Key Points for Critical Phase Selection and Inspection (Field Studies)

Rick Hoffman
Quality Assurance Specialist
Monsanto Regulatory Affairs
January 20, 2011
THE REQUIREMENT FOR A QA INSPECTION

160.35 Quality Assurance Unit, (b) The quality assurance unit shall:

3. Inspect each study at intervals adequate to ensure the integrity of the study...
CRITICAL PHASES

- These are study activities deemed by the Quality Assurance unit to be critical to meeting study objectives and ensure study integrity.
  - Adequate planning
  - Competent study execution
  - Sufficient documentation
- Critical phase inspections are part of the in-life inspections ‘suite”
THE QA BASIC BUCKET LIST

- Accountability
- Accuracy
- Traceability
- Appropriate
  - Personnel
  - Training
  - Methods
  - Equipment
  - Facilities
- Non-bias
- Documentation
  - Plans
  - Records/data
  - Reports
  - Amendments, deviations
- Change Control
Any and all activities that the SD identifies as being critical to completing the study successfully.

If people are going to be involved and they are supposed to do something, then it’s probably a critical phase.
IDENTIFYING CRITICAL PHASES

Specific activities conducted by people at the times & places directed by the protocol

- Study Startup activities
  + Seed organization
  + Plot preparation and identification
  + Planting

- Spray activities
  + Calibration
  + Material prep
  + Application
IDENTIFYING CRITICAL PHASES (CONT)

- Study Maintenance Activities
  - Weed/insect management

- Study Observation Activities
  - Growth stages
  - Stressors (diseases, biological, environmental)

- Sample Handling Activities
  - Sample container preparation
  - Sample collection

- Materials Disposal Activities
IDENTIFYING CRITICAL PHASES

Specific activities conducted by people at the times & places directed by the protocol

Activities that may be difficult to verify later
WHAT CRITICAL PHASE TO SELECT?

- Use a risked based analysis to determine the most critical phases
- Prioritize
- Try to have a plan B
MAY NOT BE A CRITICAL PHASE

- Training files
- Equipment records
- Characterization data
- Method validation
CRITICAL PHASE INSPECTIONS

Not a “snap shot in time” of the study...

More like a video clip
ONLY CRITICAL PHASE INSPECTIONS?

- In-life, non-critical phase
  - Chain of custody, freezer temps
- Facility and process inspections can be used as precursors to the critical phase study inspection
TIPS FOR THE CRITICAL PHASE INSPECTION

- Communicate & coordinate with the SD BEFORE showing up
- Inspect what you can before activities start
In General, observe – but *do not*:

- Be late
- Be unprepared
- Get in the way
- Distract study personnel
- Be part of study conduct
WHAT IF YOU FIND SOMETHING?

- They are in the middle of doing something **critical**...
  - Does it need to be brought to their attention NOW?
  - Give them a chance to find/fix it themselves
  - Consider HOW to communicate and to WHO
PART OF THE “INSPECTION SUITE”

- Critical Phase inspections do not stand on their own
- Non-critical phase inspections are still required
- All other inspection planning, scheduling, reporting rules apply
Critical Phases
- Direct affect on study integrity
- Unique to each study type
- Involve people doing things

Critical Phase Inspection
- Identify the critical phases
- Select the critical phase
- Do in conjunction with other inspections
QUESTIONS?

Contact information:
Rick Hoffman
Quality Assurance Specialist
rick.g.hoffman@monsanto.com