

Field Quality Assurance Professionals

“What your Sponsor wants you to know”

Annette Leslie, Quality Assurance Specialist

Pioneer Hi-Bred International

Email: annette.leslie@pioneer.com

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Outline of this Training

- QA vs. QC – *Understanding the difference*
- In-Process Inspections – *helpful hints to prepare for the inspection and tips to consider during the inspection*
- Raw Data Auditing of the Field Trial Notebooks (FTN) – *Objectives and past concerns*

QA vs. QC

Knowing the Difference

- **Quality Control**: Assuring a quality product is met by:
 - Assuring blanks are crossed through
 - Proofreading for grammatical and typographical errors
 - Checking units of measure
 - Checking calculations
 - Checking page numbers/study numbers, etc.
- **Quality Assurance**: Assuring the intent of the GLPs are met by:
 - Assuring protocols, and SOPs are followed
 - Assuring deviations are documented and reported
 - Assuring personnel are properly trained and that it is documented
 - Assuring equipment meets GLP & SOP requirements
 - Assuring problems are reported to management and study directors immediately

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General Approach to In-Process Inspections

General Approach to In-Process Inspections

■ Preparation for the Inspection:

- Review all protocols, amendments, and deviations that apply in order to familiarize yourself with the phase you are auditing.
- Prepare notes and have appropriate documentation with you during the audit (*copies of the protocol, amendments, SOPs, etc*).
- Prepare a checklist of requirements that you will be auditing against.

General Approach to In-Process Inspections

■ During the inspection:

- Verify whether the protocol, amendments and the appropriate SOPs were followed.
 - Is there good documentation of all events that may impact the study?
- Review raw data to date.
 - At a minimum, review raw data of the current phase being inspected.
- Review equipment logs for equipment utilized during that phase.
 - Were the SOPs followed?

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Raw Data Auditing
Field Trial Notebooks (FTN)

FTN Raw Data Auditing

Objectives to Meet

- Review the raw data to assure it accurately reflects the:
 - Protocol - has the protocol been followed?
 - SOPs

- Review the raw data to assure:
 - Observations made during the course of the study are accurate and reconstructable.

- Good documentation practices were followed according to your GLPS (study conduct section).

Previous FTN Concerns (continued)

- Chain of Custody Documents did not reflect what was actually received/shipped.
 - No GLP deviation on file
- During sampling, samples were not handled as per protocol requirement.
 - No protocol deviation on file
- Samples were not stored at the minimum temperature requirement as stated in the protocol.
 - No protocol deviation on file

Previous FTN Concerns (continued)

- Herbicide calculations and units were not correct.
 - Not corrected prior to returning the FTN to the Sponsor
- Plot maps/diagrams were not recorded as required in the protocol.
 - Not corrected prior to returning the FTN to the Sponsor
- Temperature & precipitation were not recorded for all days during the trial and no explanation.
 - Not corrected prior to returning the FTN to the Sponsor

Closing Remarks

- Remember, the protocol takes precedence over the FTN
- Always look for new ideas and improvement opportunities for your procedures, forms, and checklists!
- Look for things outside the ordinary
- Think outside of the box (look at training records during an in-phase inspection)
- Give feedback to your sponsor
- Seek answers from your sponsor QAU!

Last, but certainly not least...

- **Field QA professionals can add success to the overall process!**
- **Remember you are part of your Sponsors' QAU team. You give them a quality product that meets the intent of the GLPs!**

Questions?

Thank you for your time and attention today

Annette Leslie

Pioneer Hi-Bred International

Johnston Iowa

515-270-3967

annette.leslie@pioneer.com