Effective Writing for the QAU

Why are we writing instead of meeting?

- Without documentation, the necessary information is lost. Audit findings must be directed at the point of study control & to management. We expect a documented reply, or “response” to our findings.

Audit/Inspection Findings = Opportunities

- 1. Who is the receiver?
- 2. What is the purpose of including a finding?

We'll evaluate and edit three findings:

A. 160:120 – did not include (8)

B. the test material had been pre-weighed into a Whirl-pak bag but the label did not comply with 160:107(c)

C. QA could not locate training for technician B.R.

“160:120 – did not include (8)”

This finding is frustrating to respond to because the reader is not given any details. Citing chapter and verse is not helpful. Follow with an explanation of what is wrong, and maybe a way to correct.

One suggestion for revision:

- The **study protocol** does not include *the description of the experimental design and methods to control bias*. Please issue an amendment to include this information, or an explanation why it is not applicable.

Now, the **focus** is identified, the *deficiency* is clearly stated, and an action item is provided.

"The test material was pre-weighed into a Whirl-Pak bag, but the label did not comply with 160:107(c)"

- *This finding is limited, and lacks sufficient detail for response.*
- Possible re-write:
- The test material was pre-weighed into a Whirl-Pak bag but the label **did not show the batch number or the expiration date. After dosing, the bag was discarded**.
- **SOP 501.03** requires all container labels to include this information (or not applicable) to comply with 160:107(c) **[maintain proper identification throughout the distribution process]**. **Additionally, the bag should have been retained.**

SOPs and impact on GLP compliance

- The relationship between SOPs and GLP compliance is stressed, since the SOP assists compliance.
- There were two departures from SOP – would you request a deviation be prepared at your facility?

More refinements to this finding:

SOP 501.03 requires all container labels to include this information (or not applicable) to comply with 160:107(c) [maintain proper identification throughout the distribution process]. Additionally, the bag should have been retained. **Please prepare an SOP deviation for this instance.**

- Management and the SD are now aware that other SOP departures may be occurring, and could respond with oversight and training. What about QA? Make the most of your time by keeping track of findings (trends, metrics), so that any loosening of standards can be made an inspection focus.

QA could not locate training for Technician B.R.

- *What training is being referenced?*
- *Did the QA mean there were no records at all?*

Adding the missing text -

QA could not locate **GLP** training for Technician B.R.

- *This is more clear, but what was the impact on the study?*
  - *We need to remember the focus on "studies" but also realize that more than one may be affected by what we have found during this inspection.*

A more serious issue is found -

QA could not locate GLP training for Technician B.R. **, who was preparing stock solutions, weighing reference substances and completing logs.**

- Comparing this final version to the first draft of the finding, the deficiency is now clear and warrants the attention of SD and Management.

Value-added QA: Make findings do more!

- Consider how the QAU should respond to any suspected trends and include this in QA SOPs, or as general operational policy.
- How would you keep track of a QA focus item for a given study so it is not forgotten later?