



Western Region Training: Webinars and Meetings

Past Webinars and Training

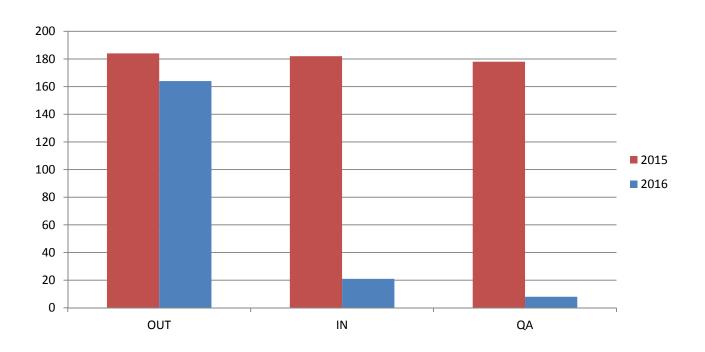
More Information

2016-2017 Training: Webinars and Hands-On Meetings

Webinar Time: 11:00 AM - 12:30 PM (Pacific Time)

Date	Topic(s)/Presenter or Discussion Leader
November 14, 2016	Webinar: GLP History & Practice – Field Office, QA and Lab
February 28 - March 1, 2017	IR-4 National Educational Conference, Orlando FL
April 10, 2017	Webinar: Topics TBD- Field Office, QA and Lab
July 10, 2017	Webinar: Topics TBD- Field Office, QA and Lab
November 6, 2017	Webinar: Topics TBD- Field Office, QA and Lab

Field Data Notebook Status in the Western Region



2015

- 182/184 received by RFC Office 99%
- 178/184 off to QA 97%

2016

- 21/164 received by RFC Office 13%
- 8/164 off to QA <1%

It's not done until responses to eQA are complete and SD signs off!

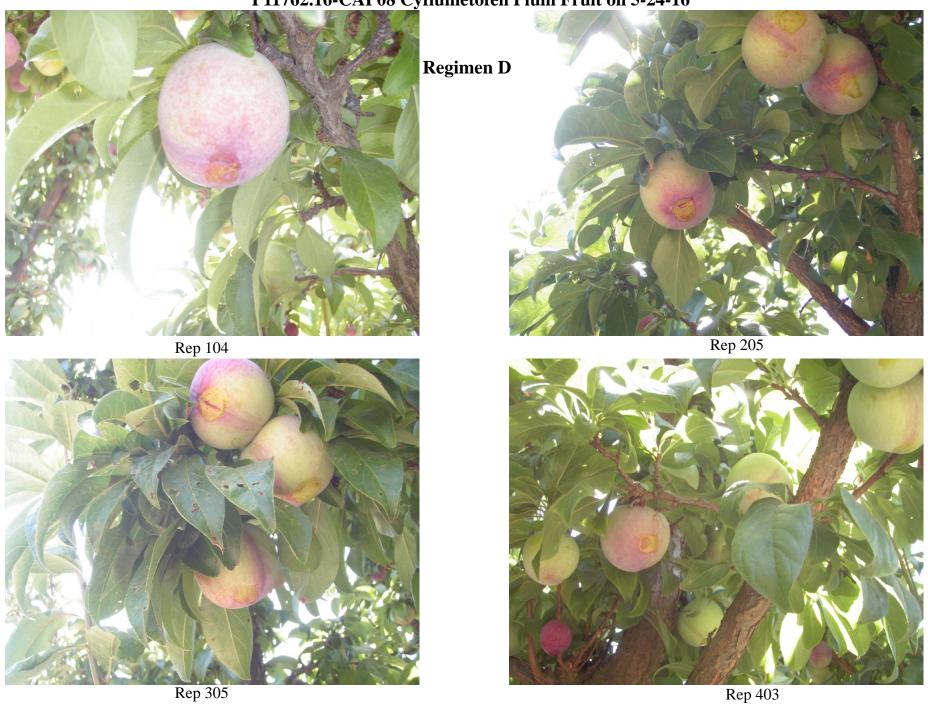
Wrapping up the year in the field...

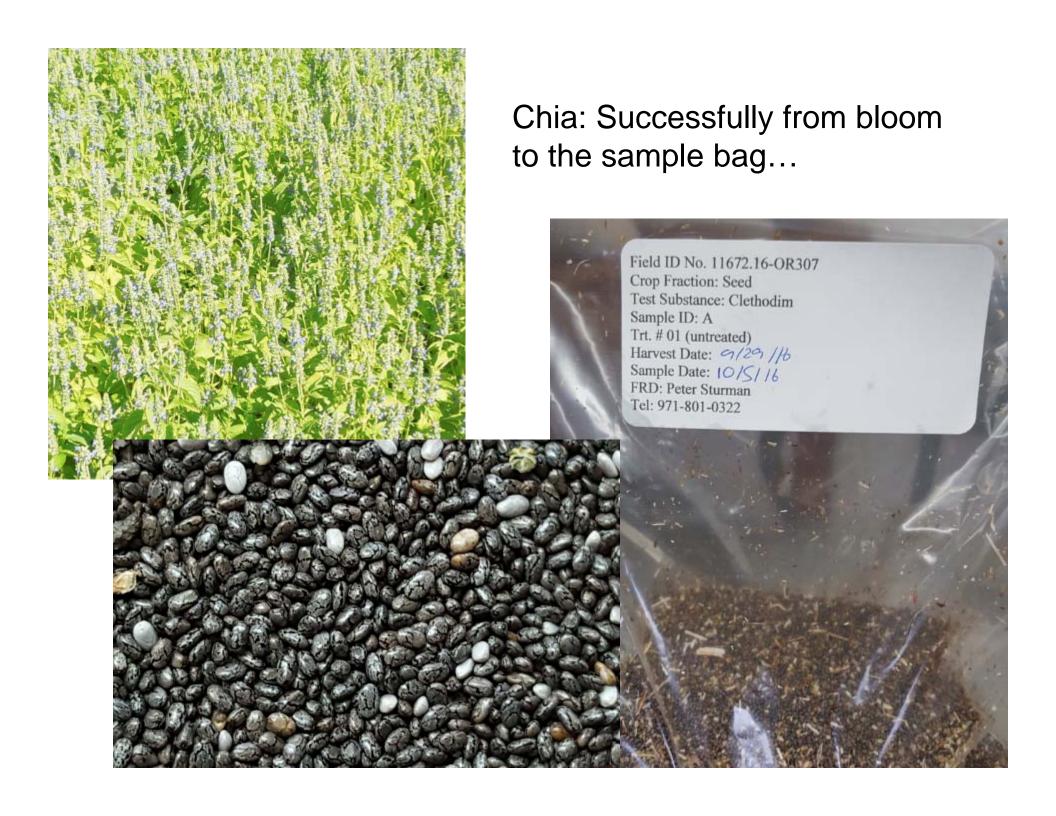
What's happened in 2016?

- -Crop Safety studies
 - Chia, Chia
 - More Sesame



P11762.16-CAP08 Cyflumetofen Plum Fruit on 5-24-16

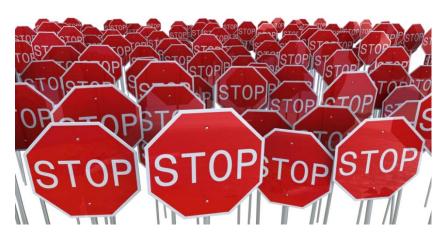






Sesame: Still lush and growing two months after cutting the water.

When something doesn't seem quite right



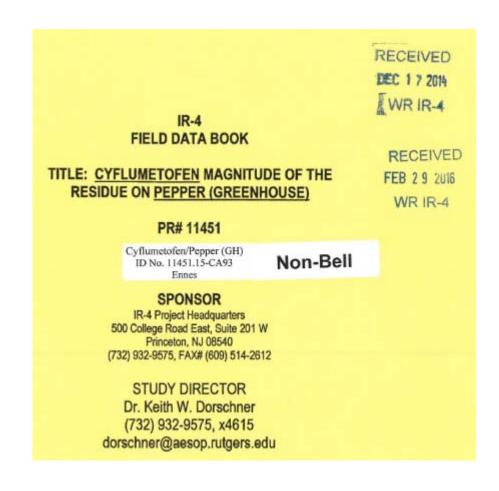






Focus on Notebook Pages

Field Data Notebooks





Revisiting the GLP compliance statement:

Remember:

What's Critical (Red)

What'sNot(Green)

WhatDepends(Blue)

GLP Compliant		nt	DATA CATEGORY
YES	NO	NA ¹	FIELD PERSONNEL SHOULD NOT LINE OUT BLANK CELLS ON THIS PAGE
	Х		Weather, irrigation, and soil characterization data are not required by the protocol to be compliant with GLP's and are noted as non-compliant in the final report for the study.
			TEST SITE HISTORY (chemical applications prior to the trial year) (FDB Part 5)
			CULTURAL PRACTICES (dating back to harvest of the previous crop), MAINTENANCE FERTILIZERS AND PESTICIDES (current trial year) (FDB Part 5)
			In U.S. trials, GLP-compliant equipment must comply with 40 CFR 160, Subpart D, which includes 160.81 (b) (11). Adjuvants in U.S. trials must comply with 40 CFR 160.83.
			ADJUVANT LABELING AND RECEIPT INFORMATION (check missing items): Receipt of the adjuvant at the field facility (usually the purchase date): Identity and concentration of the adjuvant (on the adjuvant label): Recommended storage conditions (on the adjuvant label): Expiration date (if not on the label, then assigned by field personnel):
			ENVIRONMENTAL MONITORING DEVICES for test substance storage (FDB Part 4)
			GLOBAL POSITIONING DEVICE used to determine plot location (FDB Part 5)
			FLOW METERS and similar SPRAYER OUTPUT CALIBRATION EQUIPMENT used to measure water (excluding marked, calibrated beakers, graduated cylinders or flasks suitable for scientific research) (FDB Part 6)
			pH METER or STRIP for measuring the acidity of the carrier (water) (FDB Part 6)
			RESIDUE SAMPLE WEIGHING EQUIPMENT (FDB Part 7)
			ENVIRONMENTAL MONITORING DEVICES for sample storage (FDB Part 7)
			List below additional non-compliant items (additional pages may be used for more items)

^{1&}quot;NA" should be checked for equipment that was not used in this trial and if adjuvants were not used.

Sampling Descriptions

How to write good harvesting/sampling descriptions



- Describe what you did not just repeating the protocol
- Use additional space if needed



Sampling Descriptions

Are all the protocol elements addressed?

17. RESIDUE SAMPLE COLLECTION:

All bulb onion trials: Collect two samples from each plot. Each sample should be representative of the entire plot (except plot ends). At 30 (±1) days after last application starting with the untreated plot, harvest the plots as done commercially.

All bulb onion trials. Bulb onions should be dried before sampling, if drying is a local commercial practice. If so, describe the drying procedure in the Field Data Book. The preharvest interval is the time between the last application and pulling the bulbs from the soil. If removal of roots, tops, and outer sheaths prior to drying and removal from the field is a local commercial practice, then that should be done at this time. It is acceptable to move the harvested onions from the field plots to a protected area for drying if environmental conditions will not permit drying in the field.)

At the appropriate time for onion collection following any drying time, collect a minimum of 24 onion bulbs per sample. Each sample should be collected during a separate run through the entire plot. Avoid sampling from plot ends. (If the onions have been moved for drying, it is acceptable to collect 24 onions per sample at that time as described above and place them in the drying area, keeping the samples separate.)

If excessive soil adheres to the bulbs, remove it by lightly brushing it off (document what is used to remove the soil or debris, e.g. a clean brush, clean gloved hand, clean dry towel, or similar method). If necessary, lightly rinse off with a minimal amount of clean water (do not scrub). Pat lightly while drying with clean paper towels. DO NOT RUB WHILE RINSING OR DRYING THE BULBS.

Samples should weigh a minimum of 4 lbs (but preferably not more than 6 lbs). If not done at harvest, cut off roots and tops and remove outer sheaths (or husks) on the sampling date. Retain trimmed bulbs. <u>Cut onion bulbs into quarters with a clean knife (unless they are very small) and retain all quarters for the sample. If the sample weight will exceed 8 lbs, then two quarters from each onion may be discarded, retaining opposite quarters.</u>



Start description on Part 7 A1



BRIEFLY DESCRIBE PROCEDURES UTILIZED TO HARVEST CROP. Provide enough details in addition to data entered above to ensure that protocol requirements have been met and to inform a data reviewer exactly how this crop was harvested. Examples: "Hand-picked berries from one side of the row, then the other. Collected fruit from high and low, exposed and shielded areas." "Barley was cut 3-4 inches above the ground with a scythe and left on the ground to dry for hay samples. Each entire plot was cut." ATTACH A SEPARATE SHEET IF NECESSARY.

Preked fruit from how and low areas
and from exposed and swelded grees. Fid
not pick the end byshes Fruit picked
directly into prelicing bucked. Fruit down and
Were harvested crop items collected directly into residue sample bags? YES NO can't
IF NO, PLEASE EXPLAIN Pouned trust than picking buckers
into labeled sig lock bag their into Elocu
ABOVE DATA ENTERED BY: Schools boig. COC DATE: CO-2415
PART 7 PAGE Trial Year 2015
Total number of pages in this section at initial pagination:

Finish on Part 7 A2

PART 7. SAMPLE COLLECTION AND STORAGE

A.2. GENERAL SAMPLING INFORMATION--Complete a separate form for each sampling date.

DESCRIPTION OF SAMPLED CROP STAGE (if different from harvested crop, such as dried plums, mint oil)

IF THE SAMPLING OCCURRED AFTER THE HARVEST DATE, DESCRIBE SAMPLE COLLECTION.
ALSO, DESCRIBE ANY MODIFICATIONS TO THE HARVESTED CROP SUCH AS TRIMMING, CLEANING,
CUTTING, DRYING AND/OR COMPOSITING SAMPLES. IF THE MODIFICATIONS ARE TOO COMPLEX TO
BE DESCRIBED BELOW, ATTACH A SEPARATE SHEET THAT CLEARLY DESCRIBES THE MODIFICATION
PROCEDURES

Include a description of equipment, duration of procedure(s), temperatures, estimated moisture content, etc., as appropriate.

Cont. the of stems. Picked from from
both sides of sincle rous. Rucad bac
in partie bug their recorded monget
and time of campie completion. Peternade
sepate run through pot to collect truit
for sample I, while I collected fruit
for Sample A were fireshed pured
both bace toraller into another play the
both bage together into another plus tree big their into cooler in back it truck

Type up on separate sheet and insert in notebook

Making sure to enter data promptly...

And beware the perils of copy and paste



Trifluralin / Sesame ID No. 11147.15-NM299 Hamilton

Trial Trifluralin/Sesame 11147.15-NM299

10-1-2015 B

Part 7. Sample Collection and Storage:

Sesame plots were harvested and sampled on 10-1-2015 from plots. CH and JG wore latex gloves during harvesting of the sesame seed. We used a Kincad small plot harvester to cut and thresh the sesame plant. The plant was harvested approximately 10 inches above the ground. Chris Peirce, Senior Research Specialist for the alfalfa-breeding program at NMSU ran the harvester. CH and JG collect the seed from the bottom of the harvester where the seed bin is located. Only the middle six rows of the sesame were harvested in both the untreated and treated plots. The first five feet into the plots and outside rows were not harvested. Plots are 60 feet long in both the untreated and the treated. At every 15 feet the seed bin was empty into the appropriate bucket. For the treated and untreated plots flags were placed at every 15 feet. Buckets A and B were used to collect seed. The first 15 feet seed was collected and placed into bucket A, the next 15 feet seed was collected and placed into bucket B, the process was then alternated throughout the plot. The same process was then repeated throughout the plot and conducted in the same manner for the treated plot. Latex gloves were worn and changed out between the untreated and treated plots. The small plot harvester was cleaned out by using a leaf blower to blow out left over debris and all screens and racks were cleaned out with leaf blower as well moving from the untreated plot into the treated plot. After all seed was collected into buckets A, B, C, and D debris was cleaned out of buckets containing seed by using a number 7 and number 6 screen. The number five screen was used for samples A and B and the number 6 screen was used for samples C and D. Once seed was clean, the seed was mixed thoroughly and a 2-pound sample was then taken from each bucket and placed into the appropriate labeled IR-4 bags. IR-4 bags, A and B were placed into the untreated transport cooler with blue ice and a min/max-digital thermometer. The max was 62 degrees Fahrenheit, the min was 32 degrees Fahrenheit. IR-4 bags, C and D were placed into the treated transport cooler with blue ice and a min/max-digital thermometer. The max was 64 degrees Fahrenheit, the min was 31 degrees Fahrenheit. Coolers with samples were then transported to freezers at NMSU, Skeen Hall.



Include pictures of harvest

Trifluralin/Sesame ID No. 11147.15-NM299 Hamilton





Include pictures of drying set-up



Flumioxazin+Pyroxasulfone'Grasses (seed crop) ID No. 10885.15-WA2 Groenendale

Grass drying in bean room for hay harvest samples:



In the fore ground are the Control samples from Trt #01. In the back in similar fashion are the Treated samples from Trt #02. The hay samples have a hobo to monitor the temperature as the material grass dries. We have to share this drying room so there are some alfalfa samples drying in the blue tarps in the center of the room.



JA 5/14/16



Include pictures of sample reduction



FORAGE SAMPLING

Imidacloprid/Corn (seed crop) 11270.14-HI195 Coughlin







TRIAL YEAR 2014

Sampling Descriptions

Common missing information

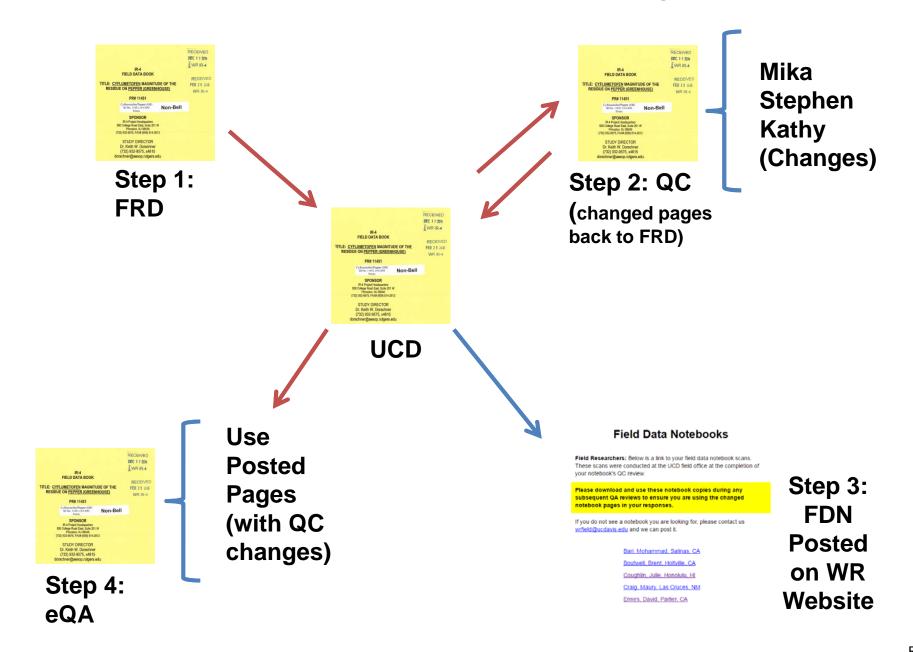
- Sampling equip (snips, etc.)
- How equip was cleaned
- Who collected which samples







Flow of Notebooks in the Western Region



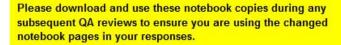
eQA Audit Responses

Please use the copy on the WR website for responses (it's the most complete version)



Field Data Notebooks

Field Researchers: Below is a link to your field data notebook scans. These scans were conducted at the UCD field office at the completion of your notebook's QC review.



If you do not see a notebook you are looking for, please contact us writed@ucdavis.edu and we can post it.

Bari, Mohammad, Salinas, CA

Boutwell, Brent, Holtville, CA

Coughlin, Julie, Honolulu, HI

Craig, Maury, Las Cruces, NM

Ennes, David, Parlier, CA

Groenendale, Dan, Prosser, WA

Hamilton, Cary, Las Cruces, NM

Kam, James, Honolulu, HI

Keenan, Debra, Chico, CA

Koskela, Gina, Aurora, OR

Kyser, Guy, Davis, CA

Leach, Nathan, Riverside, CA

Meeks, Will, Kimberly, ID

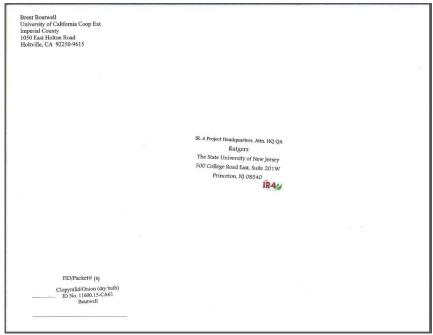
Mitchell, Michelle, Paso Robles, CA



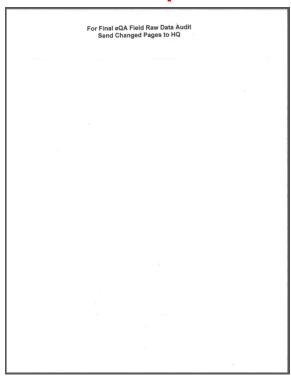
Hard copy notebook page changes

Envelopes (WR field office will provide) Send to HQ

Front of envelope



Back of envelope





Let's talk about drying hops....

Wet hops?
Thick bags?
Ideas?
Airflow?
Vent?





Drying Bags

Burlap standard

May take longer to dry

Make your own
Hole punch paper bags
(great idea Keri Skiles!)

WR Field Office has mesh drying bags available
We'll send upon request







EPA Inspection Highlights

- EPA currently down to two inspectors
- Master Schedule
 - Inspector should be able to independently select a current study.
- Cancelled trials
 - Include more detail in the amendment or correspondence when a trial is cancelled.
- QC reviewer's CV
 - Qualified to make authorized changes?



EPA Inspection Highlights

- UAN or antifoam products used as part of a tank mix should be labeled as reagents
 - Name
 - Concentration
 - Storage conditions
 - Expiration date



EPA Inspection Highlights

Pressure gauges in two places, tank and boom:

Read and record the pressure directly from the same gauge at both the calibration and the application

Don't transcribe!







SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

syngenta.

CGA169374/SYN545974 SC (125/075)

Version 1 - This version replaces all previous versions. Revision Date 05.08.2013

Print Date 05.08.2013

2.2 Label elements

Labelling: Regulation (EC) No. 1272/2008

FTH 545 / Cherry AAFC16-047R-229 Ennes

Hazard pictograms



Signal word : Warning

Hazard statements Very toxic to aquatic life with long lasting effects. : H410

Precautionary statements Avoid release to the environment. P273

> P391 Collect spillage.

P501 Dispose of contents/ container to an approved waste

disposal plant.

Hazardous components which must be listed on the label:

Labelling: EU Directives 67/548/EEC or 1999/45/EC

Symbol(s)



for the environment

R-phrase(s) : R50/53 Very toxic to aquatic organisms, may cause long-term

adverse effects in the aquatic environment.

S-phrase(s) : S2 Keep out of the reach of children.

S13 Keep away from food, drink and animal feedingstuffs.

S20/21 When using do not eat, drink or smoke.

S35 This material and its container must be disposed of in

a safe way.

S57 Use appropriate container to avoid environmental

contamination.

Additional Labelling Caution - this mixture contains a substance not yet fully tested.



SDS may have incomplete information

Proceed with caution



Resources on WR Website



Equipment Ideas & Examples



- · Greenhouse Sprayer
- · Airblast Sprayer: Drift Demonstration
- Fruit Pitters: Plums, Cherries/Olives
- Mazzei, Dosatron & Bulk Injector Systems
- CO2 Regulators for Backpack Sprayers
- Sprayer Output <u>Catch Jigs</u>
- Tractor Mounted Offset Boom
- How to Hit 5 GPA <u>Low Volume Applications</u>

Home | IR-4 | PST | Food Use | Ornamentals | Biopesticides | Resources | Events | Contacts | Webinars

Photo Library | Special Projects



How to hit a Low GPA without running through the plot...





Custom Notebook Pages

 Custom Pages from Field Research Centers (multiple sections of the notebook): KARE, UCD, DREC, WSU, NMSU

Application & Sampling

- Drip Injection Forms: Example, Template
- Measuring Devices: Kearney, UCR UH Example/Filled Out Form
- Commodity Drying Forms: WSU-Hay form WSU-Hop form Hop example form, Stover example form
- Application Warning Signs: <u>Re-Entry Signs</u>



Notebook General

- Deviation (2016) PDF Fillable
- . Memo to File: Example document

• FRD Planning Forms:

NCSU-Batts, OSU-Sturman, OSU-DeFrancesco, Univ of Idaho-Meeks

- Field Data Notebook Checklists: <u>NCSU-Batts</u>, <u>KARE-Ennes/Skiles</u>, <u>WSU-Groenendale</u>
- Field Data Notebook <u>Authentication Checklist</u>

Other

- Seed Treatment Studies: Chain of Custody Form
- Borrowed Equipment: Example Form

On the Origin of GLPs



The Dark Ages

- Before The GLPS "Trust" and "Faith"
- Good faith reliance upon the integrity of the sponsor submitted data
- General thought that the Data was "accurate, complete, unbiased, and told the complete story"
- No System of Periodic, Routine, On-Site Inspections of Facilities - Only "For Cause" Inspections

Where it all Began

• 1972 - Dr. Adrian Gross reviewed an article for pre-publication concerning the antibiotic Flagyl

 He requested clarification of the 1970 rat trial data submitted by Searle

 Individual animal data sheets appeared not to support summary conclusions

Searle (1974)

- Searle submits two mouse studies and "Corrected" report
 - Animal data sheets in the "Corrected" report had been changed to support the summary and not the other way around
- The "unusual" nature of the corrections triggers a series of "For Cause" inspections of Searle
- The investigators were unable to complete their investigations because Searle could not provide all requested documentation

Searle (1975)

- Aldactone: March 1975 Submission
 - Again, discrepancies between summary tables,
 statistical analyses and individual animal data sheets
 - FDA re-investigates Searle in July of that year
 - In July 1975, a Searle-submitted pathology report was also found by the FDA to have questionable results

A Taskforce Evolves

- July 1975 Kennedy Hearings on drug industry research
 - FDA concluded that it was necessary to investigate the animal studies submitted to the FDA in support of all 7 Searle products marketed since 1968.
 - Taskforce formed in Fall of 1975, reviewed 25 studies
 - FDA Commissioner informs Senators of FDA's findings

• January 1976 – EPA acknowledges that they found similar problems with their data submissions

The Findings of the Taskforce

- Poorly conceived, carelessly executed reported studies
- Inadequate education, training and experience of personnel
- Inadequate monitoring of contract testing labs by the sponsor
- Accuracy and completeness of report data was not verified

- Selective reporting of data and of contributing scientist reports
- Personnel were not supervised

It was unlikely that the test animals received the intended dosages.

The Plan

Based on the Taskforce Findings, the FDA Commissioner plans to:

- Inspect additional manufacturers and contract laboratories
- Develop a monitoring and audit system to assure quality animal studies
- Disseminate the standards for good laboratory practices





IBT (1977)

• IBT (Industrial Bio-Test) was an contract industrial product safety testing laboratory.

• IBT conducted safety tests for many of the major companies, the US Army, EPA, FDA, and WHO since 1953

• IBT data was used to support the marketing of many products in the USA and overseas

IBT (1977)

- Dr. Gross randomly pulls the IBT Naprosyn study for review after a sponsor employee questioned the data.
- The inconsistencies and questions raised led to two inspections of IBT (April, July 1976)
- "And what we found there is enough to make your hair stand up".
- Thousands of studies were revealed to be fraudulent

What did they Find?

- INACCURATE data
 - Protocol not followed
 - Poor animal husbandry
 - Made up data
 - Borrowed from other studies
- INCOMPLETE data
 - Some data lost, some never collected
 - All studies or data evaluations not reported

What did they Find?

- BIASED reporting
 - Data selectively reported and manipulated to support the desired result
- Sponsors and FDA were not fully informed about;
 - Study problems
 - Results of data detrimental to the desired goal

Craven Laboratories (1990)

• Craven was a contract analytical laboratory

• Favored by the pesticide manufacturers for high, consistent recoveries

 Performed studies for 260 pesticide companies, including Monsanto

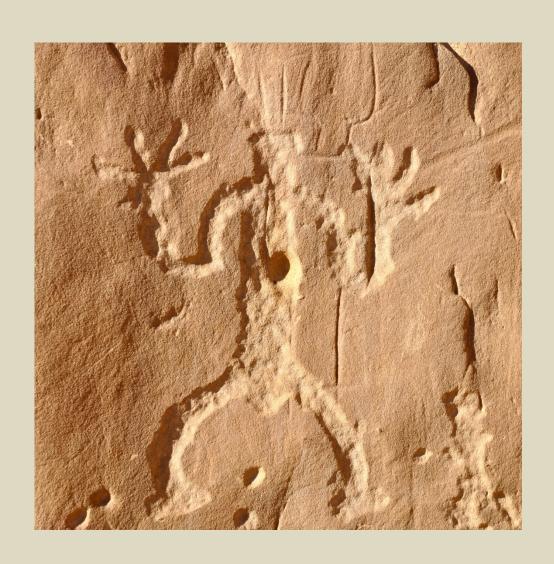
Craven Laboratories (1990)

- Anonymous tip by a QAO reported that Craven was falsifying data
- The Craven Tricks; over-spiking, diluting standards, altering peak heights
- EPA were prevented from entering building
- Court order issued and US Marshals were sent in
- Results; 14 employees were fined or imprisoned, Monsanto lost \$6.5 M

The Need for Quality Assurance

- Someone to inspect field trials and sample analyses to ensure integrity of the study
- Someone to review the study final report to assure that the results accurately reflects the raw data.
- Someone to ensure testing facilities are compliant with the GLPs

Questions



Deviation Déja Vu

Haven't we met before?



- Understanding intent of GLPs in relation to deviations
- Why be resistant?
- You can be right, but you still have to write...the deviation



Deviations

example	CHEMICAL/CROP/FIELD ID NO: Meeks
	IR-4 FIELD DATA BOOK
Will!	DEVIATION FORM (PHOTOCOPY THIS PART IF NECESSARY)
	THE DATE THAT THE DEVIATION OCCURRED
	THE DATE THAT THE DEVIATION WAS RECOGNIZED 9-26-16
	THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED 9-26-16
	METHOD OF NOTIFICATION (e.g. telephone, email, fax) (Include telephone notes or copy of email or fax in Part 3 of this book)
	THE DEVIATION IS FROM (check appropriate) PROTOCOL SOP'S
	SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED BRIEF DESCRIPTION OF DEVIATION: That for her yest and pick from
	more than 50% of the liver to on how ED, who 9-26-16
	Samples. Approx 1/3 of the bines, were sampled from in the UTC Mat only has than 50% of Treated
	Mat was harvested
	the bines due to look growing
	conditions Specific Reason unknown.
	9-26-16 WM
	ABOVE DATA ENTERED BY: 11 ill Meche DATE: 9-26-16

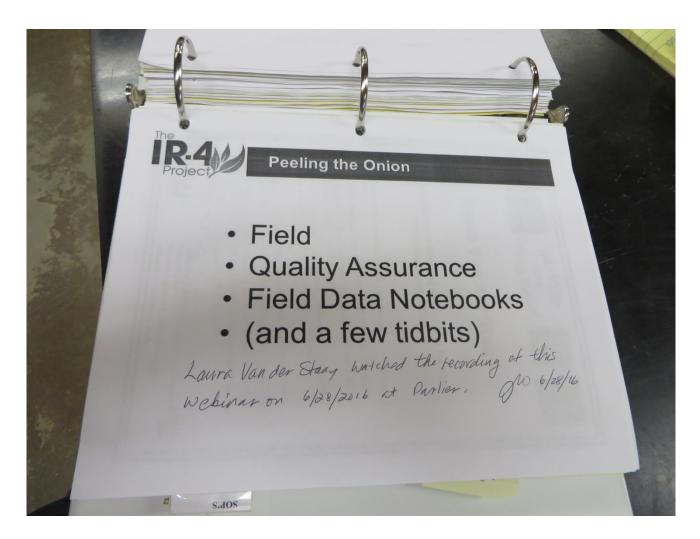
FIELD PERSONNEL: DO NOT WRITE BELOW THIS LINE



A good

Thanks

Documenting past webinars you watch



Also helpful to add the date of the webinar (e.g. June 2016)



Test Site History – Part 5 E

Test Site History of Perennial Crops



- Entire history of previous year's crop
 - From harvest to harvest
- Not just a calendar year before the trial start date

PART 5. TRIAL SITE INFORMATION

E. TEST SITE HISTORY FORM

INSTRUCTIONS: Complete this form or provide equivalent information. Enter all pesticide and fertilizer applications for the time period specified in the protocol, a minimum of 1 year prior to planting of an annual crop or 1 year prior to the cropping cycle of a perennial crop (e.g. all chemicals needed to produce that crop of peaches). Note the active ingredient applied, along with the trade name (e.g. carbaryl/SEVIN 80 S), the rate of chemical and the units measured (e.g. lbs active ingredient {ai} per acre or pints {pts} product per acre), the approximate date (at minimum season and year) the pesticide/fertilizer was applied and the crop growing on the plot.



MPT

2017 National Training

February 28-March 1, 2017

Rosen Centre Hotel in Orlando, Florida





Overview of meeting topics





Next Western Region 2017 Training Webinar

DATE: Monday, April10th

TIME: 11:00 am - 12:30 pm PDT

AUDIENCE: All

Topic: TBD



Western Region 2016 Training Webinars

Thank you for attending

Training documentation will be provided Concerns, Questions, Feedback

Mika Tolson, Stephen Flanagan and Becky Sisco (530) 752-7635, 752-7634 wrfield@ucdavis.edu