Quality Assurance Reports

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Monsanto Company

NAICC 2014
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

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

**Audits by Type**

<table>
<thead>
<tr>
<th>Type</th>
<th>Report</th>
<th>Phase Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data</td>
<td>26</td>
<td>21</td>
</tr>
<tr>
<td>26</td>
<td>21</td>
<td>34</td>
</tr>
<tr>
<td>Finding Classification</td>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>GLP Deviation</td>
<td>Departure from GLPs</td>
<td></td>
</tr>
<tr>
<td>Protocol Amendment/Deviation</td>
<td>Planned or unplanned changes to a protocol</td>
<td></td>
</tr>
<tr>
<td>SOP Deviation</td>
<td>Process or procedure was not performed as stated in the SOP where the recommended corrective action would be to document a SOP deviation</td>
<td></td>
</tr>
<tr>
<td>Lack of SOP/Procedure</td>
<td>No approved formal written procedure or process</td>
<td></td>
</tr>
<tr>
<td>Reconstructability</td>
<td>Data is not present to support conclusion, does not accurately reflect the activities or enable the reconstruction of events</td>
<td></td>
</tr>
<tr>
<td>Data Inconsistency</td>
<td>Conflict or disagreement exists within the data</td>
<td></td>
</tr>
<tr>
<td>Inadequate Documentation</td>
<td>Data which is expected, is missing</td>
<td></td>
</tr>
<tr>
<td>Documentation Error</td>
<td>Documentation or transcription error in the data</td>
<td></td>
</tr>
<tr>
<td>Calculation Error/Sig Fig/Rounding</td>
<td>Gives an incorrect result</td>
<td></td>
</tr>
<tr>
<td>Training Record</td>
<td>Lack of training or missing documentation of training</td>
<td></td>
</tr>
<tr>
<td>Report does not Reflect Data</td>
<td>not accurately reflect raw data generated or activities performed.</td>
<td></td>
</tr>
<tr>
<td>Report Error</td>
<td>Errors found within the report that are not a direct result of the data (e.g., copyright, incorrect reference, inconsistency in positioning, nomenclature, ect.)</td>
<td></td>
</tr>
<tr>
<td>Report Inconsistency</td>
<td>Conflict or disagreement exists within the report</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Cannot be classified in one of the other categories; used infrequently</td>
<td></td>
</tr>
</tbody>
</table>
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