FY 2022 GOOD LABORATORY PRACTICE FDA 483 OBSERVATION TRENDS

Acronyms

FDA (Food and Drug Administration)

GLP (Good Laboratory Practices)

QAU (Quality Assurance Unit)

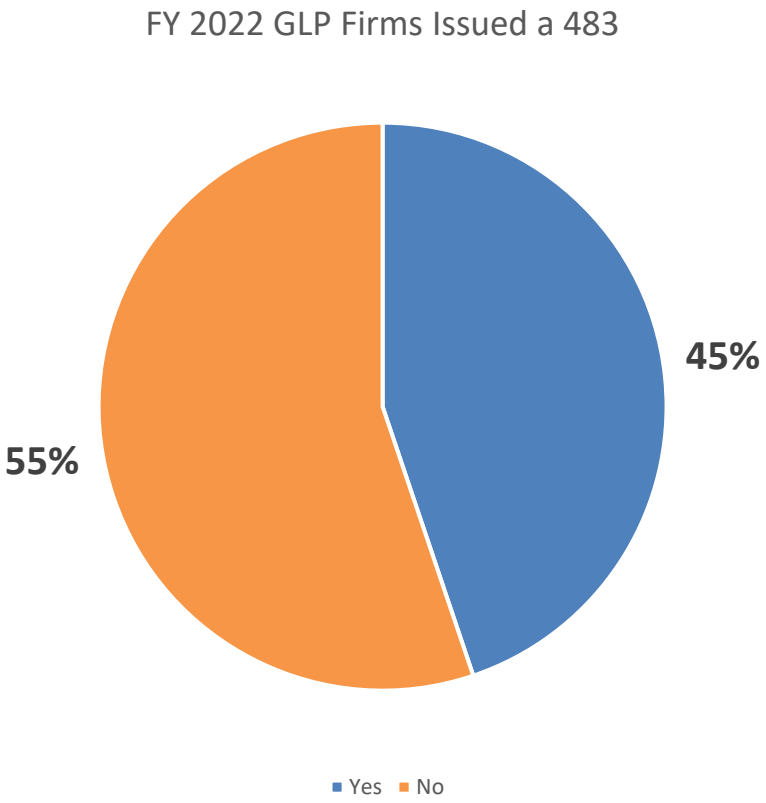
SOPs (Standard Operating Procedures)

Purpose

Broadly written regulations do not always convey the specific details of the observed violation(s).

FDA 483 citations issued during this fiscal year were reviewed and sub-categorized into more granular themes in order to identify trends.

These data slides are the result of the sub-categorization efforts.



During FY 2022, of a total of 29 nonclinical inspection conducted, significant observations were noted resulting in the issuance of Form FDA 483 Inspectional Observation to just under 50% or 13 inspections.

At the conclusion of these 13 inspections, 78 significant observation cited.

Following slide will discuss the top three areas where deficiencies were noted during the inspection.

Trends and Themes Identified in FY 2022 GLP Data

Training – inadequate training at multiple levels

Failure to follow written procedures

Study Director oversight

Training

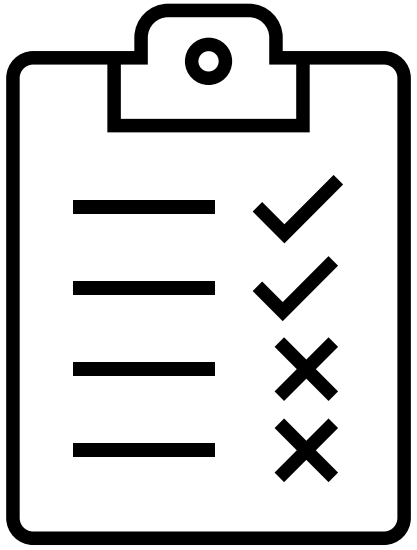
FY2022, significant observations were cited 41 times which could be attributed to lack of or inadequate training such as:

- Deviations from the study procedures without proper documentation or approval
- Employees not understanding their roles
- Equipment not being calibrated timely
- Errors in the final study report
- Inadequate labeling of test articles
- Failure to ensure all data are recorded and verified
- Failure to document unforeseen circumstances
- Failure to have all procedures required by regulation

Standard Operating Procedures

Failure to have or follow a written procedures were cited three times in FY2022 such as:

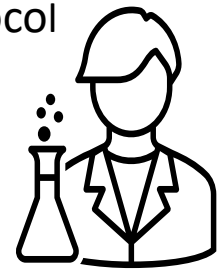
- Failure to establish a standardized reporting of test result which resulted in the repeat test or dilution factors not being report.
- Procedure failed to specify the time samples may be held prior to testing.
- Failure to use the appropriate form for calibration of balances.



Study Director

Study director is responsible for overall conduct of the nonclinical laboratory study
Observations related to the study director were cited ten times in FY22 such as:

- Failure to ensure the protocol adequately defined criteria for evaluating target organs resulting in the employees mentally making notes of gross observations.
- Failure to ensure the calculation for anesthesia were accurate.
- Failure to ensure software modules used for dose calculations were validated.
- Failure to ensure all equipment were calibrated or standardized prior to use in the study.
- Study data in the final study report were being edited by the CEO not the study director.
- Failure to report all adverse events in the final study report.
- Failure ensure all study documents have been archived such as the signed protocol amendments
- Failure to ensure the test article was stored as specified in the protocol
- Failure to ensure the test article was administered as required by protocol



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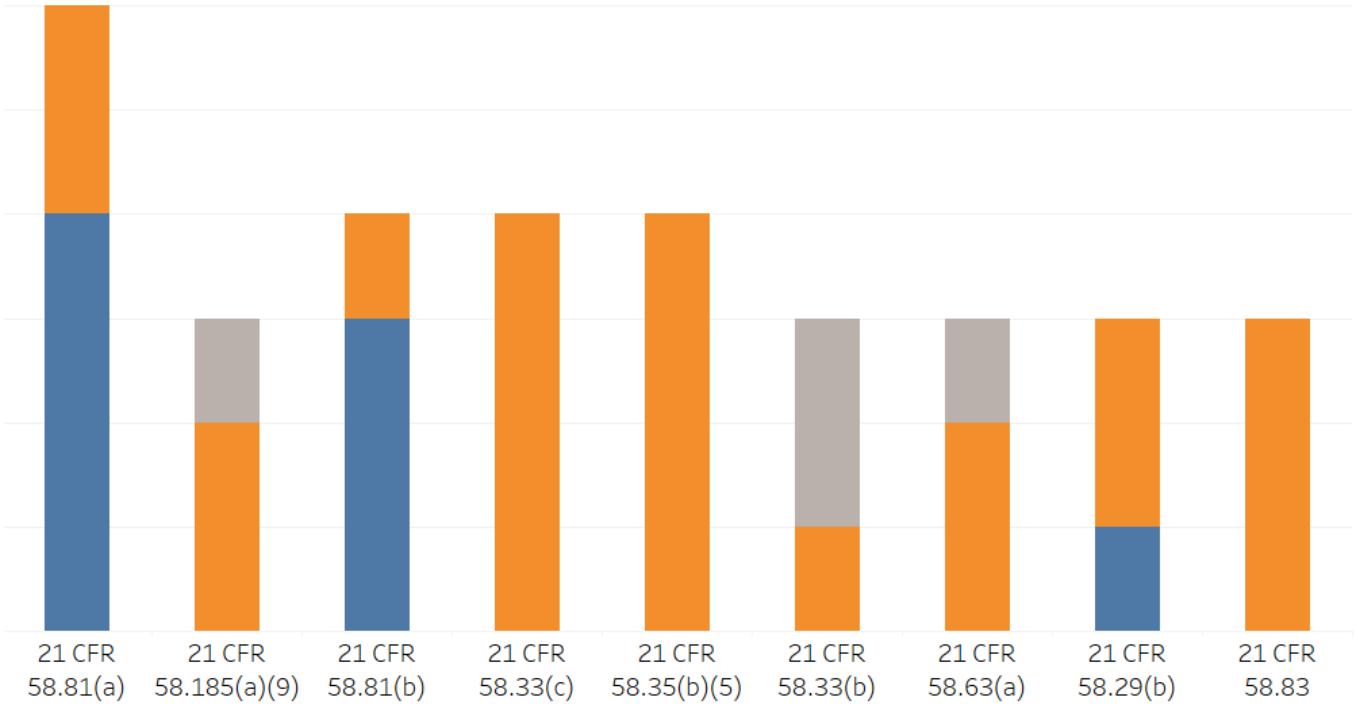
FY 2022 GLP Top Cites by Theme



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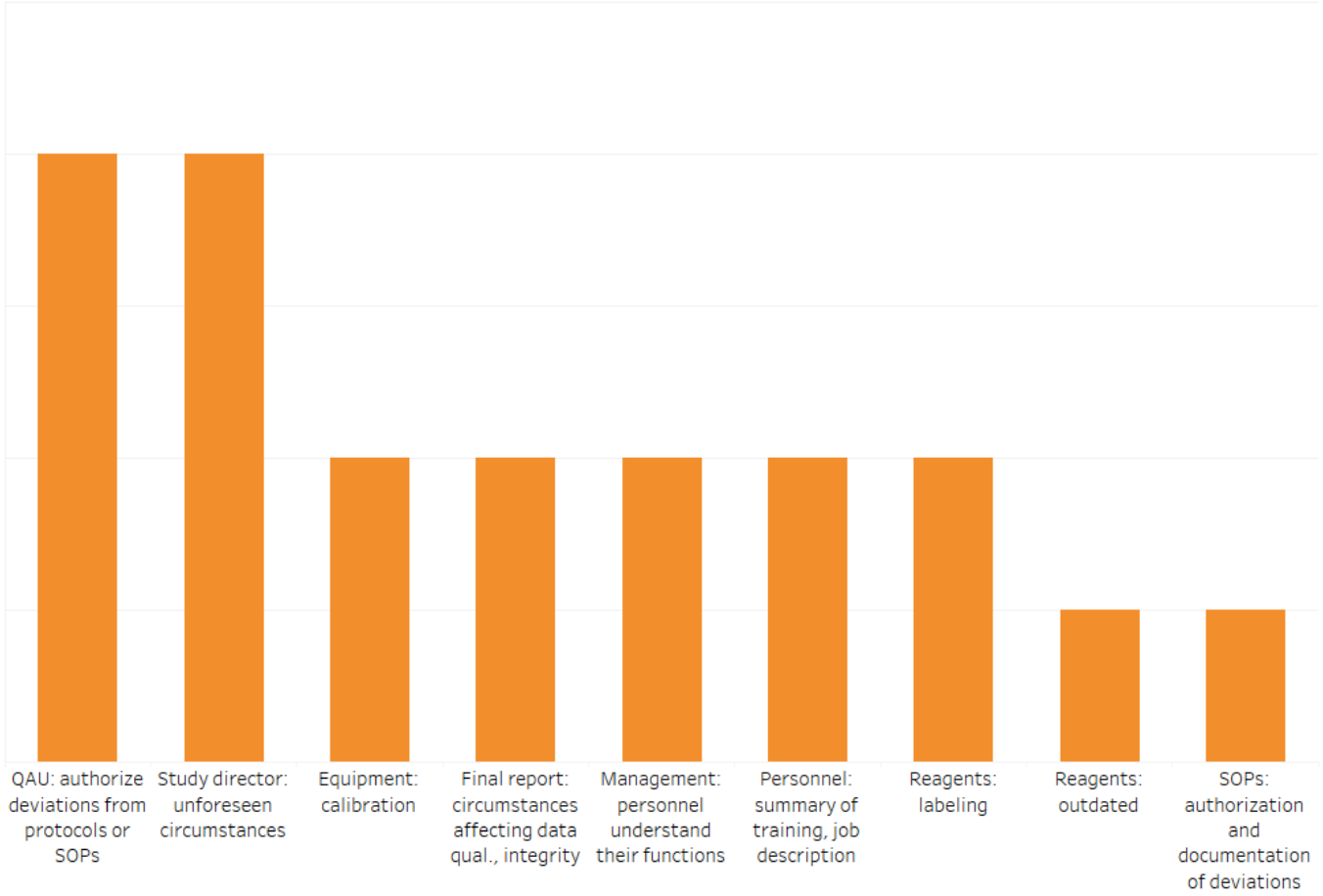
Training Details



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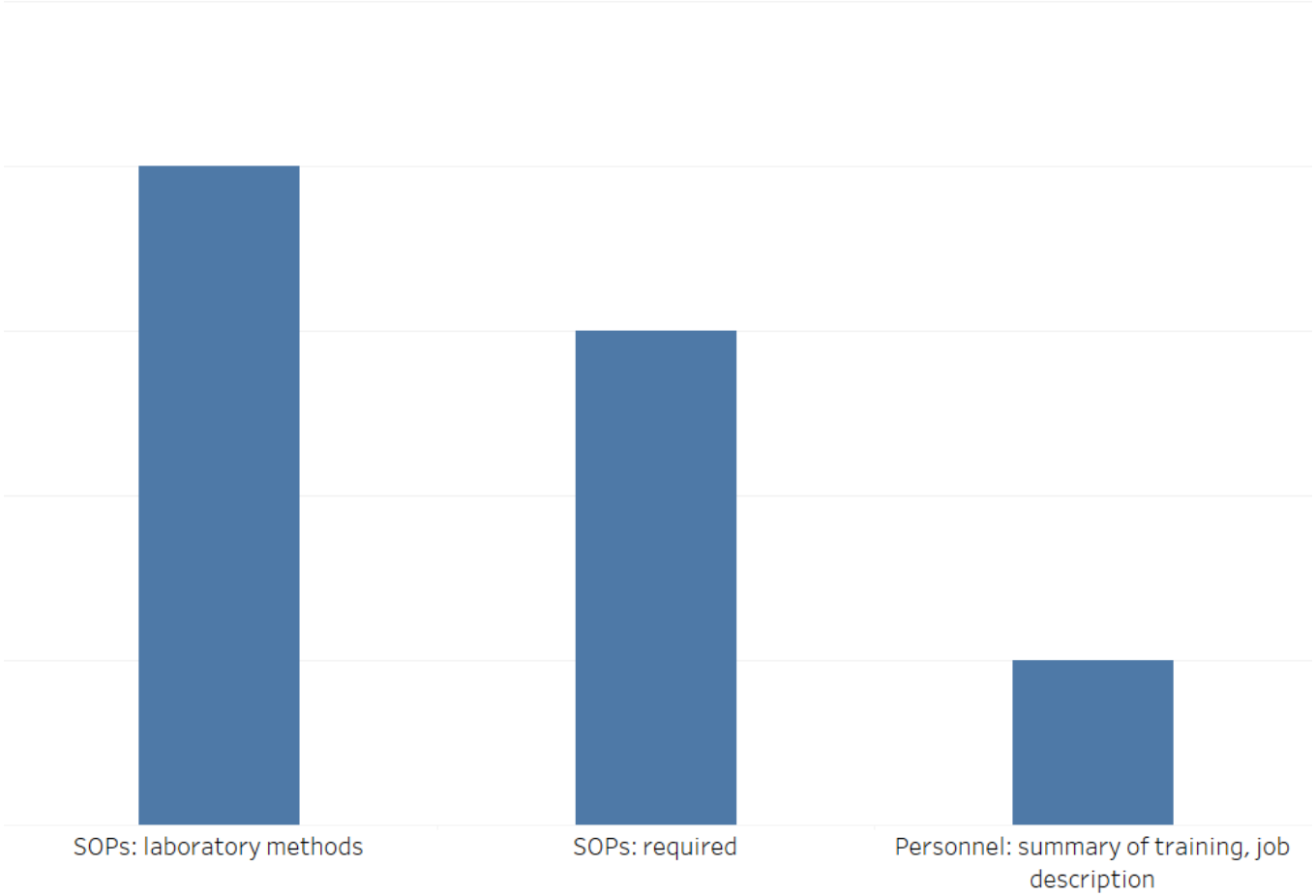
Standard Operation Procedures (SOP) Details



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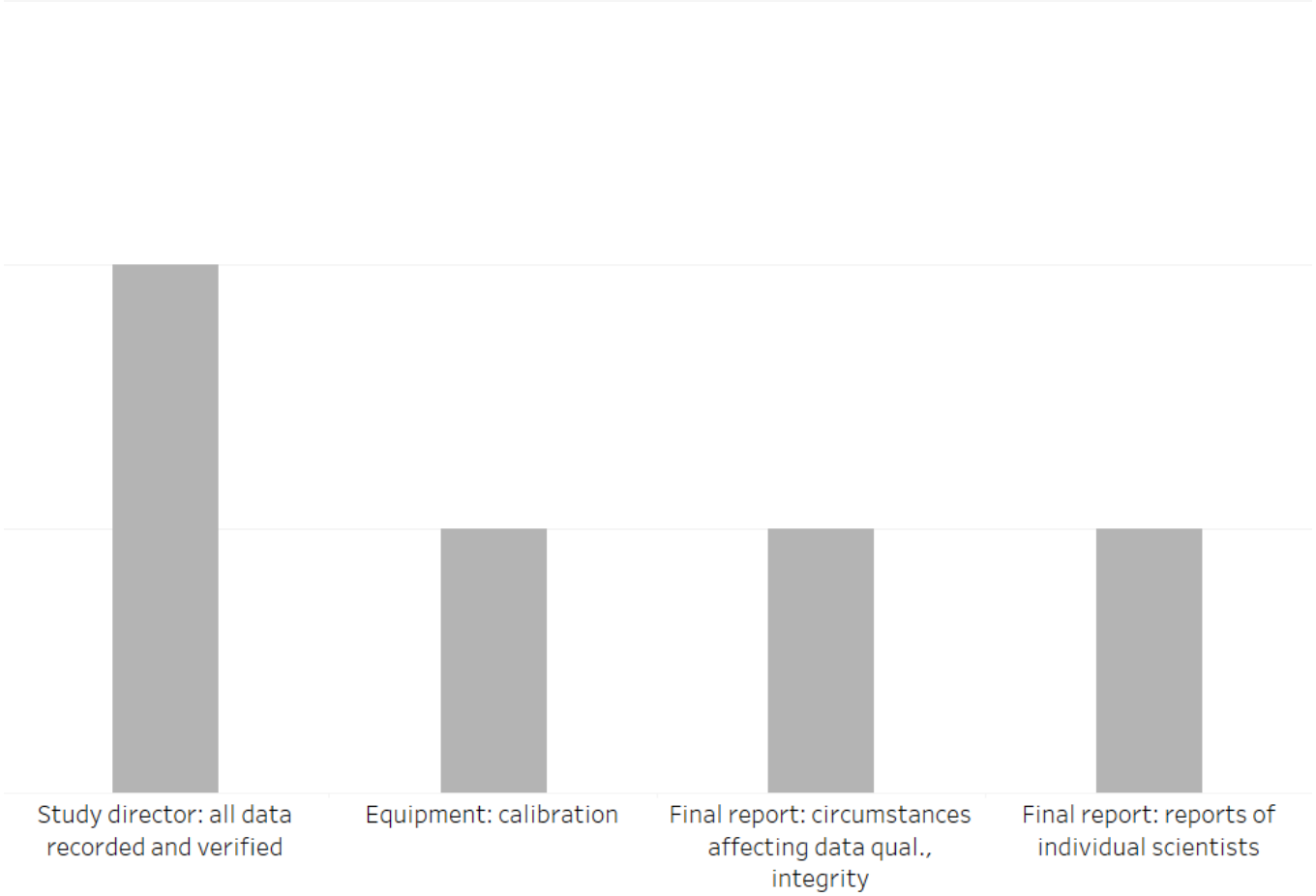
Study Director Details

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