/Implications
Legible	• Human readable, clearly • Free from potential misunderstandings • Enduring, maintainable over retention period • Appropriate pens • Copy thermo paper

„The **“C”** in ALCOA stands for **Contemporaneous.** This element of data quality refers to the timing of data collection with respect to the time the observation is made. In short, the more promptly an observation is recorded, the better the quality. **Data should be recorded at the time** the observation is made (i.e. contemporaneously). The GLPs address this at 21 CFR 58.130(e) as discussed above. Specifically the regulation at 21 CFR 130(e) states, “. . . *data shall be recorded directly**, promptly**, and legibly. . .”*

The requirement that data be contemporaneous is also implied in the regulations that require the date of data entry to be recorded. For example, 21 CFR 58.130 (e) also requires “All data entries shall be ***dated on the date of entry*** and signed or initialed by the person entering the data”. The longstanding and virtually universal requirement in FDA regulations for dating record entries is intended to assure, or at least document, the extent to which data is recorded contemporaneously with the observation being made.“ (1)

Principle	Data Expectation [2]
Contemporaneous	• Recorded or observed at the time the activity is performed

Principle	Meaning/Implications
Contemporaneous	• At time of observation or conduction (as near as possible) • Documented Date/Time • Defined Date/Time format

„The **“O”** in ALCOA stands for **Original.** Original data is generally considered to be the **first and therefore the most accurate and reliable recording of data**. The terms source data or raw data embody this concept of the first recording of data, and are sometimes used interchangeably. … the GLPs were the first and only place the concept of raw or source data is actually put explicitly into FDA regulations. The definition at 21 CFR 58.3 (k) states in part *“Raw data means any laboratory worksheets,* records*, memoranda, notes, or exact copies thereof, that are the result of* ***original observations*** *and activities of a nonclinical laboratory study. . .”* Although the GLPs and GCP do provide for the substitution of certified copies of source/raw data in lieu of the original record, the concept that the original recorded data is of the highest quality is retained. The concept of originality being an element of data quality is further reinforced in 58.130(e) which states “... **data shall be recorded directly**...” (1)

Principle	Data Expectation [2]
Original	• Original data is the first recording of data, or a true copy which preserves content or meaning

Principle	Meaning/Implications
Original	• Keep Printouts in all versions etc. • Don't change or repeat records • No interim "post-it"s • Protect original data • Retrieve forms from original source • Differ form text from recorded text • Control documents/records, copies

„The last **“A”** in ALCOA stands for **Accurate.** Accuracy is an implied element of data quality under the GLP regulations. The Merriam Webster Dictionary defines accurate as

1: *free from error* especially as the result of care <an *accurate* diagnosis>
2: *conforming exactly* to truth or *to a standard*: EXACT <providing *accurate* color>
3: able to give an accurate result <an *accurate* gauge> synonym see CORRECT

Accuracy is probably the most intuitive element of data quality. The most direct reference in the GLPs to the expectation of accuracy is found in 58.35 (b) which requires the QAU to assure the final report **accurately** describes the study conduct and that the reported results **accurately** reflect the raw data.

The first two definitions of “accurate” above are also implicit in the GLP regulations at 58.130(a) and (b). For example, under definition two, accuracy involves conforming exactly to a *standard.* For the conduct of a nonclinical study, the product standard is the protocol. 58.130 (a) requires that a study must be conducted in accordance with the protocol.“ (1)

Principle	Data Expectation [2]
Accurate	• Free from error • No editing performed without documented amendments • Conforming to truth or standard

Principle	Meaning/Implications
Accurate	• According to SOPs • Check calculations by 2nd person • Correct rounding • Complete • Devaluate empty fields • Document Control

ALCOA

Principle	Data Expectation [2]
Attributable	• Attributable to the person or system generating the data • Identify the person or system performing an activity that creates or modifies data • Linked to the source of the data
Legible	• Readable and permanent • Accessible throughout the data life cycle • Original data and any subsequent modifications are not obscured
Contemporaneous	• Recorded or observed at the time the activity is performed
Original	• Original data is the first recording of data, or a true copy which preserves content or meaning
Accurate	• Free from error • No editing performed without documented amendments • Conforming to truth or standard

ALCOA**PLUS**

Principle	Data Expectation [2]
Complete	• All data, and relevant metadata, including any repeat or re-analysis performed
Consistent	• Application of good documentation practices throughout any process • The application of date and time stamps in the expected sequence
Enduring	• Recorded in a permanent, maintainable form for the retention period
Available	• Available and accessible for review, audit, or inspection throughout the retention period

Add-On to ALCOA: Assure Complete-ness at Point of Acquisition

Questions

Acknowledgements

References

(1) **Stan W. Woollen:** “The Compass-Summer 2010 - Newsletter of the Southern Regional Chapter Society for Quality Assurance - Data Quality and the Origin of ALCOA“

(2) **ISPE:** “ISPE GAMP Guide: Records and Data Integrity“

Workshop ALCOA+

Stefan Godersky – SGMP (GMP PROJECTS & INTERIM)

Content Workshop ALCOA+

- Workshop
  - Sharpen „ALCOA-Glasses“ to support GDocP and Data Integrity
  - You will find Samples for sharpening Aspects of ALCOA+ in the Handout
  - Please discuss the aspects of ALCOA+ in small Groups
  - Take notes upon Decisions and Reasons for Decisions
  - **Time Objective: 30 min**
  - Discussion and Comparison of Results: 15 min