

# Effectively Preparing & Presenting QA Inspection Findings

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Helping Grow Your Business with Good Science & Compliance

Session: QUALITY ASSURANCE FINDINGS AND REPORTING

# **OVERVIEW**

## **I. EFFECTIVELY (Effective Communication)**

- Knowledge & Skills (Technical and People)
- Attitude & Style
- QA & Mgt

## **II. PREPARING QA Inspection Findings**

- Identification
- Timely communication (prevention; correction)
- Management Support

## **III. PRESENTING QA Inspection Findings**

- Oral (Verbal) with Practice Set
- Body Language
- Written
- Management Support

## **IV. Reduction in Number of Findings**

- Metrics on Lessons Learned
- GLP Training Needs

## **V. Practice Sets: Written Findings**

## ABSOLUTE TRUTHS

- 2 pm on a Friday afternoon is the \_\_\_\_\_ time to give a QA presentation
- Nothing ever goes wrong except when QA is around.
- Be a big tipper. It feels good!
- Magical Moments of Life: Grab this moment! It's God's special gift to you!
- **“Treat people as if they were what they ought to be and you help them to become what they are capable of being” Goethe**
- **PROBLEM = an OPPORTUNITY in disguise**

# LET US LOOK AT PROBLEM OF GLP FINDINGS

## IN A WHOLE DIFFERENT LIGHT

- If PROBLEM = an OPPORTUNITY in disguise, then  
Mistake => GLP FINDING => a LEARNING OPPORTUNITY  
That is, we often best learn from our mistakes
- **What do we want to accomplish by identifying FINDINGS?**
  1. Correct mistake to improve data quality & integrity
  2. LEARN where to focus attention in order not to repeat a mistake
  3. Evaluate Findings to LEARN where QA needs to conduct GLP training

EXAMPLE: Frances Liem's EPA Update - Summary of GLP Observations  
FY20xx located on NAICC website under annual meeting tab

## References

### **e-CFR 40 CFR 160 EPA/FIFRA Good Laboratory Practice Standards**

- <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=2fa63db747b1db14f3f8059c80184006;rgn=div5;view=txt;node=40%3A23.0.1.1.11;idno=40;cc=ecfr>

### **e-CFR 40 CFR 169.2(k) EPA Books and Records**

- <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=05b0825eaa6509f6895df90fda2ca4b2&rgn=div5&view=txt&node=40:23.0.1.1.19&idno=40>

Also excellent guidance in **OECD GLP Documents No. 4 Quality Assurance and GLP, No. 6 Field Trials, & No. 13 Multi-Site Studies**

- [http://www.oecd.org/document/63/0,2340,en\\_2649\\_34381\\_2346175\\_1\\_1\\_1,00.html](http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1,00.html)

# INSPECTIONS

- Facility
- Protocol
- Study Critical Phases (field, analytical lab, modeling, etc.)
- Raw Data/Records (study & facility)
- Reports (Field, Analytical Lab, Interim & Final)

## KEY QA ACTIVITIES & WORK PRODUCTS

- Acquire knowledge & skills (e.g., trained in GLPS, SOPs, auditing skills)
- Train colleagues in GLPS
- Earn colleagues respect for me and my job function
- Earn colleagues appreciation of my contribution to their quality work products
- Host agency and sponsor QA inspections
- Participate in sponsor/study staff visits
- Conduct inspections and issue written inspection reports
- Achieve compliant data and reports by colleagues (or non-compliance identified)

# I. EFFECTIVELY (EFFECTIVE COMMUNICATIONS)

- KNOWLEDGE, TECHNICAL SKILLS & PEOPLE SKILLS of QA PERSONNEL

See References on a previous page

40 CFR 160 GLPS

40 CFR 169.2(k) Books & Records

OECD Principles of GLP



# **PERSONAL & CORPORATE (MANAGEMENT)** **ATTITUDES & STYLES**

- **Have you deliberately selected a personal attitude style?**
- **What is your “Corporate Culture” for QAU personnel?**
  
- **Management support of GLPS and QA is CRITICAL to QA success!!**
  
- **Styles/Roles Observed in QAU:**
- **Police Officer**
- **Theologian**
- **Sales Person**
- **Friend/Buddy/Colleague**
- **Teacher/Trainer/Facilitator**
- **Coach/Mentor**

# What attributes

- **Make for effective communication?**
- **And make you want to work with and do business with this person?**
- **And make you want this person on your team!?**
- **Do these same traits contribute to being a successful QA person?**
- **Anyone need an Attitude Adjustment?  
Need a Corporate MakeOver?  
Training in “Communication Soft Skills”?**

# What attributes

- **Aggressive**
- **Mean-spirited**
- **Tyrannical**
- **Task master**
- **Do It My Way, or else**
- **Accusatory**
- **Hostile**
- **Rude**
- **Name Calling**
- **Nitpicky**
- **Sloppy-dressed, messy appearance**

## **MORE TRUTHS:**

- **Some people are just bitter and negative about life**
- **Cannot please everyone all the time**

# What attributes

- **Knowledgeable about product**
- **Communication Skills**
- **Helpful/Attentive – customer service**
- **Humility**
- **Tactful**
- **Smiling**
- **Friendly**
- **Cheerful**
- **Supportive**
- **Encouraging**
- **Well-dressed**
- **Cultivates relationships**
- **Fair**
- **High Standards**

## II. PREPARING QA Inspection Findings

Identify, Confirm & Characterize an Observation:

- Identify: Knowledge & Observational Skills
- Confirm: Researcher Mistake or QA misunderstanding (timely questions)

• Characterize:

e.g., Basis: GLPS, SOP, data entry, protocol deviation, industry standard

e.g., Category: Finding, Recommendation, Comment

e.g., Relative Seriousness: Company SOP or see EPA Memo 8-April-95  
Guidelines for Study Rejection Based on GLP Considerations

<http://www.epa.gov/compliance/resources/publications/monitoring/fifra/glp/glpstudyrejection.pdf>

Timely communication:

- Relative seriousness per 40 CFR 160.35(b)(3)
- Prevention during inspection - interruption of workflow by QAU
  - timely data audit & probing questions
- Correction

Management Support

### **III. PRESENTING QA Inspection Findings**

#### **Oral (Verbal) & Body Language**

**consistent with your chosen ATTITUDE & STYLE**

- Initial Interview of Facility Inspection
- Exit Interview of Facility Inspection
- During critical phase inspection
- End of critical phase inspection
- FAIR, FIRM, CLEAR, CONCISE, PRECISE, STICK TO FACTS, CONFIRM OBSERVATIONS, DO NOT MAKE JUDGEMENTAL STATEMENTS, THIS IS NOT THE TIME FOR “BUDDY TALK” – BE PROFESSIONAL!
- BE PREPARED TO ANSWER THE QUESTION: show me where it says that in the GLP regulations, SOP, or EPA guidance document
- Understand where you have management support, and where you will need to obtain management support (train management)

**Oral (Verbal) & Body Language**  
consistent with your chosen ATTITUDE & STYLE

Was your **presentation successful** if you elicited:

- “thanks” or other form of appreciation?
- swift response to investigate and take corrective action?
- anger, hostility, upsetness, passive aggressive behavior, complaints to your management or request to leave site?

## Oral/Body Language Practice Set

When and how should QA personnel alert a PI that QA observed the following potential mistakes during a critical phase QA in-life inspection of 2nd application to tomato?

- a calculation error in the amount of test substance planned to be added to tank mix due to a transposition of digits (43,650 sq ft/A was used instead of 43,560 sq ft/A).
- protocol requires non-ionic surfactant (NIS) in tank mix, but it has not yet been added – it was inadvertently about to be omitted during mixing in the field due to workflow interruption by a cell phone call.
- were these mistakes made during the 1st application?

NOTE: QA does not want to be the cause of a Finding due to distraction of PI by talking, etc. during inspection.



## Written Findings per 40 CFR 160.35(b)(3-6)

- **Who and how many are your potential customers?**
- **What writing style is appropriate for all of them?**
- **i.e., who may review the written report, as you will have to write so that everyone will be able to understand your Finding from just your written words (and if any attachments)**

|                         |                                     |
|-------------------------|-------------------------------------|
| 1 Yourself              | 2 PI                                |
| 3 PI Mgt                | 4 PI QA                             |
| 5 SD                    | 6 SD Mgt                            |
| 7 SD QA                 | 8 SD QAU Mgt                        |
| 9 Sponsor Rep           | 10 Project Mgt Co Rep               |
| 11 Project Mgt Co QA    | 12 EPA Investigator(s)              |
| 13 OECD Investigator(s) | 14+ Attorneys, Judges, Jury members |

- **All these people have very busy schedules or may feel overloaded. To gain their favor, be considerate of people's time (be time-sensitive!), so be: FAIR, FIRM, CLEAR, CONCISE, PRECISE, STICK TO FACTS, CONFIRM OBSERVATIONS, DO NOT MAKE JUDGEMENTAL STATEMENTS, THIS IS NOT THE TIME FOR "BUDDY TALK" – BE PROFESSIONAL!**

## FORMAT OF FINDINGS LISTING: Is it governed by one or more SOPs (company culture or way of doing it) from Sponsor, Test Site QAU, Contract QAU?

### Examples:

- Typical: 40CFR160.35(b)(7) & (c) requirements & signatures page, narrative & checklist, list of observations, corrective actions, status report section
- List in a special order: e.g., Findings, Recommendations, Comments; most serious first, EPA severity (1-3) class, company ranking system, or by page number in Field Notebook or Report. Can you aggregate Findings by type (e.g., The following pages had entries that were not initialed and dated: 3, 4, 6-9).
- Do you need to cite the GLP regulation, SOP, or protocol source for the deviation?
- Does management instruct by SOP that the QAU make written recommendation(s) as to appropriate corrective actions? If a science matter, is the QAU skilled to do so?
- Is it appropriate to indicate the % of data audited (study director may not know the test site standard)?

## Examples (cont):

- What reference system is used so that the PI or Study Director can quickly find the location of the Finding in the study file? e.g., FDB pg 25; Analytical Rpt pg 45
- Which Findings are reported? e.g., All or only those not corrected by the end of the inspection
- For an EPA inspection, best if all dates and signatures are on the first page, or page without any listing of observations.
- Understand where you have management support, and where you will need to obtain management support (train management)

## IV. Reduction in Number of Findings

- QAU Conducts Metrics on Lessons Learned (Findings) in order to identify
- GLP Training Needs; reported to mgt in a Status Report

## **V. Practice Sets: Written Findings**

### **Example of Written Findings from Oral discussion during Critical Phase inspection**

1. Field Notebook, Part 6. The PI addressed the following items observed by QA prior to making Application #2:
  - A. Page 34. Prior to mixing, a calculation error in the amount of test substance to be used due to a transposition of digits (43,650 sq ft/A was used instead of 43,560 sq ft/A) was corrected.
  - B. Page 36. PI added NIS surfactant into tank mix, which was inadvertently about to be omitted during mixing in the field due to workflow interruption by a cell phone call.
  - C. Also PI re-checked data for application #1 for the above two items and did not find them in Application #1.

FIELD ID NO: ORLANDO-27 - X

FIELD DATA BOOK

PART 4. TEST SUBSTANCE RECORDS

F. BALANCE CALIBRATION CHECK

INSTRUCTIONS: Complete this form or provide equivalent information when the test substance is a dry formulation. Check balance calibration by weighing standard weights that bracket the desired measurement. Record date(s) that the balance calibration was checked, the standard weights, and the results. In addition, provide dates and a brief description of maintenance and repair work completed on the balance relevant to the trial. Be sure to initial all entries.

MAKE, MODEL, SERIAL NUMBER OR ASSIGNED IDENTIFIER: OHAUS 280

| Date    | Stated Wt. | Recorded Wt. | Stated Wt. | Recorded Wt. | Initials |
|---------|------------|--------------|------------|--------------|----------|
| 6-20-10 | 5g         | 5.00g        | 30g        | 30.1g        | FP       |
| 6-28-10 | 2g         | 2.00g        | 15g        | 15.01g       | FP       |
|         |            |              |            |              |          |
|         |            |              |            |              |          |
|         |            |              |            |              |          |
|         |            |              |            |              |          |
|         |            |              |            |              |          |
|         |            |              |            |              |          |

Stated Wt. = Stated mass of the standard weight used in the calibration check  
Recorded Wt. = Actual recorded mass of the standard weight

RECORD DATES AND BRIEF DESCRIPTION OF ANY CALIBRATION, MAINTENANCE AND REPAIR WORK DONE ON BALANCE

no repairs to date

ABOVE DATA ENTERED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

PART 4 PAGE 3

COMPLETE IF APPROPRIATE: "THIS IS A TRUE COPY OF THE ORIGINAL"  
THE ORIGINAL IS IN (3-4 FIELD DATA BOOK NO. \_\_\_\_\_ INITIALS \_\_\_\_\_ DATE \_\_\_\_\_

## V. Practice Sets: Written Findings (cont.)

**Practice Set: Create a “Best Practices” inspection Finding**  
by selecting from the choices below, or create your own.  
Explain why you selected or did not select each choice.  
FDB = Field Data Book

- 1A. FDB Part 4F
- 1B. FDB Part 4 Page 3
- 1C. FDB Part 4 Page 3, F. Balance Calibration Check.
- 1D. \_\_\_\_\_
  
- 2A. Form F is missing the dated initials of the person hand-entering repair notes.
- 2B. The hand-written entry “no repairs to-date” is missing dated initials in the form’s line “ABOVE DATA ENTERED BY: \_\_\_\_\_ DATE: \_\_\_\_\_”.
- 2C. \_\_\_\_\_

## **V. Practice Sets: Written Findings (cont.)**

- \_\_\_ 3A. Please make appropriate corrections.
- \_\_\_ 3B. Please correct with dated initials on a Late Entry Error Code notation indicating when you entered the information (if you can accurately remember).
- \_\_\_ 3C. Please add your initials and appropriate date. I am really tired of having to cite you for this in every report. You'll buy me a beer for every time you do this in the future.
- \_\_\_ 3D. \_\_\_\_\_



## V. Practice Sets: Written Findings (cont.)

\_\_\_ 4A1. This late entry of date and initials is a GLP Deviation of 40 CFR 160.130(e) “dated on day of entry and signed or initialed by the person entering the data.” Please address whether it should be noted in the PI’s GLP Compliance Statement.

\_\_\_ 4A2. \_\_\_\_\_

\_\_\_ 4B1. This is also Protocol Deviation (protocol page 4 section 20.0 states “All ... data ... appropriate to this study should be **recorded directly and promptly** into the Field Data Book ...” If appropriate, please write a protocol deviation and submit to study director within 14 days per protocol section 21.0.

\_\_\_ 4B2. \_\_\_\_\_

\_\_\_ 4C1. This is also a SOP Deviation (Facility SOP No. XYZ.0x, section x.x). Should a SOP Deviation be written and approved by the study director?

\_\_\_ 4C2. \_\_\_\_\_

Answers to Written Finding Set:

Group Vote Favorite: 1B + 2A + 3A (concise)

Also Good for beginners: 1C + 2B + 3B

If corrected, then no deviation exists,  
and thus not need 4A-C.

**Questions ??**