

# 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

# STUDY SPECIFIC CRITICAL BUCKET LIST

- ✘ 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 risk 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

## TIPS... (CONT)

---

- ✘ 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



# CLOSING THOUGHTS

---

## × 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](mailto:rick.g.hoffman@monsanto.com)