Important "details" field QA are expected to check

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“The Devil Is In The Details”

- The quote denotes that neglect or overlooking of details can cause greater problems as time progresses….
- expressing the idea that whatever one does should be done thoroughly; i.e. details are important.

Significance of Field QA's:

- The Sponsor and Study Director are required to sign the GLP compliance statement 40 CFR 160.12, therefore they rely upon the QA personnel to help ensure the GLP integrity of the study. The field QA are the "eyes and ears" of the Sponsor/Study Director

Significance of Field QA's:

- QA is responsible to monitor each study to "assure management that facilities, equipment, personnel, methods, practices, records, and controls are in conformance…"

Significance of Field QA's:

- "Any problems which are likely to affect study integrity found during the course of the study shall be brought to the attention of the study director and management immediately."

Before You Begin The Audit……

- Ensure that you are familiar with
  - Protocol and amendments, deviations
  - Procedures and practices
  - Applicable Regulations
  - Study file/notebook

Field Plot:

- Verify that the plot layout, crop, dimensions, labeling, etc., are all in accordance with the final approved protocol
- Is there anything “unusual” about the plot?
- Are equipment, clothing, practices in keeping with protocol & SOP’s?

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Raw Data:

- Was data reported timely and accurately?
- Be leery of pre-populated data forms
- “Data” entered before/after the fact?
- Is all of the data collected?
- Make sure you are personally verifying calculations

Audit Report/Checklist:

- Be careful of simply “box-checking”
- Make sure enough detail is collected in the report to reflect a thorough audit
- Add comments or notes that are relevant

Summary

- Prepare - Do your “homework”
  - Protocol, procedures, regulations
- Ensure all areas of the GLP’s are considered
  - Training, calibration, etc..
- Verify plot adheres to protocol
  - Don’t make assumptions
- Raw Data Collected
  - Independent verification
  - Integrity of data
- Sufficient Detail in Auditor’s Report

Thank You!

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