Quality Assurance Reports

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Agenda

- Facility Issues Tracking Report
- Monthly Characterization reports
- Periodic Report to Management
- TrackWise-FARMS
- Report distribution and Record retention

Facility Issues Tracking Report (FITR)

- Not a separate audit/inspection: Fed by phase, process, and facility inspections
- Issues that have the potential to affect more than one technical center or that require resolution that is beyond the scope of an individual technical center to resolve
- FITR is issued to TFM by QA management minimally quarterly when issues are present

Monthly Characterization Reports

- Characterization of test substances
- Issued monthly
- Individual audits with audit date in the audit month
- Individual audits closed in the audit month

Periodic Reports to Management

- Quarterly summary of all audit/inspections by technology center
- All audit/inspections previously reported individually

	Q3 (July-Sept 2013)	Q2 (April-June 2013)	Q1 (Jan-March 2013)	Q4 (Oct-Dec 2012)
Total # of QA Audits	81	46	36	19
Total # of QA Findings	51	25	29	17
Most Frequent Finding Types	Inadequate Documentation	Inadequate Documentation	Inadequate Documentation	Inadequate Documentation
	Data Inconsistency	Documentation Error	SOP Deviation	

Audits by Type		
Data	Report	Phase Inspection
26	21	34

Finding Classification	Definition
GLP Deviation	Departure from GLPs
Protocol Amendment/Deviation	Planned or unplanned changes to a protocol
SOP Deviation	Process or procedure was not performed as stated in the SOP where the recommended corrective action would be to document a SOP deviation
Lack of SOP/Procedure	No approved formal written procedure or process
Reconstructability	Data is not present to support conclusion, does not accurately reflect the activities or enable the reconstruction of events
Data Inconsistency	Conflict or disagreement exists within the data
Inadequate Documentation	Data which is expected, is missing
Documentation Error	Documentation or transcription error in the data
Calculation Error/Sig Fig/Rounding	Gives an incorrect result
Training Record	Lack of training or missing documentation of training
Report does not Reflect Data	not accurately reflect raw data generated or activities performed.
Report Error	Errors found within the report that are not a direct result of the data (e.g., copyright, incorrect reference, inconsistency in positioning, nomenclature, ect.)
Report Inconsistency	Conflict or disagreement exists within the report
Other	Cannot be classified in one of the other categories; used infrequently

TrackWise-Facility & Audit Records Management System (FARMS)

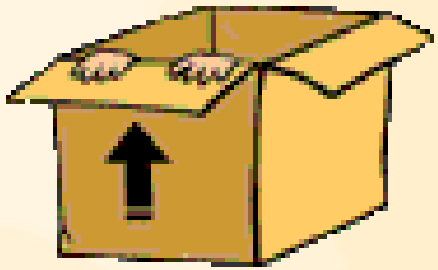
- Capture, maintain, and report audit findings
- Training Records
- Master Schedule maintenance
- Some archiving

Distribution/Retention- Current State

- Internal
  - Distribute via Microsoft Outlook e-mail
  - Retain TFM and SD ‘read receipt’
  - Retain scanned copy of any in-progress reports
- External
  - Distribute via **Fax**, Postal, or Hand deliver
  - Retain TFM/SD signature page

Distribution/Retention- Future State

- Distribution
  - Sharepoint – TeamSite Partners?
  - Password-protection?
  - Encryption?
  - Other?



- Retention
  - Evidence of sending?
  - Evidence of receipt?

Thank you

What questions do you have?

U.S. EPA GLP QA Requirements

§160.35 Quality Assurance Unit

- Monitor
- Inspect
- Periodic status reports
- QA Statement
- Maintain records

QA Statements

- To be included in final report
- List all inspection/audit dates and date reported to study director/management
- All phase, data, and final report audit/inspection reports must have been issued closed
- Does not include facility or process inspections

QA Statements

- Reviews conducted by the Quality Assurance Unit confirm that the final report accurately describes the methods and standard operating procedures followed and accurately reflects the raw data for the portion of the study conducted by Monsanto Company.
- Following is a list of reviews conducted by the Monsanto Regulatory Quality Assurance Unit on the study reported herein

  - Reviews conducted by [GLP CRO] are enclosed within the [GLP CRO] sub-report and are specified on their individual QA Statement.
  - Could incorporate CRO audits/inspections into our QA Statement.

E-signatures

- In-progress or closed audit/inspection report
- Identifies auditor and date of report issuance
- Hybrid system
  - In-progress: printed, signed/initialed, and dated
    - Scanned and attached to FARMS record
  - Closed: not printed, signed/initialed, and dated