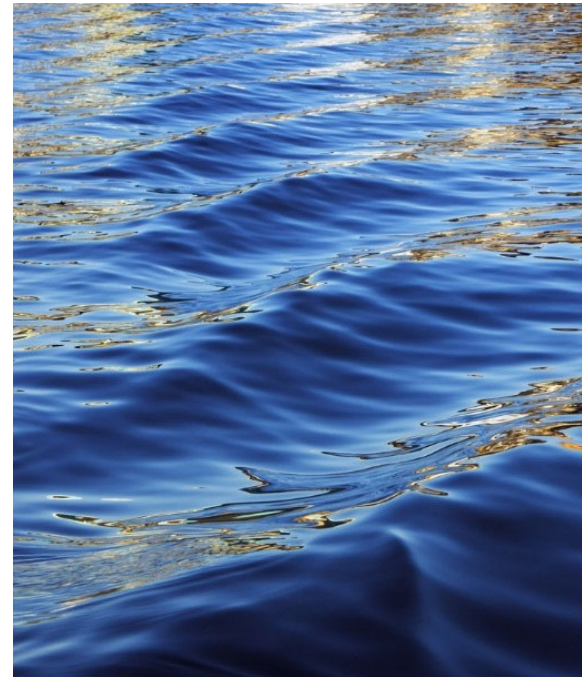


2021 IR-4 Training Webinars

August 3rd



IR-4 Training Webinar: August 3rd

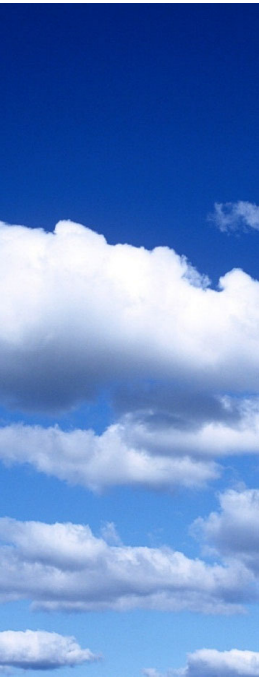
- ACDS Waybills
- Sample Shipping and Receipt Best Practices
- IR-4 Headquarters Move to NC State – Where to Ship?
- Finalizing Notebooks and Shipping to Regional Offices
- PPE for Zero Day PHI harvests
- Pre-entering Data: Solutions that are GLP Compliant and FRD Friendly
- Seed Treatment Trials
- Properly Recording GLP Training
- Purpose of SOPs



When in Doubt...

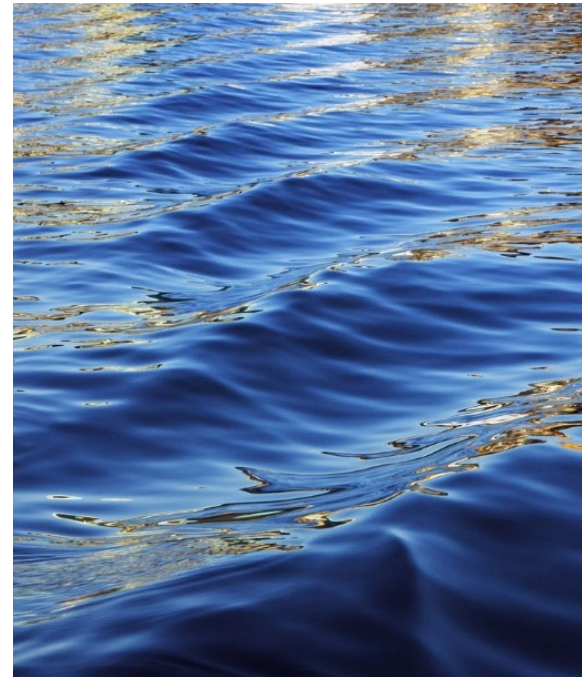


- Contact the Study Director!
 - Example: if QA is watching your trial and a recommendation is made that you're not sure about or disagree with, call your study director



Shipping with ACDS

Marylee Ross



Shipping Samples with ACDS

- Choose the appropriate shipping box
 - Double corrugated boxes preferred
 - Match the size to the contents
- Limit the weight
 - 70 pounds maximum
 - ACDS will not accept any packages over 80 pounds
- Do not tape boxes together
- [Guidance documents from ACDS](https://drive.google.com/file/d/1h27fSWc8hzej3cqo7l4cp_oozTRxo4IE/view)
https://drive.google.com/file/d/1h27fSWc8hzej3cqo7l4cp_oozTRxo4IE/view
- Contact: Kristine Milliman - ktmm2@aol.com



ACDS Bill of Lading

STRAIGHT BILL OF LADING - SHORT FORM - ORIGINAL - NOT NEGOTIABLE

THIS MEMORANDUM is an acknowledgement that a Bill of lading has been issued and is not the original Bill of Lading nor a copy or duplicate, covering the property named herein, and is intended solely for filing or record.

RECEIVED, subject to the classifications and tariffs in effect on the date of receipt by the carrier of the property described in the Original Bill of Lading.

The property described below, in apparent good order, except as noted (contents and condition of contents of packages unknown) marked, consigned, and destined as indicated below, which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed as to each carrier of all or any of said property over all or any portion of said route to destination, and as to each party at any time interested in all or any of said property, that every service to be performed hereunder shall be subject to all the terms and conditions of the Uniform Domestic Straight Bill of Lading set forth (1) in Uniform Freight Classification in effect on the date hereof if this is a rail or a rail-water shipment or (2) in the applicable motor carrier classification or tariff if this is a motor carrier shipment. Shipper hereby certifies that he is familiar with all the terms and conditions of the said bill of lading set forth in the classification or tariff which governs the transportation of the shipment, and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

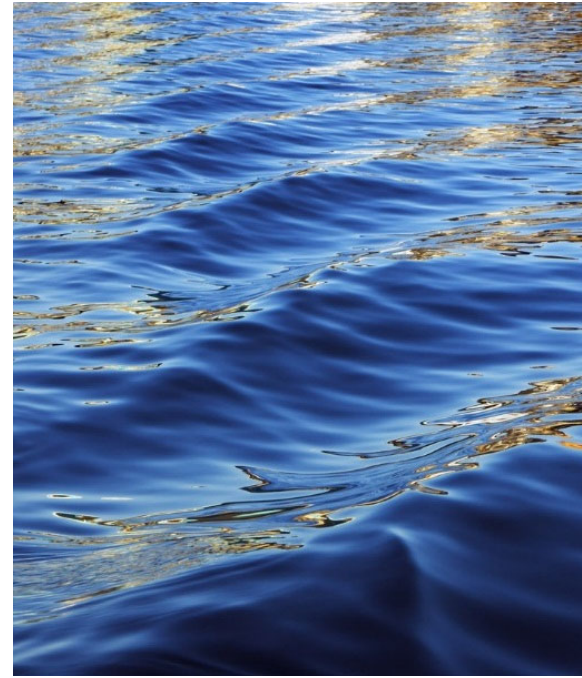
From: _____	Phone: _____	Carrier's Pro No. _____
Address: _____	Bill To: * <u>IR-4 NER</u>	Shipper's Bill of Lading No. <u>162625</u>
City: _____ State _____	Date: _____	Consignee's Reference/PO No. _____
Carrier: Agricultural Chemicals Development Services, Inc. (A.C.D.S., Inc.)		Carrier's Code (SCAC) AGCM

- Do not simply write IR-4, indicate the appropriate region to bill.
- Add the Field ID sticker to help with the billing.
- For special circumstances, contact your RFC office.



Sample Shipping and Receipt: Best Practices

Alex McFall



Sample Receipt: Western Region

- When the Sample Control Officer (SCO) is notified that samples are in transit/expected, SCO verifies tracking information and likely time of arrival, ensuring someone is present to receive samples
- Received samples are transported to main freezer for storage and routing forms are completed



ACDS Sample Arrival at UC Davis CHE

Sample Receipt: Western Region

- Each trial is individually removed from main freezer and transported to temporary freezer in sample processing room to verify all sample information is correct.
- Parts 8B and 8C are verified in each box, sample weights are taken and noted on Part 8B, along with assigned Laboratory ID numbers. All data (Field ID no., PHI, crop form, weight, etc.) are checked against protocol requirements



Example: Fresh Mint (leaves and stems)

Sample Receipt: Western Region

- An internal sample arrival check sheet is used (in place of Part 8C) to confirm all pertinent information is in agreement with the protocol. If not, a note is added and the Study Director (SD) and FRD are contacted
- Sample Database is updated with all relevant information and samples are logged in to main storage freezer
- Completed Part 8B's and internal sample arrival check sheets are mailed to SD, FRD, and Field Regional Coordinator



Communication with Sample Control

- Clear communication with your Sample Control Officer (SCO) and Study Director (SD) prevents many headaches surrounding sample transfer, receipt, and processing
- 2-3 days before harvest, notify your SCO and SD with the Field ID #, your plans to proceed, and your anticipated shipping date/method (e.g., overnight FedEx or next month's ACDS)
- If there are any updates or changes, keep the SCO in the loop.

Part 8B: Verify Before Shipping

- Make sure **Field Trial ID** is clearly listed at the top (stamps/stickers work great here)

FIELD ID NO: Fluopyram + Trifluorostrobil
Kiwifruit
FD No. 12650, 19-CA433
Enns

IR-4 FIELD DATA BOOK

PART 8. RESIDUE SAMPLE SHIPPING

R. RESIDUE SAMPLE CHAIN OF CUSTODY FORM

INSTRUCTIONS: Complete this form for each sample shipment. Use separate forms if different samples from the same trial are going to different destinations. Place a true copy within each shipping container and fax, mail, or email a true copy to the Study Director and to your Regional Field Coordinator. Retain the original in the Field Data Book.

TEST SUBSTANCE Fluopyram + Trifluorostrobil

CROP Kiwi fruit

Include protocol-specified details such as small- or large-fruited, oil or confectionary variety, or processing variety, if applicable.

FIELD RESEARCH DIRECTOR DAVID ENNS

PHONE# (551) 646-6061 FAX# (551) 646-6015

TRIAL LOCATION UCKARE Parlier, CA

NUMBER OF BOXES SHIPPED 1 TOTAL NUMBER OF SAMPLES SHIPPED 4

DESTINATION (do not enter more than one destination) UNIV. of Calif Davis, CA

CARRIER ACDS #159791

REC'D WITH SAMPLES ON 2/3/20
 ECA NO. 716
 LID 12-650-19-CA433
 INITIALS & DATE BH 2/3/20

- Number of Samples Shipped, Sample ID, and Crop Fraction entries match what is being packed?

- Treatment and Treatment Rate given clearly? Number of Applications and other info correct?

Sample ID ¹	Treatment/Rate ²	No. of Applies.	Date of last Application	Date Harvested	Date Sampled	Crop Fraction ³	LAB ID (Lab Use only)	wt. in lbs
A	TAT 01 UTC	0	None	10-29-19	10-29-19	Fruit	28216	4.6
B	TAT 01 UTC	0	None	10-29-19	10-29-19	Fruit	28217	4.6
C	TAT 02 0.445 lbs ai/A	3	10-28-19	10-29-19	10-29-19	Fruit	28218	6.0
D	TAT 02 0.445 lbs ai/A	3	10-28-19	10-29-19	10-29-19	Fruit	28219	5.4
BH								BH
2/3/20								2/3/20
OK 12-13-19								

¹See protocol for assigned ID code under Section 18, Sample ID column

²Use the rate of the last application if different applications had different rates assigned by the protocol. If there are two active ingredients (a.i.) in the test substance, enter the rate of the a.i. that is to be analyzed for that sample.

³E.g. fruit, straw, processed apple juice

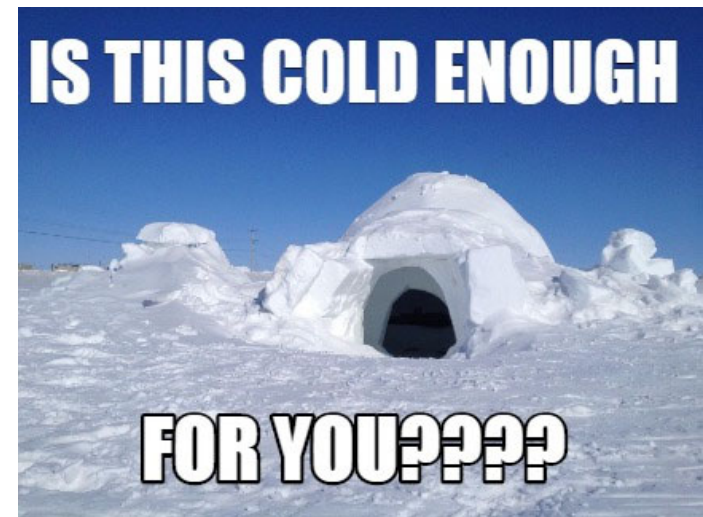
ABOVE DATA ENTERED BY: David Enns DATE: 12-13-19

PART 8 PAGE _____ Trial Year 2019

COMPLETE IF APPROPRIATE: "THIS IS A TRUE COPY OF THE ORIGINAL"
 THE ORIGINAL IS IN IR-4 FIELD DATA BOOK NO. 12650-19-CA433 INITIALS DE DATE 12-13-19

Overnight Shipping

- If samples arrive with no dry ice, SCO cannot confirm their integrity
- Shipping delays happen (often)
- Pack sufficient dry ice to give yourself a buffer, 4:1 dry ice:sample should give two full days of frozen status
- If the sample is dry (e.g., hops), more dry ice will be needed to maintain sample integrity



ACDS Shipping: Best Practices

- **Bill of Lading #** and **Field ID** are clearly written on each box
- Boxes are sturdy and properly secured with tape
- If UTC and treated samples are sharing a box, verify that there is **complete, physical separation** between the two sample types (e.g., double bagged separately, solidly divided by a cardboard barrier, etc.)
- **All boxes must contain a copy of Part 8B and 8C** in case sample boxes are separated in transit



Exhibit A: Boxes Nobody Likes

Other Recommendations

- Write **chemical and crop/fraction** on each box (makes it easier for SCO to sort and locate in the freezer when time for processing)
- Place Part 8B and 8C copies in ziploc bags to prevent damage
- **FedEx Priority** is recommended over other shipping types ("First" arrives so early that most receiving areas aren't open, and "Standard" arrives too late in the day to communicate any issues with shipping dispatcher)
- When in doubt, **communicate** with SCO and SD
- **Primary Goal: Keep all parties informed and prepared through all steps of the sample shipping and receipt process.**

IR-4 Headquarters Move – Where to Ship?



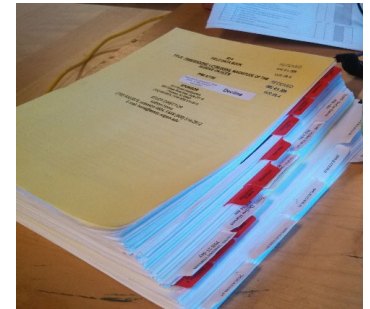
- All files have been moved from Rutgers to North Carolina State University
- Starting this week (August 2nd) all documents should be sent to the new IR-4 HQ location at NC State in Raleigh, NC
- New Shipping Address (also on footer of IR-4 webpage)
IR-4 Project
NC State University
1730 Varsity Drive
Venture IV, Suite 210
Raleigh, NC 27606

Finalizing Notebooks and Shipping to Regional Offices

When you are finished with the field trial

1. Be sure to include confirmation of samples received at the lab
2. Double check page numbering
3. Sign Compliance Statement in Part 1 just before shipping
4. Make a copy of your book and then...
5. Ship via FedEx

Western Region IR-4
Michael Horak
4218 Meyer Hall
University of California
Davis, CA 95616



PPE for Sampling before REI

- Ex: Sivanto (flupyradifurone)/Coffee in Hawaii
- Consult label for a similar use (say foliar to grapes)
- Follow PPE instructions for comparable crop

Sivanto 200 SL

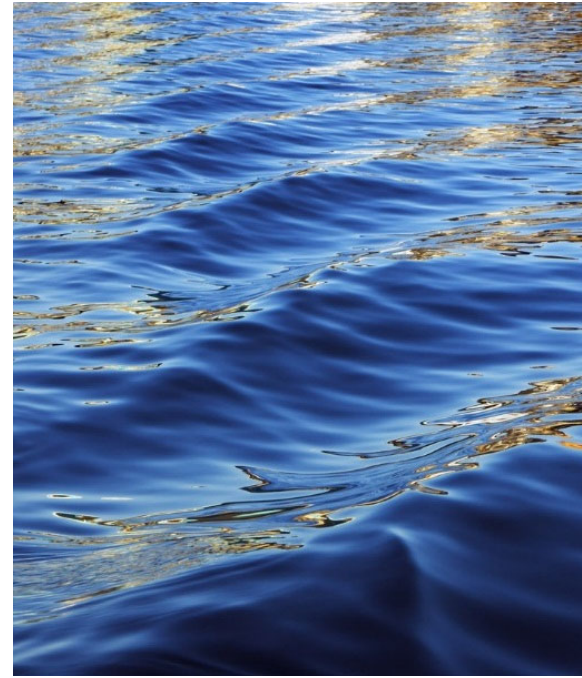
General		Crop Specific		Documents	
CA ▾ Grape (Other Cases/Foliar)					
Re-Entry Interval:		12 Hours			
Preharvest Interval:		0 Days			
Max Applications per Season:		No Maximum			
Max Rate per Season:		28 floz / A			
Methods Allowed:		Air, Chemigation, Ground			
Generic Condition:		Other Cases/Foliar			





Pre-Entering Data in Field Data Books

Martin Beran



Pre - Entering Data

Raw data is a result of an original observation or activity.

Pre – Entering Data

- We strongly discourage you from documenting that an event has occurred into the Databook before you actually completed the task. Specifically, prompts like:
 - Output Discharge and Speed Calibration
 - Transferring Test Substance from Storage to Plots
 - Cleaning Application Equipment
 - Description of Application
- When describing an activity before it happens, you run the risk of missing some component that should have been documented. Things can change.



Pre – Entering Data

- Recording Data before it happens is not considered GLP Compliant. The intent is to document an action after it is completed.
- Even though you are certain that that is the way you are going to make a calibration or clean the equipment, the Databook asks that you describe the “procedure you used” and not “will use”.
- If an auditor sees an entry for a calibration or the TS transport prompt filled the day before, you are giving the wrong impression of the timing of the event.

Pre – Entering Data

- What If I absolutely, positively, definitely have to type or hand write a description into the Databook before it actually happens?
- You have two options to give reviewers some assurance that the events happened as you've described. And, making it GLP-rific.
 - A. Confirm that the event has happened as described by adding an initialed/dated note stating: "occurred as written".**
 - B. Have a typewritten description and leaving key blanks for amounts, times or other data. Initialing and dating those added entries once you perform the activity.**

Pre – Entering Data

PART 6. APPLICATION RECORDS F.

Cary C.S. Hamilton

DESCRIBE HOLDING AND TRANSPORT OF TEST SUBSTANCE AND ADJUVANT FROM STORAGE AREA TO LOCATION OF TANK MIXING.

TS was mixed within walking distance of chemical storage and lab. TS and equipment were transported via truck in back of truck bed to trail plots. Event occurred as stated.

9-25-18

BRIEFLY DESCRIBE PROCEDURE USED FOR SPEED CALIBRATION Calculated target pass time – see

Part 6E, calculated how long (seconds) to make the 100 foot pass. Simulated application by
walking alongside the treated 90' row. Set metronome to 60 beats per minute. See Part
3 for explanation.

It has in fact occurred and is accurate
for the application. 9/25/18

Pre – Entering Data

Custom forms make data entry faster and easier.

Description of Equipment Used to Measure Test Substances, Adjuvant and Carrier Water			
FIELD ID No. _____	Indoxacarb / Avocado ID No. 0860920-CA21 Ennes	Application No. <u>1</u>	
The following equipment was used in this study:			
To remove volume of water: <u>NOHC</u>			
Scale for solid Test Substance:			
<input type="checkbox"/> Mettler Toledo Scale, Model PL 303 (0.001gr increments)			
<input checked="" type="checkbox"/> Ohaus Gold Series Serial No. 8338520113 (0.01 gr increments)			
Pipettes:*			
Test Sub. (Liquid)	Adjuvant		
<input type="checkbox"/> 5 ml	<input type="checkbox"/> 5 ml		
<input type="checkbox"/> 10 ml	<input type="checkbox"/> 10 ml		
<input type="checkbox"/> 25 ml	<input checked="" type="checkbox"/> 25 ml		
Cylinders:**			
Test Substance	Adjuvant	Carrier Water	
<input type="checkbox"/> 50 ml	<input type="checkbox"/> 50 ml	<input type="checkbox"/> 50 ml	
<input type="checkbox"/> 100 ml	<input type="checkbox"/> 100 ml	<input type="checkbox"/> 100 ml	
<input type="checkbox"/> 250 ml	<input type="checkbox"/> 250 ml	<input type="checkbox"/> 250 ml	
<input type="checkbox"/> 500 ml	<input type="checkbox"/> 500 ml	<input type="checkbox"/> 500 ml	
<input type="checkbox"/> 1000 ml	<input type="checkbox"/> 1000 ml	<input type="checkbox"/> 1000 ml	
<input type="checkbox"/> 4000 ml	<input type="checkbox"/> 4000 ml	<input type="checkbox"/> 4000 ml	
			<input checked="" type="checkbox"/> Scienco Flow meter

*The pipettes used to measure test substances or adjuvants are 5 ml, 10 ml and 25 ml (TD) plastic pipettes. The 5 ml and 10 ml pipettes measure in 0.1 ml increments and the 25 ml pipette measures in 0.2 ml increments.

**The graduated cylinders used to measure test substance, adjuvant or carrier water are 50,100, 250, 500, 1000 and 4000 ml. The 50 and 100 ml cylinders measure in increments of 1 ml, 250 ml cylinder in 2 ml increments, 500 ml cylinder in 5 ml increments, 1000 ml cylinder in 10 ml increments and the 4000 ml cylinder in 50 ml increments. Carrier water for airblast sprays is measured with a Scienco flow meter which measures water out to hundredths (i.e. 1.00)

Signature: David Ennes Date: 1-7-21

Page 9

Pre – Entering Data

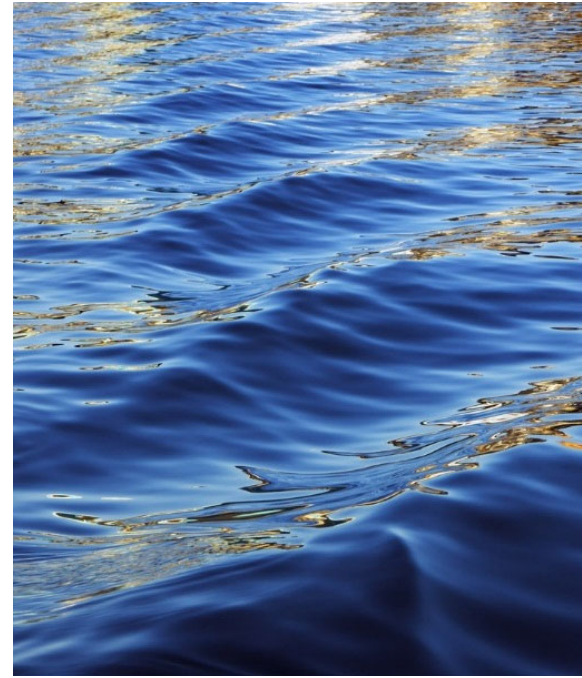
- QA has a relatively small chance of seeing this documentation occurring in the field. But in the true spirit of GLP, document what actually did happen and not what is going to happen later that day.
- If we see this in the field, we will question it, and whether this will be a finding is up to the QA. This type of documentation is not black and white. There are many hues of acceptable pre-entered data. Ultimately, documenting data as a result of an activity is the best practice.





Seed Treatment Trials

Sherita Normington



SEED TREATMENTS AND GLPS

EPA ADVISORY 45, May 1992

“While the control measures that you identified, i.e., chain of custody, secure storage, receipt, use, and distribution logs are not actually required of the treated seeds, their implementation will not conflict with the requirements of GLPS and may very well contribute to the overall integrity of the study”.



SEED TREATMENTS AND GLPS

Test substance is a substance or mixture administered or added to a test system which substance or mixture is the subject of an application for research or marketing permit.

- Chemical applied to the seed is the **Test Substance**.
- The treated seed is the **Test System**.

Apply requirements of test substance handling to treated seed:

- Verify amount of chemical applied to seed
- Identification
- Chain of Custody
- Storage
- Use logs
- Planter output calibration
- Balance calibration
- Container retention

Study Integrity and Good Science

Documenting GLP Training

“Each Individual engaged in the conduct of a study shall have education and training to enable that individual to perform the assigned function.”

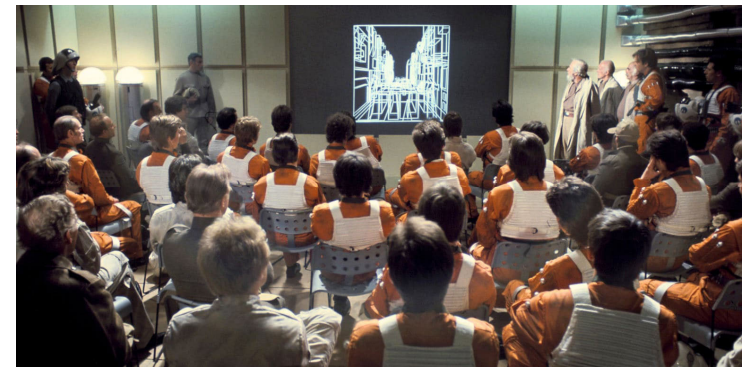
Documenting GLP Training


- Your training log should reflect all professional training, formal and informal. It should be reviewed and updated yearly just in time to be placed into a completed Databook.
- A QA reviewer is looking to see evidence of any GLP training. Often, there is no mention of this type of training for new field technicians in the Databook.
- An EPA inspector will not know that a National Education Conference or a webinar contained a segment on GLP. Stating this in the log is imperative to showcase that you have received this kind of training.

How do I document that I have been trained to participate in GLP residue trials?

Documenting GLP Training

- If a training event did not have GLP training segment, then it should not be in the title. You do not want to give a wrong impression that this kind of training occurred or you attended a GLP training event.
- If a GLP training event did occur and it is not in the title of an event, then add it. The National Education Conference or webinar will have at least one GLP topic discussed.





IR-4 Field/Lab/GLP Training



Western Region IR-4 Residue Trial Training

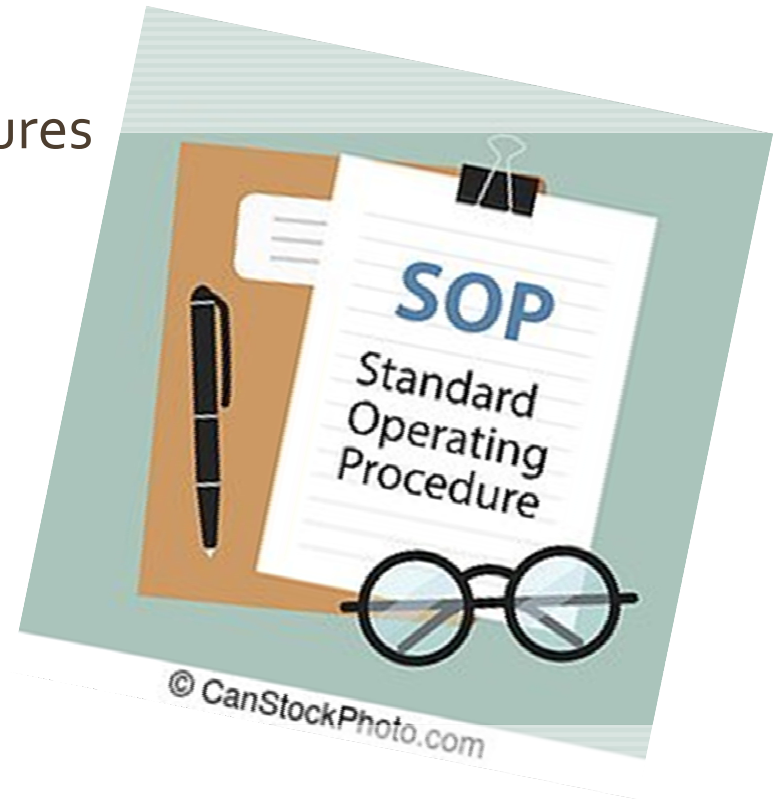
Documenting GLP Training

- Make sure to transcribe the entire title of an event to preserve the scope of the training event.
- Always be sure to highlight any GLP training in your log. This information should be brought to light. Reviewers are zeroing in on when the last GLP training event occurred. If they can't see any clear evidence of it, some questions will be asked.
- It is important to show the EPA that our field and lab folks have been trained in the GLP regulations. A current training log is one of the best ways we have to convey that.



STANDARD OPERATING PROCEDURES

- Short, concise, step-by-step procedures
- **Routine, repetitive** activities
- Readily accessible in work area



WHY DO WE NEED SOPS?

- GLP requirement
 - Facilitates consistency in quality and integrity of data
 - Allows each person to perform the activity properly
 - Useful for personnel training
 - QC, QA, Study Directors, and EPA to reconstruct the study
 - SOPs are for you, not just for QA
-
- READ them!
 - FOLLOW them!
 - REVISE them!

Thank You for Attending!

- Please send ideas for future training or questions to wrfield@ucdavis.edu
- **GLP training certificates will be sent to all attending**
 - If multiple people connected on one computer, send chat with all names + emails
- **Next Webinar:**
Tuesday, November 9th