

Sponsor Management's View: QA Evaluation & Effectiveness



NAICC Annual Meeting, 1/21/2011, Kathryn Hackett-Fields, RQAP-GLP

IR-4... is the ONLY



**Publicly funded program that
conducts research and submits
petitions to EPA for pesticide
tolerances and clearances**





IR-4 has a unique QAU

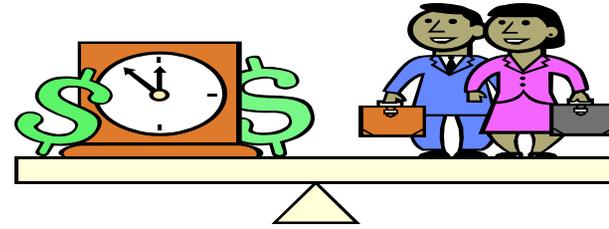
- **Four independent, Regional centers and Headquarters personnel comprise one QAU**
- **Contract auditors, or local university QA officers, may assist with audits or QC.**
- **Opportunities for discussion and group exchange are limited.**
- **Most Regional QA's travel "in season," while HQ personnel don't generally perform site inspections or CPIs, but are available when needed.**
- **QA staff supervision is done by the Regional /HQ Project Management Committee (PMC) members**



“Evaluation” of QA in a decentralized setting

- *Standardization* allowed us to reinforce One QAU:
 - One set of QA SOPs and checklists is used by all
 - Decisions are made based on group input & discussion or email
 - Our field raw data notebook template is used by all researchers being inspected/audited, which speeds collection and review
 - Our report format is also standardized to a large extent
 - “Advisories” guide researchers & others into consistency
- Variation contained, we then developed *standards*
 - Each QA responsibility was examined to determine how much *time* was typically needed for effective QA
 - Travel & recovery time; experience; size of data package; priority
 - Regional & HQ workloads were considered separately
 - We considered the impact of atypical projects or remote locations on both the researcher and the QA officer.

More Balance Achieved!

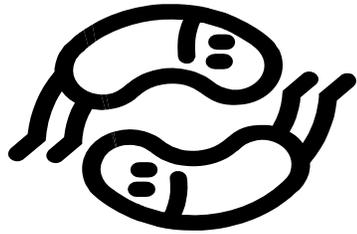


- When all impacts of travel throughout a Region for critical phase inspections & facility evaluations were considered, it was an eye-opener!
- Agreeing upon time frames for key responsibilities was worth the time spent.
 - Auditing of a “typical” field data book – most of a work day
 - Travel for a critical phase, possible overnight stay, doing the inspection and preparing the report – 2 to 3 days or more!
- We achieved a means to not only balance our work, but to evaluate our QA officers, as well as contractors.
 - These time frames are not used in a punitive or inflexible way
 - Newer QA’s can clearly see the QAU’s standards and use them as markers for their own progress.



HQ as QAU & Project Resource

- We improved and later expanded our archival capacity, providing a safe , documented repository to store and archive raw data, protocols, final reports and QAU records.
 - This served our QAU and field sites, reducing paperwork and procedural burdens
 - Improving the sharing of scanned PDF files of SOPs was a positive result of our increasing team work
- Electronic communication, such as the IR-4 Website, allowed us to notify the QAU and other personnel as needed for critical protocol and study changes.
 - QAU Management, the Registration Team and the Study Directors cooperate to manage priorities for submittal.



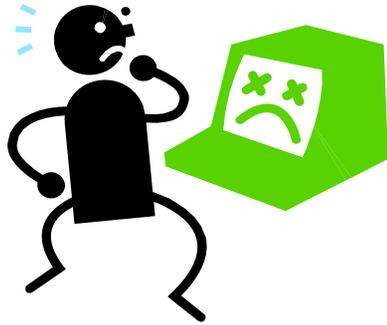
Evaluation of QA by Others

We have new perspectives coming from QA & also QC staff all of the time! But new viewpoints can also cause frustration in those being audited. Conflicts can arise without intention.



Yet, this feedback is very valuable. It helps us with QA evaluation, coaching and training. First, the real problems are isolated, to *depersonalize the audit*. What are the objections?

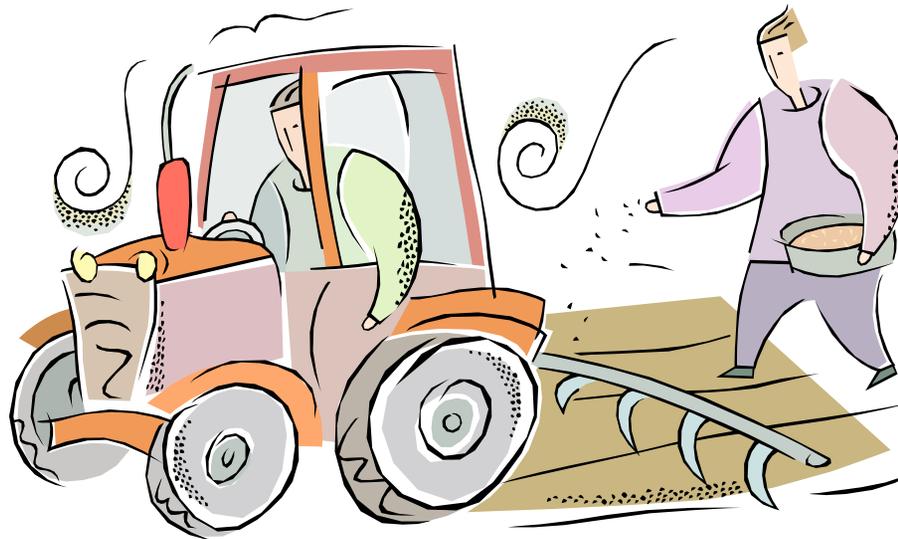
Sometimes, we can peg it to the new perspective brought to the process, and let it be a reminder of the complexity of GLP interpretation. This will point to a need for education.



Not the time for email!

These explanations are best made personally, or by phone. Email is a poor choice for training, persuasion or discussion of a sensitive issue!

Our field researchers (like yours) are busy people. They just need to know how to get the job done.





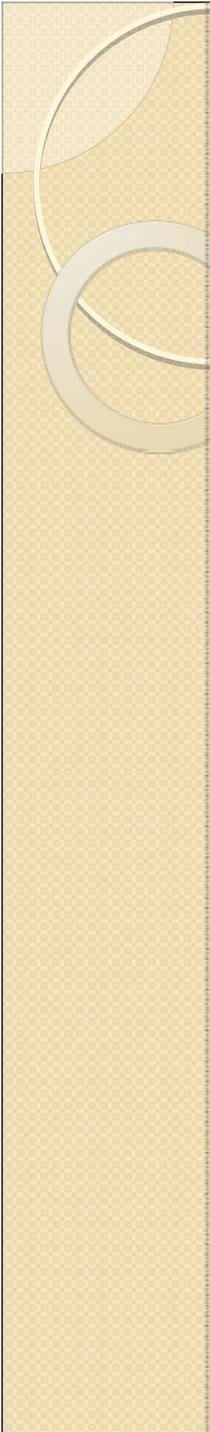
What do we consider “effectiveness” in our QAU?

- More than “knowledge” of GLP – we need to be able to tactfully educate and expand a field site’s expertise
 - Nobody wants to be *argued into* compliance!
- An appreciation of the complex & demanding nature of conducting GLP agricultural projects is essential
- Courteous and professional relationships with all
- Clearly-written audits with simple directions for response
 - Relative consistency within the entire QAU is a goal
- A willingness to contribute ideas in group discussion while remaining open to opposing views & solutions
- Responsiveness to change – especially where workload is affected – and regulatory or industry challenges.



Evaluation and Effectiveness

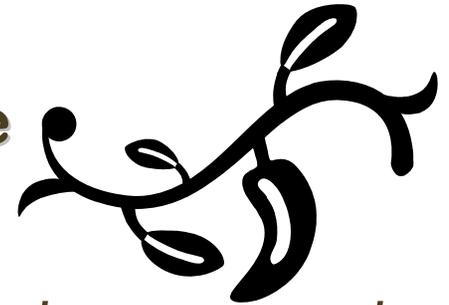
- Our QAU performs data audits of researchers within and outside of “their” Regions to increase uniformity
- Regional Research Coordinators receive feedback from the audited personnel, and pass this along to HQ
 - When necessary, discussions are held to rectify any misunderstandings or to explain why the issue is important
- Clarity in preparing audit findings, and asking for a particular response, is a key to our effectiveness. Therefore, it is always a part of evaluation of job performance for QA officers.
 - University researchers are faced with a wide variety of responsibilities and appreciate brevity, direction.



Ways you can benefit from our experience:

- Focus more attention on newer researchers, and after the inspection, allow time for discussion, education and asking questions of each other.
 - QA may not be aware of obstacles or confusion about how to carry out GLP projects
 - SOPs and Equipment – help your researchers “think GLP” when they prepare procedures for the staff, or when they plan to acquire new equipment.
 - Are there maintenance and use logs to be retired and archived?
 - Are facility records archived with enough frequency to avoid loss or damage of raw data? ETC!
 - Listen to your customers! Avoid placing blame. Focus on the issue to discover the true source of the problem. Thank the “complainer” for presenting an opportunity for improvement!

Sponsor QAU Evaluation, IR-4 Style



- By combining *standardization, standards, documents and perspectives*, we can evaluate a national QAU.
- Clear expectations allow resource allocation and goal-setting by newer QAs, and serve as evaluation tools.
- Listening to complaints is good!
 - It can uncover a larger problem
 - We use the events in a positive way.
- Self-evaluation is better!
 - Our QAU is committed to meeting future challenges and producing excellence.

