

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



Building Classifications (Continued)

- ❑ 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

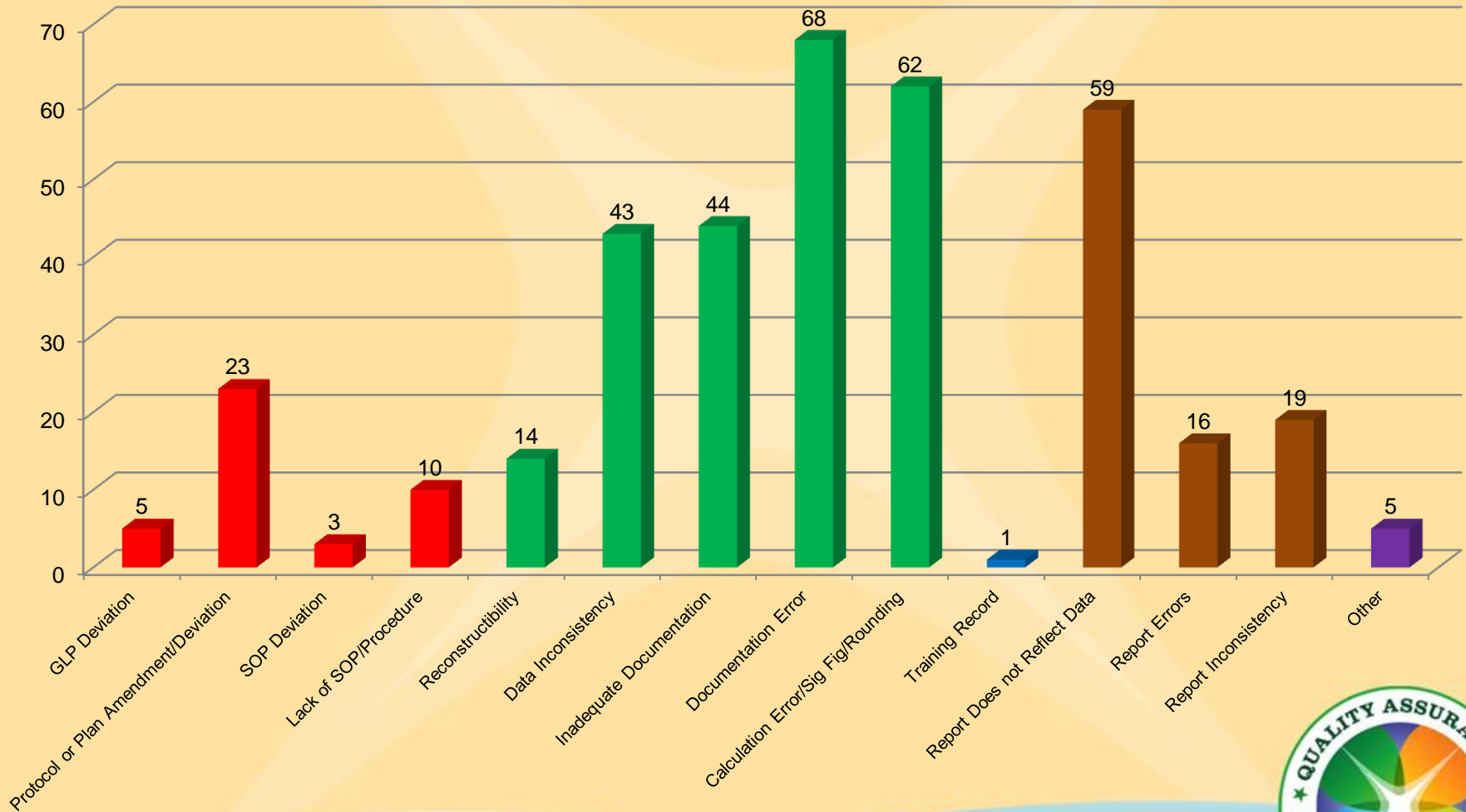


How to Report Trends

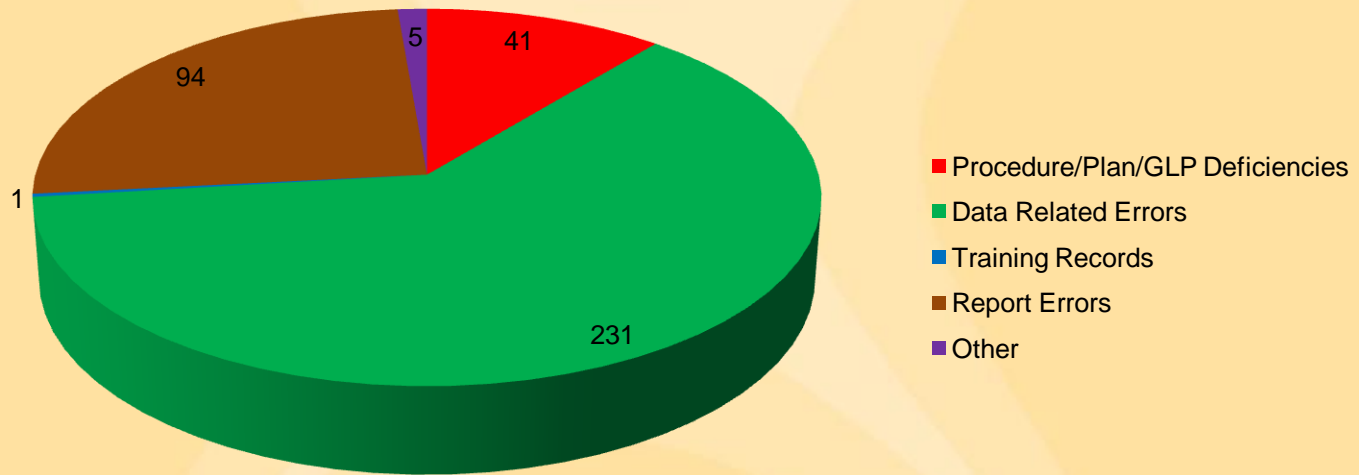
- Graphical methods are most effective
 - They allow management to “see” trends
 - Graphical methods are quite flexible



Example Trend Report



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
- ❑ The number of findings per researcher is not a valuable metric.
 - Data package size varies; study complexity varies
- ❑ Findings are rarely 'black and white'....this data should not be used as a personnel evaluation method



Acknowledgments

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Questions?

