An Approach to Trending Findings

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What is “Trending Findings?”

- Trending findings involves tracking all findings by category in order to identify patterns, deficiencies, and strengths in systems and processes.
Why Trend Findings?

- To identify potential areas where process improvements are needed
- To measure the effect of process improvements after they are put in place
- To identify training needs
- To identify procedures that may not be clear
- To look for unexpected changes
Considerations when Trending Findings

- Inconsistency between auditors can make categorizing findings difficult
- Potential for strains on relationships with customers
- This trending process only trends issues identified by QA—items found outside of QA are not trended.
Tools needed

- Finding classifications
  - These are the categories into which findings are dropped and trended

- Electronic trending system
  - Difficult to track findings if they are simply recorded in word documents
  - Trending can be done simply in a system like MS Excel or Access or in a proprietary system that specifically meets your facility’s needs
Building Classifications

- Consensus is crucial
  - QA auditors must be consistent and agree on particular finding types
  - After classifications have been identified, they should be vetted with customers
    - Are they appropriate?
    - Are they in line with areas management would like to trend?
- Do not limit trending to data and report audits, include phase and facility inspections
Categorize findings by general error type (procedure, data, report, etc) and then sub-categorizing by specific error type.

Less is more
- Every finding cannot be its own classification

Accurate trending requires each finding to be reported separately—multiple findings cannot be combined.
Example of Finding Classifications

Fourteen Finding Classifications, in five Categories

- **Procedure/Plan/GLP Deficiencies:**
  - **GLP Deviation:**
    - A deviation or departure from a GLP requirement as cited in the appropriate CFR Part, Subpart or section.
    - Test substance was not characterized prior to initiation of the study
  - **Protocol or Plan Amendment/Deviation**
    - Planned or Unplanned changes or departure from any protocol, plan, or directive document.
    - Protocol stated to plant 12 rows, 20 feet in length, but, according to the data, 20 rows, 12 feet in length were planted
Example of Finding Classifications

- **Procedure/Plan/GLP Deficiencies (continued):**
  - **SOP Deviations**
    - Process or procedure was not performed as stated in the SOP
    - SOP requires the planter to be cleaned between planting each entry but data shows that planter was not cleaned until after the entire study was planted
  - **Lack of SOP/Procedure**
    - No approved formal written procedure or process exists
    - No procedure exists for operation of the moisture tester used in study.
Example of Finding Classifications

- **Data Related Errors:**
  - **Lack of Reconstructibility**
    - The data and/or documentation is not present to support the conclusions or does not accurately reflect the activities or enable the reconstruction of events.
    - Protocol stated that data was to be collected from rows three and four of each plot, but the row numbers were not identified in the data.
  - **Data Inconsistency:**
    - A conflict or disagreement exists within the data.
    - On one page the study notebook stated that a 10 GPA spray rate was used but on another page it stated a 15 GPA spray rate was used.
Example of Finding Classifications

- Data Related Errors (Continued):
  - Inadequate Documentation
    - Expected data and/or documentation is missing
    - Chain of custody documentation was not provided
  - Documentation Error
    - A documentation error or transcription error within the data
    - The raw data states that the plant height of plant five from row two of plot 12 was 15 in but transcribed spreadsheet gives a value of 14 in.
  - Calculation Error/Significant Figures/Rounding
    - Incorrect calculation, rounding, or significant figures were used.
    - Plot weight data was recorded to four decimal places (seven significant figures) but only two decimal places (five sig figs) were used in the yield calculation.
Example of Finding Classifications

- **Training Record:**
  - Lack of training or missing documentation of current training. This could be discovered in phase inspections or training record audits.
  - An employee has not documented reading the SOP on operation of the planter but his job description requires him to operate the planter.
Example of Finding Classifications

- **Report Errors:**
  - **Report Does not Reflect the Data**
    - The report does not accurately reflect the raw data or activities performed. This could include missing data to support the report.
    - The final report states that a four row planter was used to plant the trial while the data states that a two row planter was used.
  - **Report Errors**
    - Errors in the report that are not associated with the data.
    - A reference cited in the report was not listed in the references section.
Example of Finding Classifications

- Report Errors (Continued):
  - Report Inconsistency
    - A conflict or disagreement exists within the report.
    - A data table in the report stated that average yield for entry two was 54 bu/ac while the conclusions section lists the yield as 53 bu/ac.
Example of Finding Classifications

- **Other**
  - Any finding that does not fit into the other finding classifications. This should be used rarely.
  - This is case-by-case, so no examples apply here.
How to Report Trends

- Graphical methods are most effective
  - They allow management to “see” trends
  - Graphical methods are quite flexible
Example Trend Report

- GLP Deviation: 5
- SOP Deviation: 23
- Lack of SOP/Procedure: 3
- Reconstructibility: 10
- Data Inconsistency: 14
- Inadequate Documentation: 43
- Documentation Error: 68
- Calculation Error/Sig Fig/Rounding: 44
- Training Record: 62
- Report Does not Reflect Data: 59
- Report Errors: 16
- Report Inconsistency: 19
- Other: 5
Example Trend Report
Report Frequency

- How often do you report trends?
  - Monthly?
  - Quarterly?
  - It depends…
Watch Outs!!

- The number of findings per audit is not a valuable metric.
  - Data package size varies; study complexity varies

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  - Data package size varies; study complexity varies

- Findings are rarely ‘black and white’….this data should not be used as a personnel evaluation method
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Questions?