

Analytical Laboratory GLP Issues

FIRM FOUNDATIONS

NAICC ANNUAL MEETING 2013

LABORATORY QA – A PLACE FOR US!

- ✘ A few starting points were selected for this first session: Inspecting, Documentation & QA Role
- ✘ After today's session, some time will be devoted to taking suggestions for 2014
- ✘ Ideally, we would have a point person for the Lab QA personnel to help with communication

TODAY'S TOPICS AND PRESENTERS

- ✘ Inspections common to the laboratory
- ✘ Documentation helps and pitfalls
 - + Kathryn Hackett-Fields, IR-4 Project/Qualistat, Inc.
- ✘ QA Trending Reports
 - + Philip “Keith” Braddock, Monsanto
- ✘ QA Findings – effective writing
 - + Kathryn

(Thanks to Torrance Lee of Valent for his initiative)

SO, WHAT ARE THE “FOUNDATIONS” OF GLP?

- ✘ Accuracy
- ✘ Complete and consistent entry
- ✘ A study can be reconstructed from raw data
- ✘ Training: sufficient and recorded
- ✘ Personnel responsibilities understood/accepted
- ✘ Security
- ✘ Need for checks and controls

INSPECTIONS COMMON TO THE LABORATORY

- ✘ Critical Phase Inspection
 - + How do you select them?
- ✘ What do the GLP Preambles say we should include?
- ✘ Training Records
- ✘ Protocol
- ✘ SOPs
- ✘ Equipment, records
- ✘ And...
- ✘ Raw Data Audits
 - + How much and When?
- ✘ Criteria for quality – is there a QC step?
 - + Can you turn back a data package mid-audit?
- ✘ Value of tracing one sample from receipt to storage.
- ✘ Do calculation examples use actual data points?

WHAT ELSE?

- ✘ Checklists –
- ✘ When you see a problem –
- ✘ Random inspections – do you conduct these?
- ✘ “Edge” inspection points – have you looked all around or at the before-and-after aspects of procedures?

DOCUMENTATION ISSUES

- ✘ How can your forms be improved?
 - + Compare to the GLP requirements
 - + Review/audit periodically to prevent “carry-on” error
 - + Consider scientific and auditing information
 - ✘ Is the Equipment ID shown?
 - ✘ Units of measure, ratio (v/v), time, full date?
 - ✘ Study-specific details present?
 - + Method details, documentation of changes
 - ✘ What about communication, Study Director decisions – where & how are they documented?

EMAIL IN RAW DATA

- ✘ The field researcher shipped samples in Dec 2011
- ✘ Looking for receipt from lab
- ✘ Response – documentation was sent and added to the field raw data
- ✘ Do you have any questions?

WHICH “FOUNDATIONS” AFFECTED?

- ✘ **Standard Operations**
 - + If it's standard practice to return the form, what happened this time?
- ✘ Why is the communication important?
(Discuss)

DETECTIVE WORK!

INTACT FOUNDATIONS ARE CRITICAL TO SUCCESS

- ✘ We are the GLP and Quality System resources for our companies and clients.
- ✘ New equipment, technology still subject to the “old” GLPs – *the predicate rule*.
- ✘ Our value comes from providing information first, not correcting the defect – that is Management’s responsibility.
 - + BUT – make sure QA is brought into the discussion!