

# FIELD QA — BEYOND THE BOX

Please Note: No PI's or summer students were hurt during the making of this presentation. In addition all photo evidence was staged and no trials were compromised to create these photos.



# WHO ARE WE?



- Heather Griffiths MSc
- Contract QA in Canada since 2002
- EPA and OECD
- Wide variety of trials from residue, soil, pollination, aerial, processing – anything not in a lab
- Experience - PI at a CRO (VARs) in Canada in early 90's for a few years and then came back to QA in 2002 and have been doing QA ever since. My background is field research.



# WHO ARE WE?

- Lisa Wheelock-Roney
- Quality Assurance Auditor since 2005
- EPA GLPs, APHIS, EFSA
- Experience with RAC, biotech and biological trials.
- Lead auditor for Great Lakes Agricultural Research Service, Inc., and for hire for other research farms and labs.



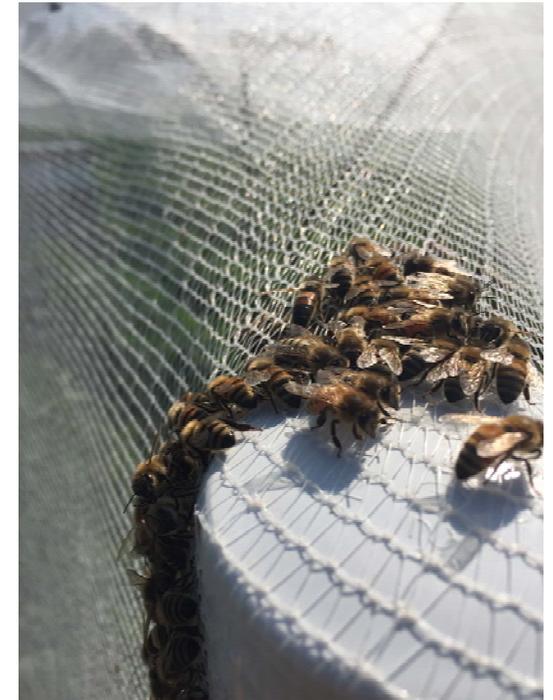
# WHAT IS THIS ALL ABOUT?

- This is not a presentation on basic GLP's or how to do the basics of an audit
- Scenarios that we have encountered in the field, in the lab and seen in notebooks
- Ideas on how to take your QA audits to the next level requires a different mindset
  - Look beyond appearances
  - Ask the right questions
  - Step back to get the big picture
  - Dive into data to be able to reconstruct what happened



# HOW DO I SEE IT ALL?

- Reality – you don't
  - You are only there for one critical event – usually.
  - Notebook audits require that you can recreate what happened.
    - Does what is documented in the notebook make sense?
- Look for evidence of what you haven't seen
  - Can you piece together what happened?
  - Ask questions.
  - Do some sleuthing



# BEFORE YOU GET THERE - PLAN YOUR AUDIT

- **Read** the Protocol/ Study plan
- **Prepare**
  - Is there something that you aren't familiar with? **Investigate**, if you know time will be tight ask questions before hand.
- Ex. First aerial application



# PLAN YOUR AUDIT

- Create a **study specific checklist**
  - Use your standard field checklist but also have notes on what the protocol/ study plan require.
  - Know what you are looking for before you arrive.
- Have an idea of what you expect to see in the field
  - What do you expect to see first and then after?



# LOOK UP FROM THE CHECKLIST

- Easy to get focused on checking the boxes
  - Take a step back and look at the bigger picture of what is going on.
  - Alternatively zoom in as well.
  - Have eyes for everyone.
- 
- Example
    - Spilled Test Substance
    - Could have had test substance in the UTC



# SCENARIO ONE — KNOW WHAT YOU EXPECT TO SEE

- Trial is pre-plant incorporate – the bare soil plot is sprayed and then a cultivator runs through the plot and then the plot area is planted.
- PI is offsite and is not able to use their equipment, so the co-operator has agreed to do the cultivation and the planting.
- PI makes the application
- PI then goes to set up the planter and make sure that the proper amount of seed is ready to go, as the area has to be planted within 2 hours of the application. There is some stress about making sure that runs smoothly so that timelines can be met.
- The co-operator lines up the cultivator in front of the treated plot.





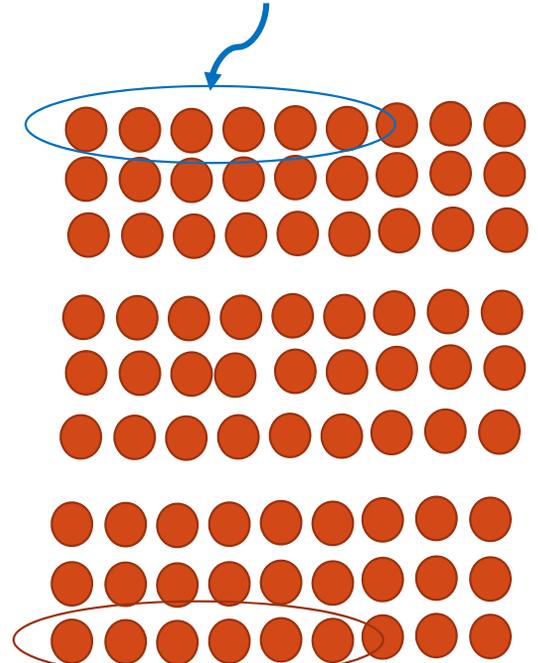
# SCENARIO 2: PLOT LAYOUT



Cherry Treated



Peach Untreated



Peach Treated

★ Cherry Tree

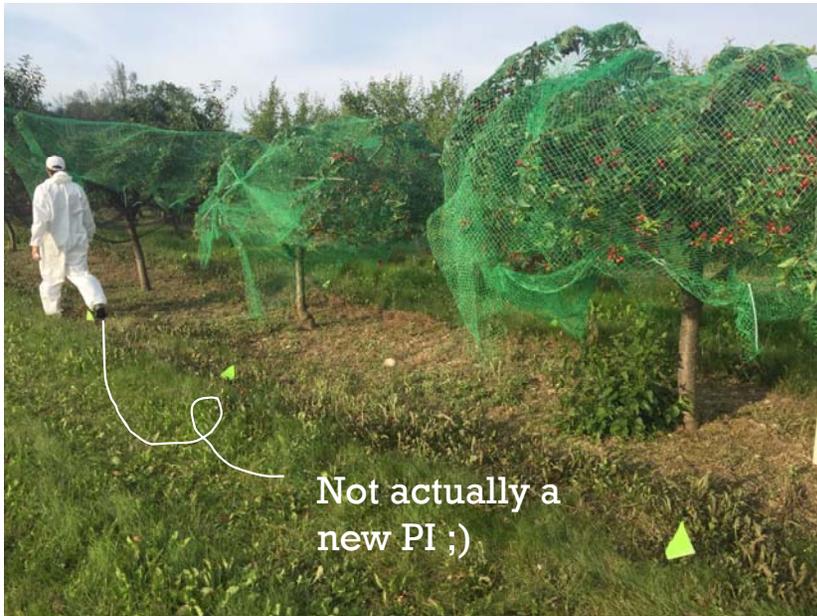
● Peach Tree



**WAIT A MINUTE!**



# SCENARIO 3: NEW PI



- We R G8 Inc. is run and owned by Joe Schmoe
- PI (Nancy) quits for a less stressful job, with one application left in this study
- Joe decides to hire a new PI, Fred, who is straight out of high school, with no field experience
- Joe goes out and does the application with the new PI



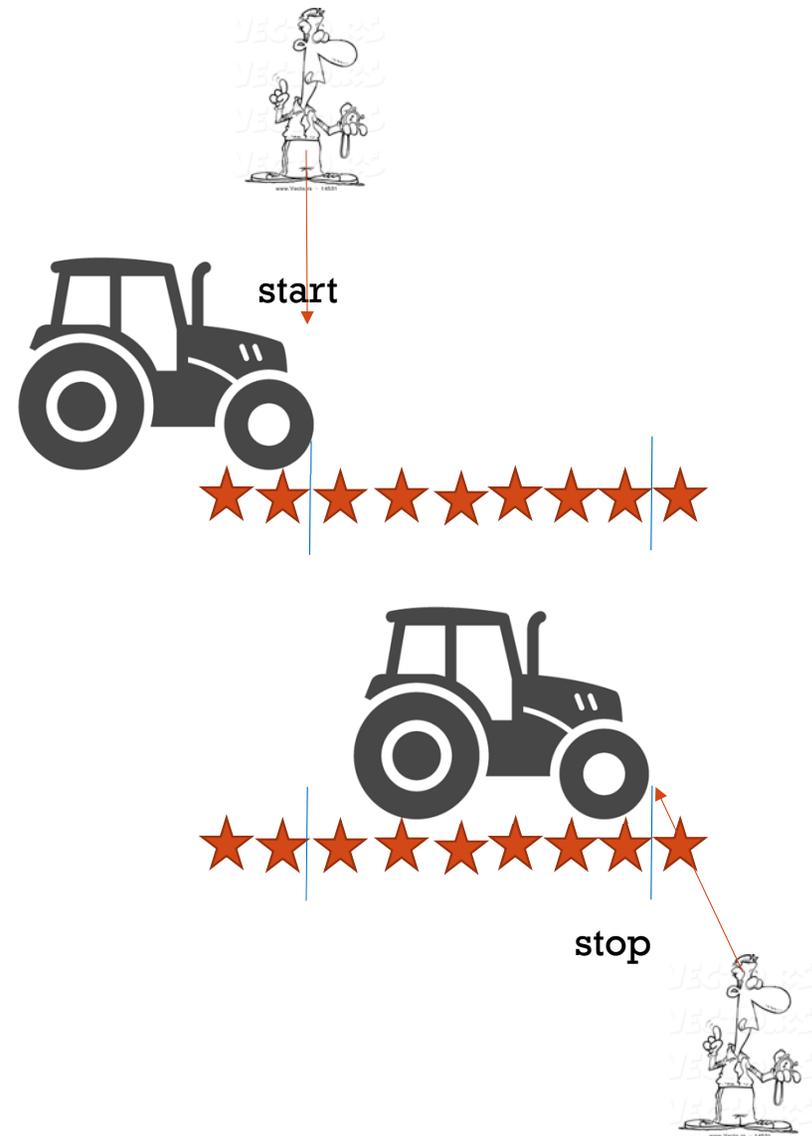
# SCENARIO 4: PASS TIME?

- Orchard application and the audit was the last application of 6, on a 7 day interval.
- The PI completes the calibration and the mixing.
- The ground speed calibration is completed while I am checking calculations
- Assistant is timing the application.
- You notice that the assistant starts moving before the tractor is even started to enter the plot and doesn't seem to stop the watch until the sprayer is turned off.



# PASS TIME ASIDE

- Timer placement crucial as well
- Lining up with the start of the plot and not viewing from an angle increases accuracy.
- Start – timer is lined up
- Stop – timer is not lined up, an element of guess has been added to when the nose actually crosses the line.



# PASS TIME?



- How much can one person do at a time?
- Can the applicator time themselves?
- It depends...

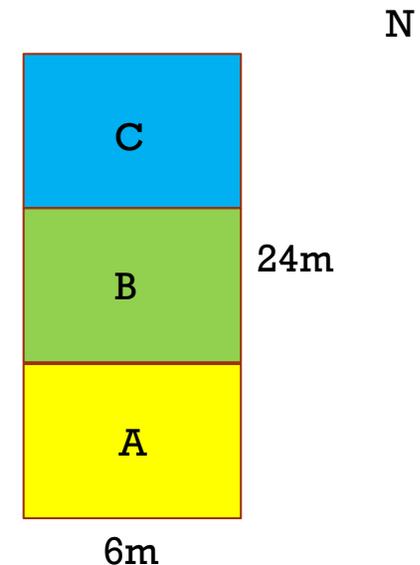


# PASS TIME ASIDE



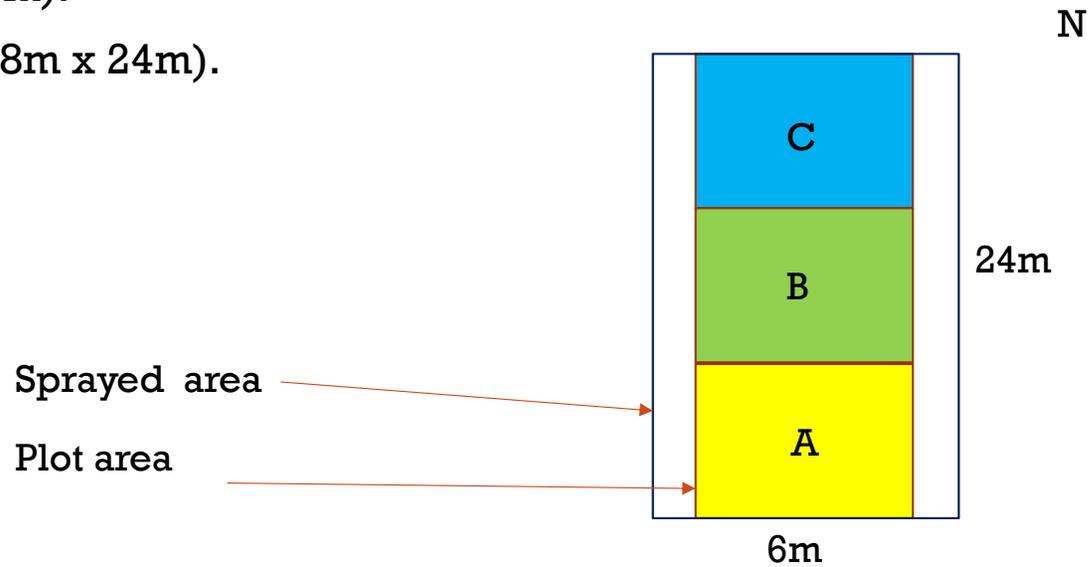
# SCENARIO 5: SPRAY CALCULATIONS

- Soil study with application on bare soil.
- 3 Sub plots
- Plot is 6m x 24m (0.0144ha)
- SD present and calculations checked by multiple people.
- Tractor mounted sprayer with a 16 nozzle boom, on 50 cm nozzle spacing

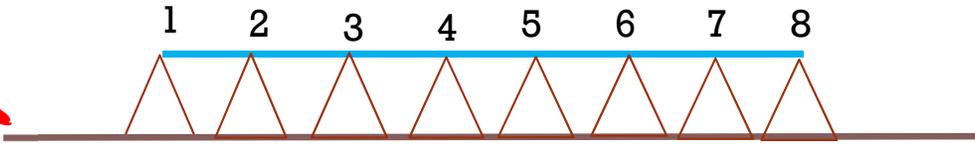
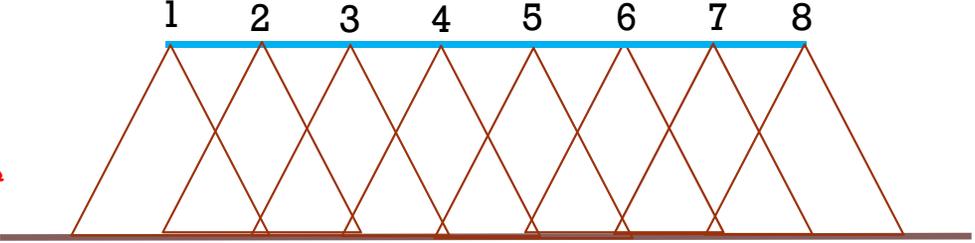
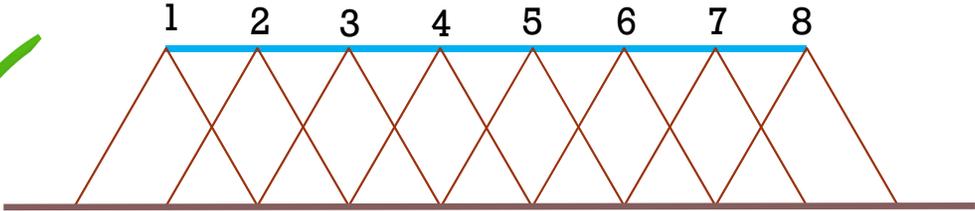


# SCENARIO 5: SPRAY CALCULATIONS

- Plot is 0.0144ha (6m x 24m).
- Sprayed Area 0.0192ha (8m x 24m).



# ASIDE: SPRAY BOOM HEIGHT



**WAIT A MINUTE!**



# SCENARIO 6

- Another incorporate trial.
- Trial was sprayed in the fall, incorporated and left over the winter and then planted into this spring after a second application and incorporation.
- This is a picture of the trial before the second application.



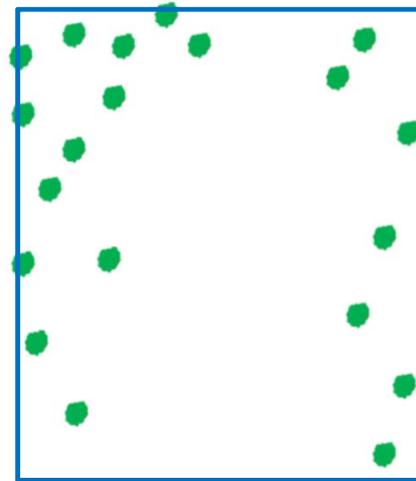
# SCENARIO 6

- You can see that one end of the plot the incorporation ran the length of the plot as expected.
- The top portion of the trial was cultivated in across the plot.



# SCENARIO 7

- You are auditing a late season spinach trial.
- The trial requires a 1kg sample and samples be taken from 12 different areas of the plot.
- UTC is full of plants and looks great
- TRT really spotty and not very many plants, especially in the middle of the trial



# SCENARIO 8 – TS USE

## 4.B. TEST ITEM USE LOG<sup>1</sup>

**INSTRUCTIONS:** Complete a separate form for each different container of test item used (i.e., different unique ID code). Enter details of each use of this Unique ID container on this form or provide equivalent information. If a transit<sup>2</sup> container is used for an application; ensure that this container is properly labelled with the Unique ID code, product or active ingredient name, the trial number, and the application number.

Does the Test Item match the product described in the Study Plan? Yes:  No:

Unique ID Code of Test Item: Cherry #1

UNLESS STATED OTHERWISE, ALL TEST ITEM AMOUNTS WEIGHED PRIOR TO THE APPLICATION DAY ARE STORED IN THE SAME AREA AS THE MAIN CONTAINER.

| Trial ID number | Application number or Purpose | Balance ID or Instrument used to measure (e.g pipette, syringe, etc.) | Amount measured units (mL) | Container TI measured into (e.g., 50 mL flask; 250 mL Nalgene bottle, spray tank, etc.) | Initials/ Date |
|-----------------|-------------------------------|---|----------------------------|---|----------------|
| 147, 148        | #5                            | Syringe   | 20 mL                      | Spray tank  | HK 1-Jun-2017  |
| 147             | #6                            | Syringe   | 10 mL                      | spray tank  | HK 8-Jun-2017  |
| 148             | #6                            | Syringe   | 10 mL                      | spray tank  | HK 9-Jun-2017  |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |
|                 |                               |   |                            |   |                |

HK 11-Nov-2017



# SCENARIO 9 SAMPLE TIMING

- A, B = UTC
- C, D = TRT

FIELD NOTEBOOK TRIAL ID: [REDACTED]

**7.A.2. SAMPLING PROCEDURES** - used for which samples (e.g.: A, B, C, D): A B C D  
 (To be completed only if Section 7.A.1 did not apply to Harvest & Sampling. Complete separate forms for each date.)

Sampling date (Date samples were collected and placed in sample bags): 15 Aug 2017

Description of sampled crop stage (e.g. mint oil, dried hops, etc.): mature fruit

| yes                                 | no                                  | n/a                      | Check « yes », « no » or « n/a » to indicate which conditions applied at sampling   |
|-------------------------------------|-------------------------------------|--------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | All samples were collected/handled using the same procedure.  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Untreated plot was sampled first (If no untreated picked at this date (decline trial), check n/a).  |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Treated and Untreated sampled by different personnel.   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Disposable gloves worn during sampling. If yes, check type. <b>Latex:</b> ___ <b>Nitrile:</b> ___ <b>Other:</b> ___                                       |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Gloves changed or hands washed with soap and water between samples  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | All sampling equipment was cleaned according to SOP before each sample is collected.  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Samples were placed in plastic bags which were then placed in the in the supplied residue bags.   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Samples were placed directly in the supplied residue bags (i.e.: were not double-bagged).   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Sample bags protected from touching plot areas at all times.  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Sample bags labelled with study, trial, and sample ID, crop, TI, sampling date, rate and PI name.   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Samples packed with <b>Blue ice:</b> <input checked="" type="checkbox"/> <b>Dry ice:</b> ___ <b>Wet ice:</b> ___ (check one) during transport to freezer. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Untreated and treated samples were placed in separate containers for transport to freezers.   |

**Describe any modifications to the harvested crop** such as trimming, cleaning, cutting, drying and/or compositing samples. If necessary, 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.

No modifications



# SCENARIO 9 SAMPLE TIMING



FIELD NOTEBOOK TRIAL ID: [REDACTED]

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| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> | Untreated and treated samples were placed in separate containers for transport to freezers.   |

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no modifications



### 7.B. SAMPLE INVENTORY

**INSTRUCTIONS:** Enter the sample IDs, crop fraction, # of fractions harvested per sample, dates samples were collected (do not enter the harvest date if different from sampling date), time of sampling, weight and PHI.

Balance ID: Mettler # 2

| Sample ID | Crop Fraction | Quantity per Sample <sup>1</sup> | Date of Sampling | Time of Sampling <sup>2</sup> | Weight (units)  | (PHI) | Initials / Date |
|-----------|---------------|----------------------------------|------------------|-------------------------------|---|-------|-----------------|
|           |               |                                  |                  |                               | Includes bag?<br>(check one)<br>Yes: <input checked="" type="checkbox"/> No: <input type="checkbox"/> |       |                 |
| A         | fruit         | 12                               | 15-Aug-17        | 10:01                         | 1.017   | 0     | HH 15-Aug-2017  |
| B         | fruit         | 12                               | 15-Aug-2017      | 10:15                         | 1.214   | 0     | HH 15-Aug-2017  |
| C         | fruit         | 12                               | 15-Aug-2017      | 9:35                          | 1.805   | 0     | HH 15-Aug-2017  |
| D         | fruit         | 12                               | 15-Aug-2017      | 9:50                          | 1.062   | 0     | HH 15-Aug-2017  |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |
|           |               |                                  |                  |                               |   |       |                 |



**WAIT A MINUTE!**



# EARLY MORNING AUDIT PERK

