

Reactions, Responses, RELATIONSHIPS

How we cope with QA Reports

REACTION!!!

IMMEDIATE

FIRST

RESPONSE

RESPONSE

Considered

Logical

Thought Out

Written

RELATIONSHIP

Work Situation

On Going

Positive

EXAMPLE FINDINGS

- Part 3, page 2. I don't like to be nit-picky, but W's initials are missing from the entry dated 12/20/10.

- Part 6 page 18: this page indicates the spray interval was 7 days. This auditor thinks it should be 14 days (7/8/10 - 7/22/10). Please review this datum and determine if it needs to be changed.

- Part 6 pages 6 and 13: These pages have mls/sec/boom that have been rounded incorrectly. Page 6 has an average time of 30.11. This auditor calculates 30.1166 which should round to 30.12 giving a total output of 115.83 vs 115.85. Page 13 average time of 29.93 vs 29.94, giving an output of 112.45 vs 112.59. Impact on final results, not > 0.1%. Other rounding issues 4.01 vs 4.00 for a result of 23.69 vs 23.68.

SUGGESTION FOR FRD - NO RESPONSE REQUIRED

- There is a small math error on Part 6 page 3. The total for the output adds up to 3.7466 (vs the presented 3.74). When the mls/sec calculation is done , this auditor gets 471.29 (vs 470.45 as presented). This impacts the final recovery by a difference of 0.1%...

- Part 5 page 7: This page asks for all supporting data for soil texture, taxonomic name, etc. A topo map showing that the test plots were actually located in the taxonomic group sited would be very helpful.

- Part 6 page 29: This page appears to be missing the average of the three times in the cell that prompts for it. Please review this datum and consider adding the average to the cell.

- The test substance container label did not give the storage conditions. Obtain this information (COA or MSDS or study director) and add it to the label.

- Backpack sprayer (CO2)
Maint. Log; the repair to the spray boom, done just prior to calibration was not recorded in the log. Please add this information to the log.

- Freezer Maintenance and Repair Log; add the identifier for the freezer to the form.

- Part 6 page 6. Some of the values calculated on this page are a little different than what I come up with. At this point I'm not going to ask you to change anything, but in the future, please be careful when rounding, although I'm not sure it is a rounding issue.

- Part 7 page 7. Sample B.
1:25 to 1:30 is 5 minutes,
but I'm not asking you to
make any changes now, the
page does say approximate
time.

- Part 5, page 2. What do you mean that this is a true representation of data which was collected with electronic equipment? If it is a copy, the the location of the original should be specified. If it is a page you typed, you...

Comments to FRDs

- Considering the complexity of the study, the work is documented well.
- This is an excellent and well organized FDB.
- Thanks for your help.
- Very nice FDB!!! It was a pleasure to review.

Comment:

- $54 \times 1.2 = 64.8$. No need to make corrections as this minor difference has minimal impact, but please double check calculations before recording calculated values.

- SOP 6.2R0, Part 3.;
shouldn't the study director
be notified first? Consider
changing sponsor to study
director.

- Part 4, page 1: Was the.... The answer is NO but the O of NO reads like a C. please correct this.

- Part 6, Page 11. The correct number of days to 1st irrigation is 4.

- Part 1, Page 7 – The copy of the SOP deviation in the FDB was not signed by the FRD.

- Part 6C, Applcn. Records; The amount sprayed out for the second calibration run is actually 6140mls not 6240mls. The total volume collected was 9000mls.

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- Consider Some Possible Responses

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- PREPARE THE **FINAL** RESPONSE!

The Last Consideration...

Does the response

address the issue raised

answer the question asked?