Disclaimer: I am no public speaker!!! Accordingly, please have a glass or two of wine and/or a couple beers…

CRO PERSPECTIVE ON GLP FIELD NOTEBOOKS:

MAKIN' IT REAL!!!

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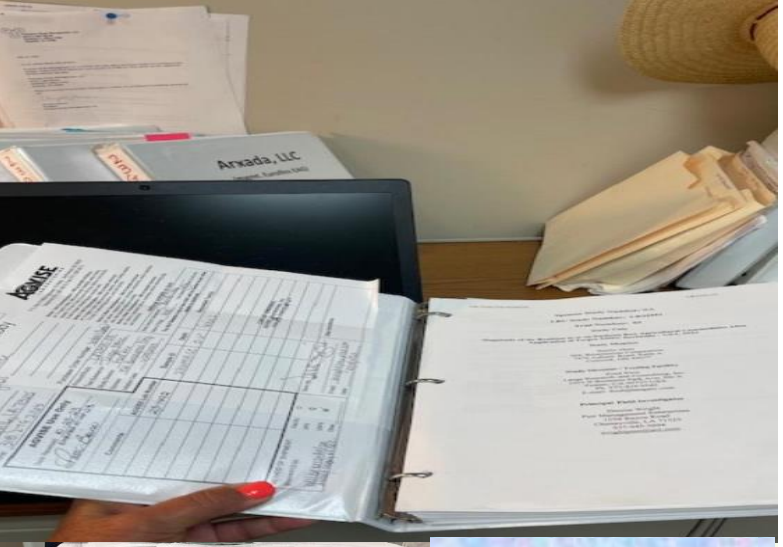
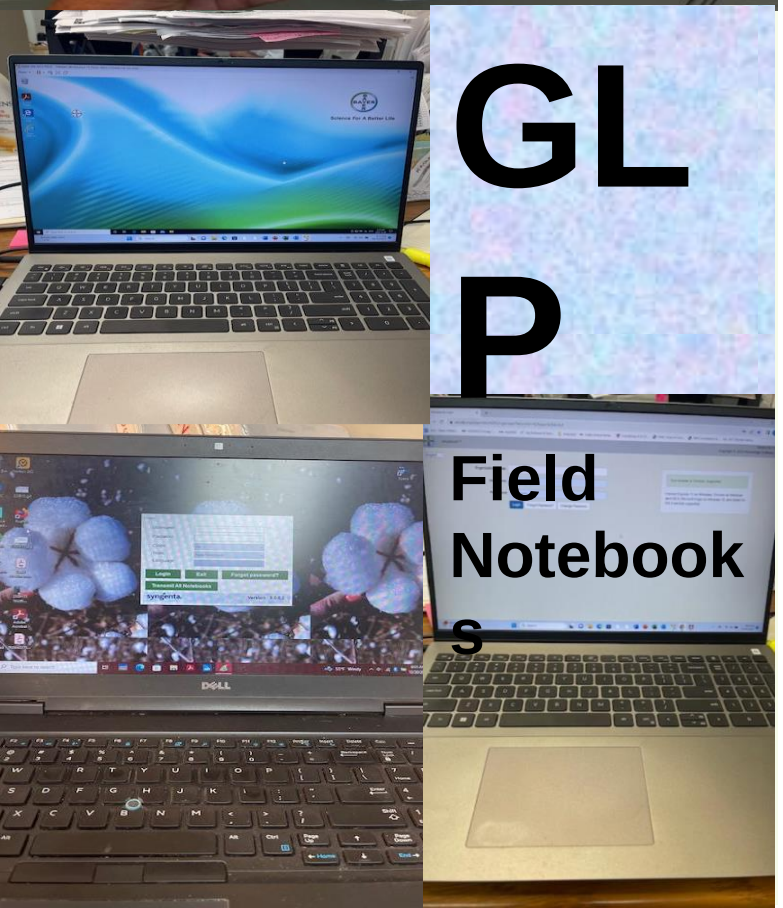
RECEIPT OF THE FIELD NOTEBOOK

Upon receiving the field notebook, the protocol should be reviewed to ensure it is in line with what was seen in the draft, and/or bid upon.

If test substance was received prior to receiving the notebook, the lot #, expiration date, and any other pertinent information should be compared to what is listed in the protocol, as well as receipt information being transcribed into the notebook. ALWAYS include any generic (in-house) forms in the notebook after transcribing or instead of transcribing (it is the preference of this PFI to transcribe information onto the notebook forms).





NOTEBOOK

During initial review of the final protocol, highlight areas that are of critical and utmost importance, especially special or unusual requirements. If test substance has been received, ensure that the TS information in the protocol matches that which is on the container and TS paperwork received with the TS. Look at prepopulated (sample #'s) items in the protocol to ensure accuracy. Whether paper or electronic, the field notebook should be reviewed to get familiar with the forms.

COMMUNICATION WITH THE STUDY DIRECTOR

Keeping the study director informed of the progress of the trial either by email and/or by sending completed notebook pages following critical events is key! The protocol and/or field notebooks will usually give a timeline for reporting these events. Picking up the phone and calling the study director when questions or problems arise is what a PFI is called to do since the study director is the focal point.

CONDUCT

CALIBRATION/APPLICATIO N

Reviewing calibration/application specifics, such as GPA, required nozzle types/sizes, and max wind speed that test substance may be applied in is critical just prior to cali/appl. Remember to check for amendments that may have changed application rates or other specification prior to starting calibration/application.

Calculations should include all units used, and all steps should be included so trial can be reconstructed.

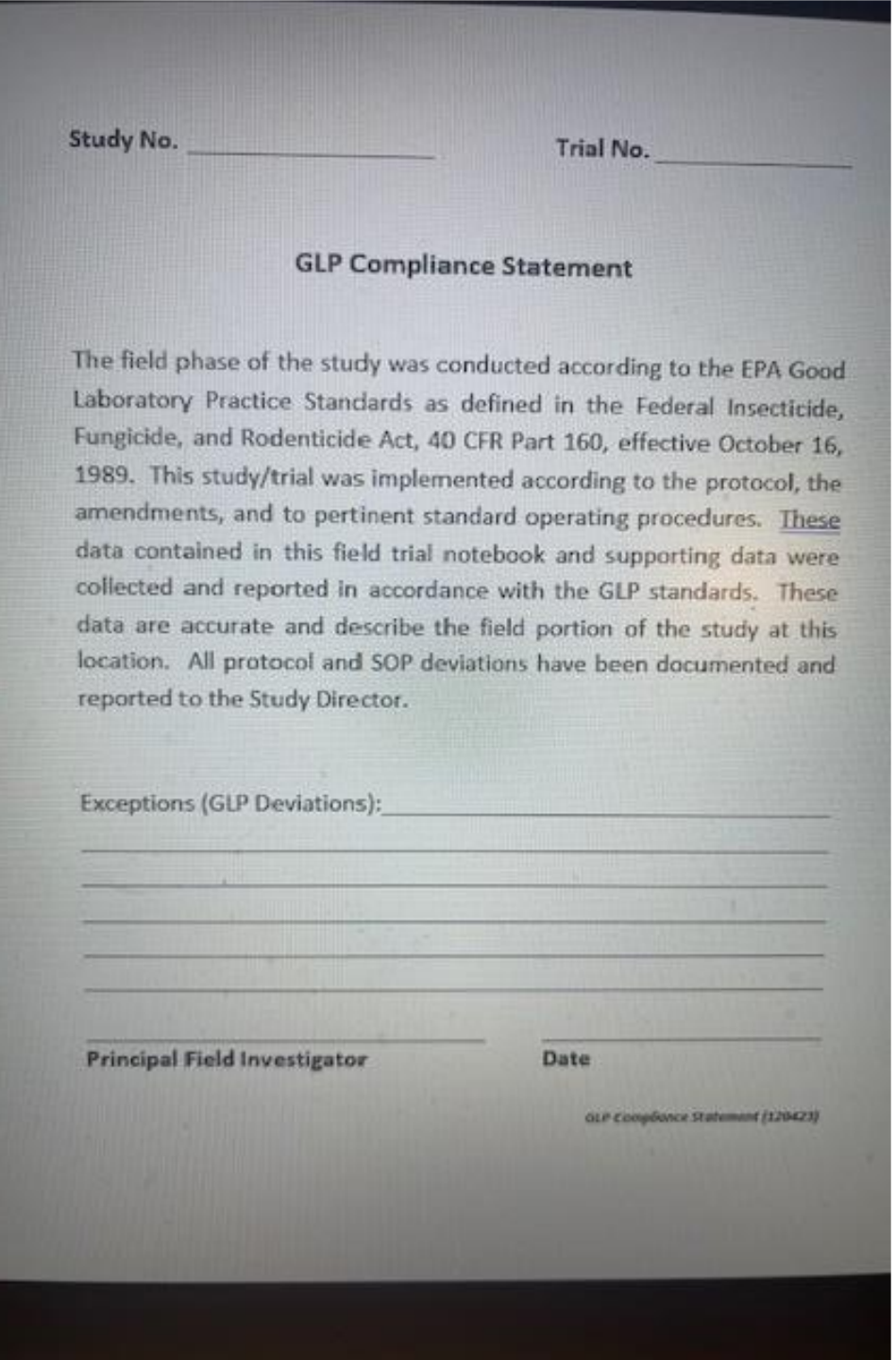
SAMPLING

Prior to sampling, review of the protocol and field notebook is necessary to make sure you know exactly what is being required. Again, remember to check for amendments that may have affected sampling. Thorough documentation of all sampling procedures is required and necessary for reconstruction of the trial. When electronic notebooks have space limitations that do not afford sufficient explanation, include handwritten or typed documentation to include in the raw data/support data package to be submitted at trial

SHIPPING/NOTIFICATIONS

Again, check for amendments that may have changed the sample shipment destination and/or sample identification number(s). ***Know who to bill for shipping***. If this information is not in protocol or the field notebook, contact the study director. Notify the lab/study director with trial ID, date of shipment, method of shipment, # boxes or containers, sample type(s), and if available, ETA. Majority of shipments are sent via ACDS freezer truck, but FedEx is often used for dry ice shipments. Ensure the proper container labeling is used for all shipments. Ensure the appropriate chain of custody paperwork is included in Box 1 of ___. Ensure exact copies of documentation are retained in the field notebook.

Shown at far left is Lilly waiting on her owner, Ronnie, ACDS driver, to return to his truck after picking up a shipment at PME, and Lilly and her brother, Buster taking a little break at Eurofins in Columbia, MO. Photos used with Ronnie's permission.



Study No. _____ Trial No. _____

GLP Compliance Statement

The field phase of the study was conducted according to the EPA Good Laboratory Practice Standards as defined in the Federal Insecticide, Fungicide, and Rodenticide Act, 40 CFR Part 160, effective October 16, 1989. This study/trial was implemented according to the protocol, the amendments, and to pertinent standard operating procedures. These data contained in this field trial notebook and supporting data were collected and reported in accordance with the GLP standards. These data are accurate and describe the field portion of the study at this location. All protocol and SOP deviations have been documented and reported to the Study Director.

Exceptions (GLP Deviations):_____

_____

_____

_____

_____

_____

_____ _____

Principal Field Investigator **Date**

GLP Compliance Statement (120423)

FINALIZING THE FIELD NOTEBOOK REVIEW

Finalizing the notebook after final sample shipment has occurred will consist of reviewing each page (form) for completion. Some support data such as maintenance pesticides applied, storage temperature data, weather data, etc. will need to be transcribed from facility records. Depending upon the requirements of the sponsor and/or management firm you are submitting the notebook to, exact copies of these records may need to be included in the field notebook at submission.

TRANSFER TO QA FOR FINAL AUDIT

If the CRO QA is to conduct a final audit of the finalized field notebook, the notebook is transferred to QA at this time. When the audit is complete, the notebook with any support data will be copied for CRO files and then sent via FedEx to the study director or designated recipient. There are instances where QA is not required at the CRO level, and the field notebook is transferred to the study director or designated recipient for final QA audit.

THANK YOU FOR YOUR ATTENTION!!!

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