Good Documentation Practices (GDP)

Presented by: Jordan Desilva
Quality Assurance Study Reviewer (QASR)
Office of New Animal Drug Evaluation (ONADE)
Center for Veterinary Medicine (CVM)
U.S. Food and Drug Administration (FDA)

Objectives

- Defining Good Documentation Practices
- Background
- ALCOA
- Error Corrections
- Common GDP Errors
- Things to Consider
- References

DEFINING GOOD DOCUMENTATION PRACTICES

Good Documentation Practices

- Good Documentation Practice (GDP) is a systematic procedure of preparing, reviewing, approving, issuing, recording, storing and archiving of documents.
- GDP describe standards by which documents are created and maintained.

The Purpose of Good Documentation

- Ensures reliable, consistent transfer of information.
- Ensures product quality and safety.
- Complies with regulatory requirements.
- Fulfills the basic premise that good science is reproducible.
- Helps prevent dishonesty and fraud; and is essential for producing quality results.
- Provides control of processes and improves performance.
- Enables important messages to be communicated clearly and accurately.

What Are Good Documentation Practices?

- Good Documentation Practices, commonly referred to as GDPs, are the guidelines that one follows in recording information in a legible, traceable and reproducible manner.
- A key to Good Documentation Practices is to consider these questions each time you record your raw data:
  1. Is it attributable?
  2. Is it legible?
  3. Is it contemporaneous
  4. Is it original?
  5. Is it accurate?
  6. Is it complete?
  7. Is it permanent?

BACKGROUND

Background – Raw Data Definitions

- Good Laboratory Practices (GLP) (21 CFR Part 58):
  - Any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments (21 CFR 58.160.3 (7)).
- Good Clinical Practices (GCP) (VICH GL9 / Guidance for Industry #85):
  - Any original worksheets, calibration data, records, memoranda and notes of first-hand observations and activities of a study that are necessary for the reconstruction and evaluation of the study. Raw data may include, but are not limited to, photographic materials, magnetic, electronic or optical media, information recorded from automated instruments, and hand-recorded datasheets (Guidance for Industry (GFI) #85, VICH GL9, 1.24).

Background – What are Raw Data?

Both the GLPs and GCPs state how raw data should be collected

- GLP:
  - All raw data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data (21 CFR 58.160.130 (e)).
- GCP:
  - Raw data whether handwritten or electronic, should be attributable, original, accurate, contemporaneous and legible (GFI #85, 8.3.1).

Background – Original Documentation is Raw Data

- Similarities between GLP and GCP definitions:
  - Any worksheets, records, memoranda and notes of original and first-hand observations and activities of a study that are necessary for the reconstruction and evaluation of the study.
- The data collected for a study are there to confirm that the study protocol was conducted accordingly and support the results and conclusion of the study.
- Raw data supports any conclusions drawn from the study. High quality raw data are the strongest support for study conclusions.
- How can raw data collected for a study meet these definitions for a GLP or GCP compliant study?

ALCOA

What is ALCOA?

- Raw data should include these attributes:
  - **A**ttributable
  - **L**egible
  - **C**ontemporaneous
  - **O**riginal
  - **A**ccurate
- Better known as ALCOA.
- If your raw data includes these attributes, they would likely be compliant with both GLPs and GCPs.

Attributable

- Documentation should provide information on:
  - what activity is being documented,
  - who is performing the activity,
  - materials and equipment used in the activity, as well as
  - the activities preceding and following the activity.
- Documentation should be traceable to the individual(s) performing an activity.
- Data should be directly recorded into the data capture form (DCF) or in the electronic data capture system (EDCs), and always sign and date each entry as required.
- If a procedure requires transcription of the raw data to an EDCs or paper record, keep the raw data as part of the record.
- GLPs require the individual to initial and date data entries.

Attributable

- Should a photocopy of a record be needed, the individual making the copy will confirm that the copy is a true and exact reproduction of the original document.
  - The copy will be stamped or labeled as “True and Exact Copy”, and the individual making this confirmation will initial and date the copy near or in the “True and Exact” stamp.
- Copies of multiple pages should include the “True and Exact” stamp on the first page, along with initials and date of the individual who made the copy.

Attributable

Signatures and Initials:

- Signatures and/or initials on a document indicates that:
  - The individual is authorized to perform, verify, review and/or approve the activity he/she signed for.
  - The individual agrees with the legitimacy of the data content and its documentation.
  - Confirms your unique identity (signatures/initials should be authentic and traceable to a specific individual).
- **Sign and/or initial for yourself only**. Never allow someone to sign or initial any document for you, unless that person is authorized in writing to do so and according to procedure.

Attributable

Signatures and Initials contd.:

- Handwritten and electronic signatures should be unique and legible.
- A signature and/or initials is not valid without a date. Dates should be documented at the time of signing any record. Multi-page data capture documentation should have attribution on each page.
- Initials and/or signatures entered into an electronic data capture (EDC) system should be consistent with log-on credentials to ensure that electronic records can be attributed to a unique individual.
    - An audit trail can serve the purpose of traceability if a history of changes can be retrieved and viewed as part of the current record.

Attributable

- If an EDC system is used for documentation:
  - Unique single sign-on identifiers can be used and if used, should only be used by the individual to which it is assigned.
    - Sign on identifiers should not be shared among personnel
  - Assignment of each sign on identifier should be documented.

Attributable Example

Study Number: 1234-56
Date: June 11, 2024

Body Weights

Animal Number	Weight (kg)
1	4.5
2	5.2
3	4.8
4	4.3
5	5.1

Scale ID: 1001

Performed by: JD 11 Jun 24, LF 11 Jun 24
Recorded by: JD 11 Jun 24

Legible

- Documentation should be easy to read and permanent.
- Handwritten entries, signatures/initials and dates on records should be clear enough to identify the individual who signed the record and should be legible to reviewers of the documents.
- The documentation should be clear to limit misinterpretation of what was performed and recorded.

Legible Example

Study Number: 1234-56
Date: June 11, 2024

Body Weights

Animal Number	Weight (kg)
1	4.5
2	5.2
3	4.8
4	4.3
5	5.1

Scale ID: 1001

Performed by: JD 11 Jun 24
Recorded by: JD 11 Jun 24

Contemporaneous

- Sign and date records with the date and/or time the data is collected/entered.
- Data entries, initials/signatures, dates, and/or times into documentation/records are made as the task is performed or observed.
- Late entries should be fully justified and supported by other documents.
- Data entries are not back-dated, post-dated, or pre-completed.

Contemporaneous Example

Study Number: 1234-56
Date: June 11, 2024

Body Weights

Animal Number	Weight (kg)
1	4.5
2	5.2
3	4.8
4	4.3
5	5.1

Scale ID: 1001

Performed by: JD 11-Jun 24
Recorded by: JD 15-Jun 24

Original

- The documentation that captures the first-time data are recorded is the original raw data.
- Data entries documented in the appropriate data capture form or EDCs as the first capture of information.
- If procedures require transcription of the data to a paper record or data entry into a computer, reference the original raw data to confirm its accurate via signature/initials and date. If possible, keep the original raw data as part of the raw data package.
- Original study documentation should be appropriately maintained.

Original Example

Study Number: 1234-56
Date: June 11 2024

Body Weights

Animal Number	Weight (kg) (1)
1	4.5
2	5.2
3	4.8
4	4.3
5	5.1

Scale ID: 1001 (2)

Performed by: JD 11 Jun 24 (1)
Recorded by: JD 11 Jun 24 (1)

(1) Body weights transcribed from original sticky note. Sticky Note attached to this worksheet. See protocol deviation 1 for more information JD 11 Jun 24

(2) original sticky note did not include the scale ID used, however the Scale Calibration records support the use of Scale 1001 for these body weights. See Scale Calibration records and Protocol deviation 1 for more information JD 11 Jun 24

Animal #	Weight
1	4.5 kg
2	5.2 kg
3	4.8 kg
4	4.3 kg
5	5.1 kg

JD 11 Jun 24

Accurate

- Documentation contains reliable data and an exact account of events conducted in an effort to comply with the protocol.
- Data makes sense.
- No approximation, but the actual values.
- Values recorded from an instrument are recorded as presented by the instrument, i.e units not converted or rounded prior to being recorded and compliant with the protocol requirements.
- If an instrument is used to collect the data, is the instrument calibrated and validated as demonstrated by appropriate documentation?

Accurate Example

Study Number: 1234-56
Date: June 11 2024

Body Weights

Animal Number	Weight (kg)
1	4
2	5
3	5
4	4
5	5

Scale ID: 1001

Performed by: JD 11 Jun 24
Recorded by: JD 11 Jun 24

Complete

- All required information should be included in the document, including all relevant details of description.
- Activities should be completely documented in their entirety so that events can be reconstructed and understood at a later time.
- Unused spaces or data entry lines should be marked with a single line through all the blank spaces, along with “N/A” written along this line; and initials and date to ensure that data entries cannot be added to it at a later time.

Permanent

- Information cannot be erasable nor be obscured in any way.
- Never use pencil or ink that can be erased.
- Never use correction fluid, correction tape, or cross out entries so that the original entry becomes unreadable.
- The recorded data should be dark enough to be legible on the original and any copies.
- Data and the medium it is collected on (paper or electronic) should be able to be stored and retain its integrity over time.

ERROR CORRECTIONS

Error Corrections

- How to make corrections
  - GLPs state “any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change” 21 CFR 58.160.130 (e)

Error Corrections

- Correction of any entry should allow the original entry to be readable and should provide information on the date of the change, and the person making the change.
- Therefore, if a mistake is made, do not correct it with whiteout or anything else that would hide or obliterate the original entry.
- **Erasures and overwriting are never acceptable.**

Error Corrections

- The individual who made the mistake should line out the mistake by putting a single line through the entry, write the corrected information next to the entry, then initial and date the correction.
- All corrections should be clear and legible.
- Date of the correction should be the date the correction was made; not the date the error was made.
- Back-dating or post-dating of information is not allowed.
- If there is insufficient room to write the correction next to the entry, then the footnote method will be used to document the correction.

Error Corrections

- Footnotes:
  - Are used when there is not enough space/room to complete the correction of an error that was crossed/lined out.
  - Provide explanations/comments when correcting errors.
  - Make multiple corrections on the same page of a document.
  - Footnotes should:
    - Correspond with a unique footnote. However, a footnote can be used multiple times if it is **the same person**, **same type of error**, AND is being **corrected at the same time**.
    - Be noted on the same day.
    - Not be shared with others.

Error Corrections

- Example of making a correction using a footnote:
  1. Draw a single line through the mistake.
  2. Add a footnote (a “1” with a circle around it) next to the mistake.
  3. On the same page, find sufficient room to write the correction and draw the circled numeral you chose earlier.
  4. Write the reason for change next to the footnote.
  5. Initial and date the correction.

Error Corrections

- For electronic records, an audit trail may serve the purpose of traceability if the history can be retrieved and viewed as part of the current record.
- Any changes to the data, forms, records/documents after it has been signed and dated as reviewed, verified, or signed (wet ink or electronic signature), invalidates the signature. The document **should be reviewed, and/or verified again and re-signed.**
- Modification(s) to verified records should be limited to authorized individuals; documentation of modification to critical data should include a reason for the change.

COMMON GDP ERRORS

Common GDP Errors

- Illegible and unclear documentation.
- Use of scrap paper or non-official forms in documentation.
- Failure to maintain original documentation (raw data).
- Obliterations or write-overs.
- Lack of corrections or excessive changes or corrections.
- Use of outdated or uncontrolled forms for documentation.
- Study procedures not initialed and dated by person performing the task.
- Incomplete study records or forms.
- Incomplete explanation of changes to data entries and how the correct data entry was confirmed.

GDP Best Practices

- Full study documentation fully complies with the protocol and standard of conduct.
- All study documentation was appropriately maintained and will be able to maintain its integrity when archived.
- Unexpected events and deviations are fully described in the study documentation.
- Study documentation fully supports all statements and conclusions in the final study report.
- All study documentation possesses all the attributes of ALCOA.

GDP Best Practices

- All study documentation possesses all attributes of ALCOA:
  - Each individual that recorded data is clearly identified.
  - If someone other than the recorder conducted the observation or observed data point, that should be documented. The person who performed the task should review what was recorded for them by the recorder.
  - Manually recorded data is recorded clearly and legibly in indelible ink.
  - Data is accurately recorded at the time it was performed or observed, including the date and time.
  - The data make sense and any meta data, such as units for values, are included and documented.
  - Narrative documentation of study procedures, events, communication and notes to file should be clear and provide a complete, accurate description of each occurrence and be fully attributable.

THINGS TO CONSIDER

Things to Consider

- Quality Control (QC) procedures should be in place to ensure data are reviewed in a timely manner to ensure quality and integrity.
- Facility or study specific correction codes can be used for reasons for correction.
  - If the code does not clearly describe the reason for change, then additional explanation should be provided if the code does not clearly describe the reason for change.

Things to Consider

- Raw data collected in an EDC System would also need to meet the attributes of ALCOA.
  - Collecting raw data in an EDC system should mimic how raw data are collected on paper.
- Individuals recording data should ensure that all data generated adheres to good documentation practices or when it does not, is documented as a deviation.

REFERENCES

References

- FDA 21 CFR Part 58 (FDA GLPs)
- Good Clinical Practices (GCPs)
- FDA Data Quality Resources Webpage

QUESTIONS?


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