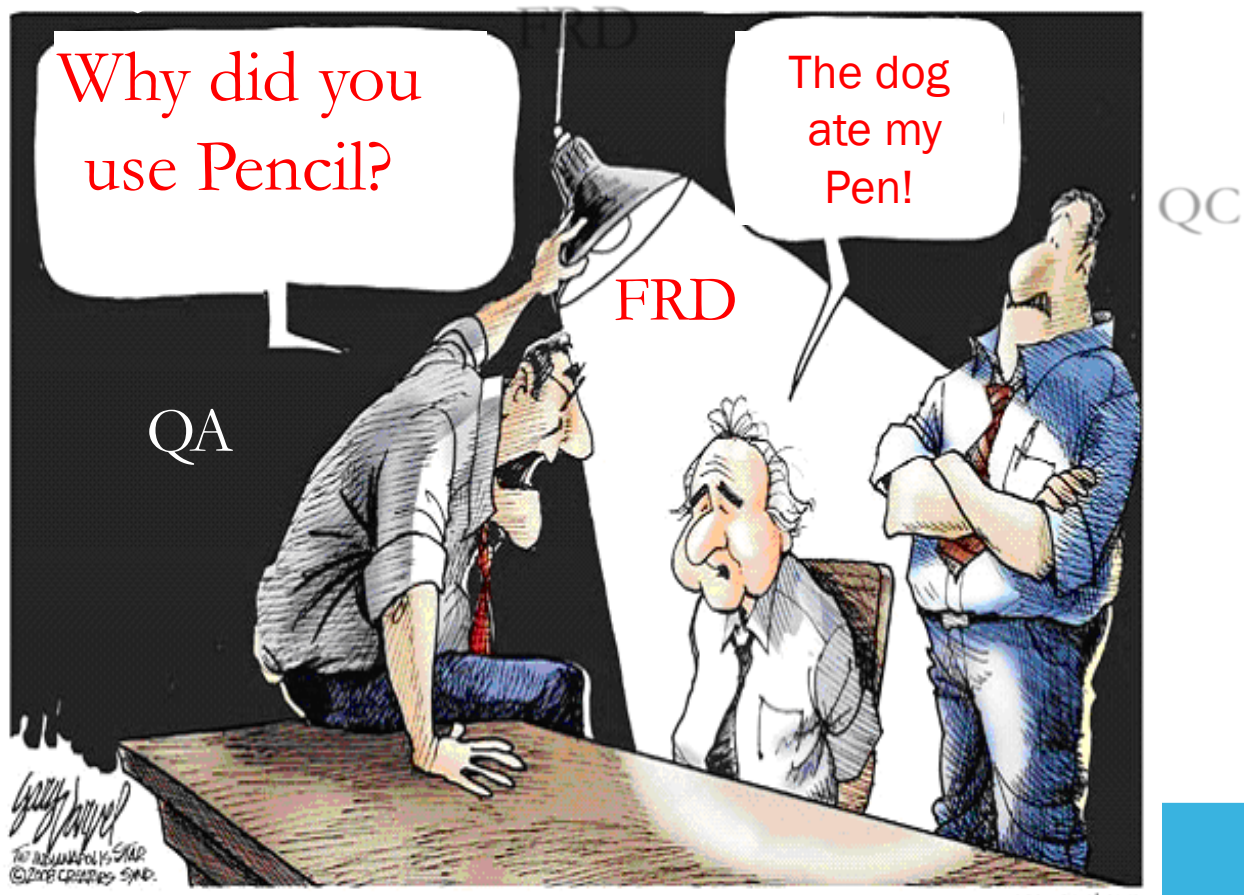
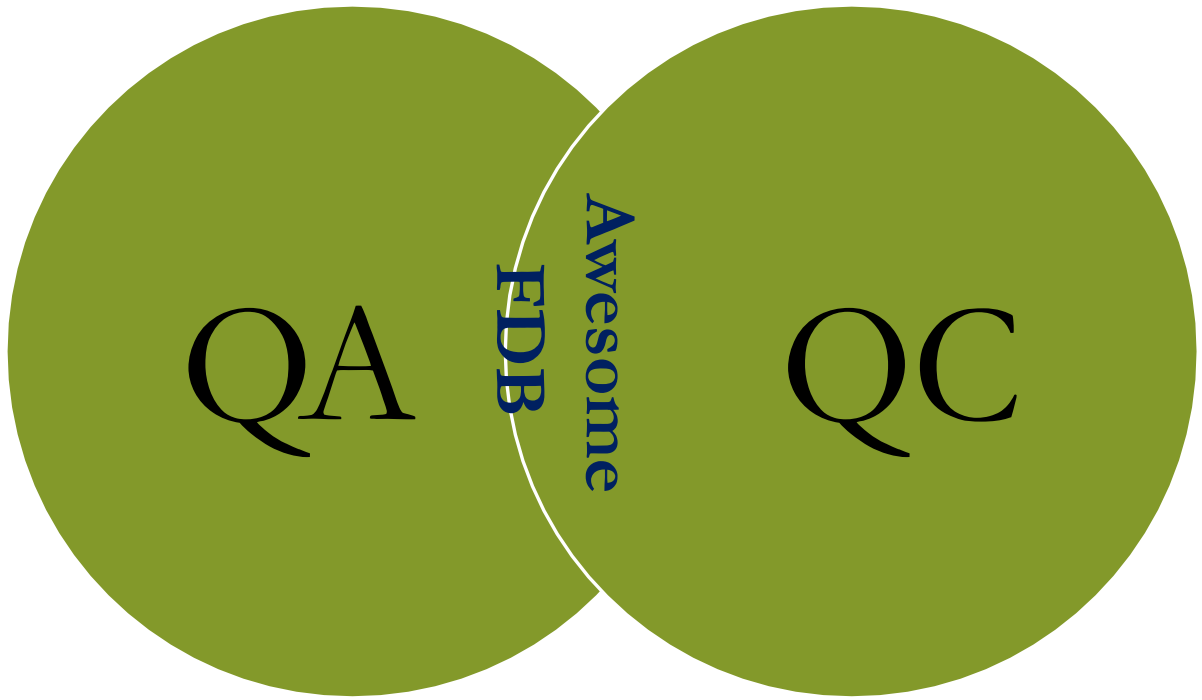
Working Together Towards Data Quality and Compliance Assurance

Grace Lennon and
Tammy Barkalow

Is this the way you see QC and QA?
It's you against THEM?



QA & QC



THIS IS THE WAY YOU REALLY SHOULD SEE QC AND QA!

QA vs QC

- Do YOU know any similarities? Differences?

SIMILARITIES

- **QC/QA** review the Field Data Book by focusing on the technical issues and GLP regulations.
- **QC/QA** look for any gaps in the data; examine the data for not only what is recorded but also assessing the data for what MAY BE MISSING.

DIFFERENCES

- **Quality Control** (QC) is an internal process to review data and verify that the work conducted meets the data standards both regulatory and technical

  "A part of quality management focused on fulfilling quality requirements".[1] ISO 9000:2005, Clause 3.2.10

- **Quality Assurance** (QA) is a regulatory required internal inspection/audit process to assure the research meets the 40 CFR Part 160, the Good Laboratory Practice Standards

DIFFERENCES, CONT.

- Some MAJOR differences between QA and QC is that QC can be part of the study and is obligated to sign the FDB upon receipt.
- **QC** can add data/documents AND make changes to the FDB with the FRD's PERMISSION.
- **QA** is NOT able to make changes to pages in the FDB. Any required changes need to be provided by you, the FRD or the SD with permission.

DIFFERENCES, CONT.

- **QC**, as a study participant views the data to assess the technical applicability of the processes used
- **QA** looks at the data to assess compliance with the GLPs and only brings up technical issues that may affect the integrity of the study

DIFFERENCES, CONT.

- **QC** verifies that the applications, timings, sample collection and other technical aspects of the trial are adequately explained in the data and are appropriate

- **QA** audits the data to assure the GLPs, protocol and SOPs were followed and that any differences from them are reported to the FRD, Study Director and Testing Facility Management

HOW TO REVIEW A FDB - 101

QC

First steps taken when a FDB comes in:

1) Sign book/log in

2) Print Checklist

http://wrir4.ucdavis.edu/resources/QC/Forms/checklist2014.docx

QA

First steps taken when a FDB comes in:

1) Sign book/log in

2) Print Checklist

http://ir4.rutgers.edu/QA/8.5%20R8%20Field%20Raw%20Data%20Audit.pdf

HOW TO REVIEW A FDB – 101 (CONT'D)

QC	QA
3) Obtain Protocol, Amendments & Deviations – all available on IR-4 website.	3) Obtain Protocol, Amendments & Deviations – all from the QA file, eDOCs or on IR-4 website.
4) √ pagination & Field ID labels on pages	4) Check eQA to see if an in-life inspection report is available for the trial (or other trials for the study)

KEY FACTORS

QC

- When reviewing PARTS 1-9 of the FDB
- All sections are reviewed for completeness and unused sections are crossed out.

QA

- When auditing a FDB the primary focus is:
  - Have the GLP compliance requirements been executed?

PART 1 – GLP COMPLIANCE

QC	QA
• SOPs, listed/Current. Reviews the data against the SOPs • Compliance Statement correctly reflects study (i.e., dry broadcast application	• SOPs listed/Current. QA reviews the data against the SOPs • Compliance Statement correctly reflects the study's departures from GLP requirements

PART 2 – PERSONNEL LOG

QC

- CVs/training records are current.
- Personnel listed on page 1 have CVs training records included.
- No additional personnel appear in the data without proper training documentation

QA

- CVs/training records are current.
- Personnel listed on page 1 have CVs training records included that verifies they are adequately trained to perform their functions
- No additional personnel appear in the data without proper training documentation

PART 3 – COMMUNICATION LOG

QC	QA
There are pages in FDB that request entries to be made in Part 3 either directly or indirectly. Ie., Part 8 – (Method of contact)	Does the communications log/section contain the correspondence for the trial and were entries made in a timely manner?

PART 3 – COMMUNICATION LOG (CONTINUED)

QC

- Look for continuity in email chains.
- If a question is asked, there should be a follow-up email that answers it.
- All trials SHOULD have some type of communication throughout the course of the trial

QA

- Ditto

PART 4 – TEST SUBSTANCE RECORDS

QC

- Most of the information on Page 1 is transcribed from other documents. Transcription errors may occur; good to verify these entries.
- Test substance use log (Part 4B) – be sure that it matches the entries in Part 6G.
- COA is present in data

QA

- Are the records complete, generated in a timely manner and cross verified to other areas in the FDB?

PART 4 – OTHER AREAS OF INTEREST (CONT'D)

QC

- Storage temperatures (high/low temps), MSDS, TS label, adjuvant label, and balance information for solid test substance

QA

- Was the test substance stored according to protocol, SOP and supporting documents?
- Are those records available, readable and cover the storage period?
- Was the material transported and did such transport concur with the storage requirements provided for the material?
- Is the data readable and collected according to SOP?

PART 5 – TRIAL SITE INFORMATION

QC

- Parts 5A-C – Be sure the narratives on these pages that request certain data are met.
- Does the plot plan have enough information to find the test plot in the future.
- Part 5C (Plot Plan) should agree with Part 5F (Test Crop Records); entries should match

QA

- Ditto, and:
- Does the data support that the plot met the needs as described in the protocol?
- Is the location of the plot sufficiently separated to prevent contamination?

PART 5 – TRIAL SITE INFORMATION (CONT'D)

QC

- Make sure Test Site History and Maintenance Chemical List do not have any similar chemistry as ts used.
- Crop Destruct – Information must show proof that the treated crop could not make it into the food chain.

QA

- Ditto
- If possible, compare the test site parameters of any other trials at this location to assure protocol requirements were met.

PART 6 – APPLICATION RECORDS

QC

- Most important advice – not to just verify the calculations that are recorded on these pages. (Don't review what is recorded ONLY; look to see what is NOT recorded.
- Take the information from this section and look at the protocol requirements. Calculate the application rate on your own; then check if you get the same results.

QA

- Ditto
- Was the application process and equipment used described in an SOP?
- Was the SOP followed?
- Was the maintenance of the equipment and its use adequately documented?
- Were the application participants adequately identified?

PART 6 – APPLICATION VERIFICATION

QC

(Excel Spreadsheet)

- Western Region website is a good source for calculation spreadsheets
- http://wrir4.ucdavis.edu/resources/QC/Calculations.html

QA

- Did the verification calculations verify that the protocol required rate was applied?
- Calculations maybe done using a spreadsheet or hand calculations
- If discrepancies result, the calculations should be provided. If not present, ask QA.

PART 7 – SAMPLE COLLECTION AND STORAGE

QC

- Find what data is requested in the protocol and be certain it is reflected in the raw data.
- All samples are correctly labeled and collected.
- Samples were placed into the freezers within the time noted in the protocol.
- Controls were handled as to avoid contamination.
- Any equipment used to harvest or dry samples has cleaning and maintenance records.

QA

- Ditto
- Samples were collected according to protocol and this is documented in the FDB (ie, high, low, representative, minimum number of fruit, etc.)
- If samples were reduced, is this adequately documented and the measures to prevent contamination addressed?
- If additional persons handled the samples, were they properly trained and this documented?

PART 8 – RESIDUE SAMPLE SHIPPING

QC

- Check amendments before shipping – was the lab changed after the protocol was signed?
- Paperwork was properly filled out.
- Sample arrival check sheet is present.

QA

- Ditto
- Ask - was the SD contacted (communicated with) and is this documented?

PART 9 – WEATHER DATA

QC

- Does the weather and irrigation data cover the start (planting: annual crops; plot set-up-perennial) and end of the study.
- The documentation of unusual weather conditions was recorded.

QA

- Ditto
- Was the location and distance from the plot provided in Sec. 10 of the FDB. Was this data representative?

ADDITIONAL INFORMATION

Jointly

- Are there unexplained data changes?
- Was pencil or white out used?
- Are there unreadable entries?
- Was the chain of custody log properly filled out?

CONCLUSION

QA versus QC