



FY 2023 GOOD LABORATORY PRACTICE FDA 483 OBSERVATION TRENDS

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 to identify trends.

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



Acronyms

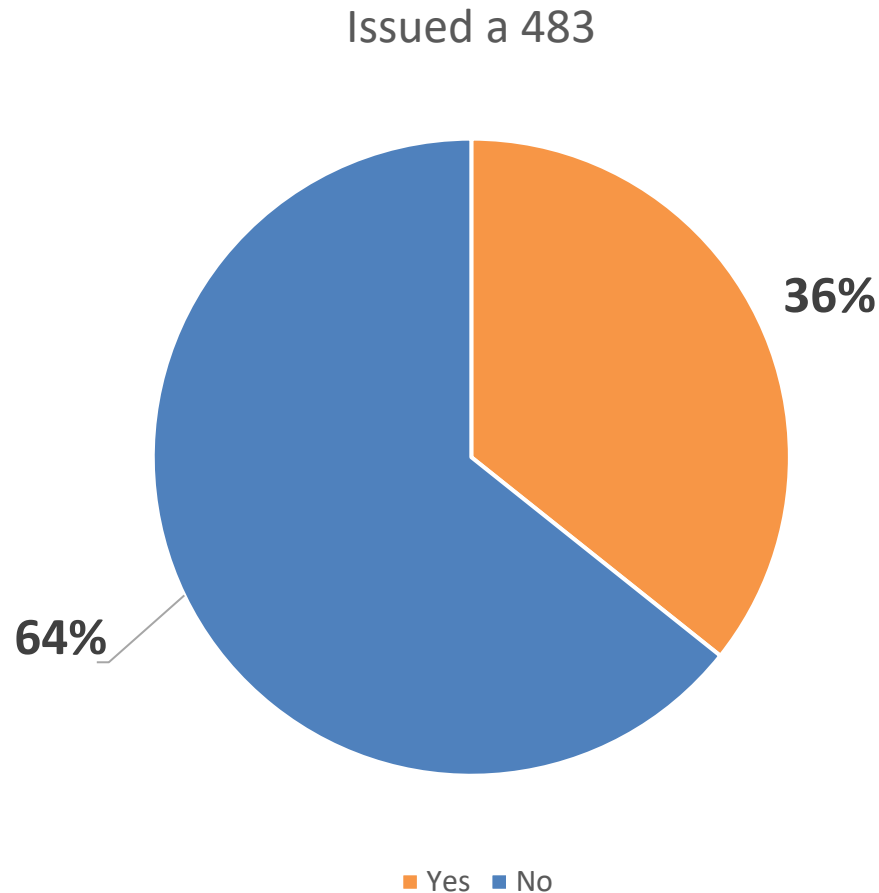
FDA (Food and Drug Administration)

GLP (Good Laboratory Practice)

QAU (Quality Assurance Unit)

SOPs (Standard Operating Procedures)

Inspections with and without FDA 483



- During FY 2023, a total of 28 nonclinical inspections were conducted. Significant observations were noted resulting in the issuance of Form FDA-483 Inspectional Observations in just under 36% or 10 inspections.
- At the conclusion of these 10 inspections, 36 significant observation were cited.
- The following slide will discuss the top area where deficiencies were noted during the inspection.

Trends and Themes Identified in FY 2023 GLP Data



A singular trend emerged from the FDA 483 observations cited in FY 2023

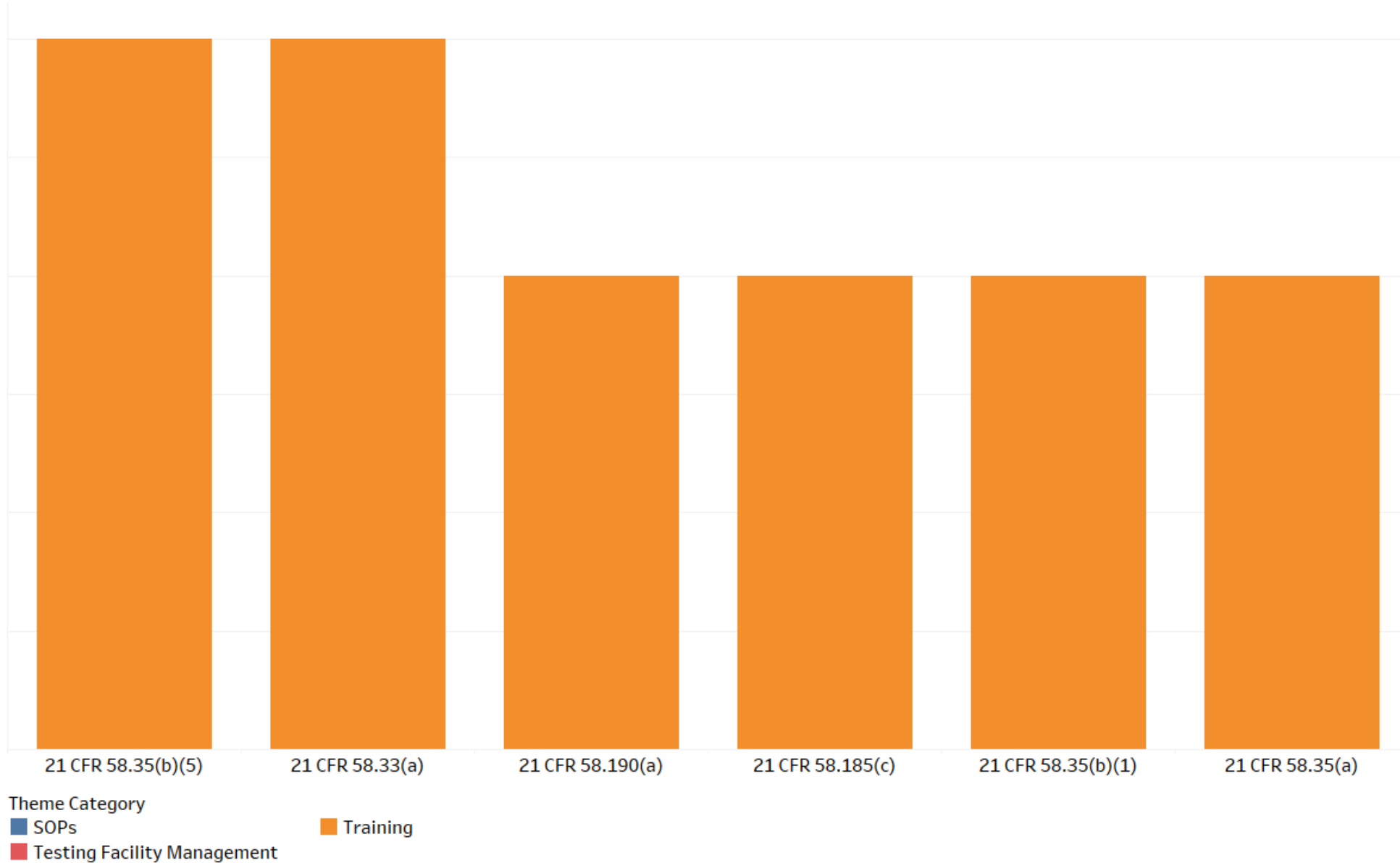
Training – inadequate training at multiple levels

Training

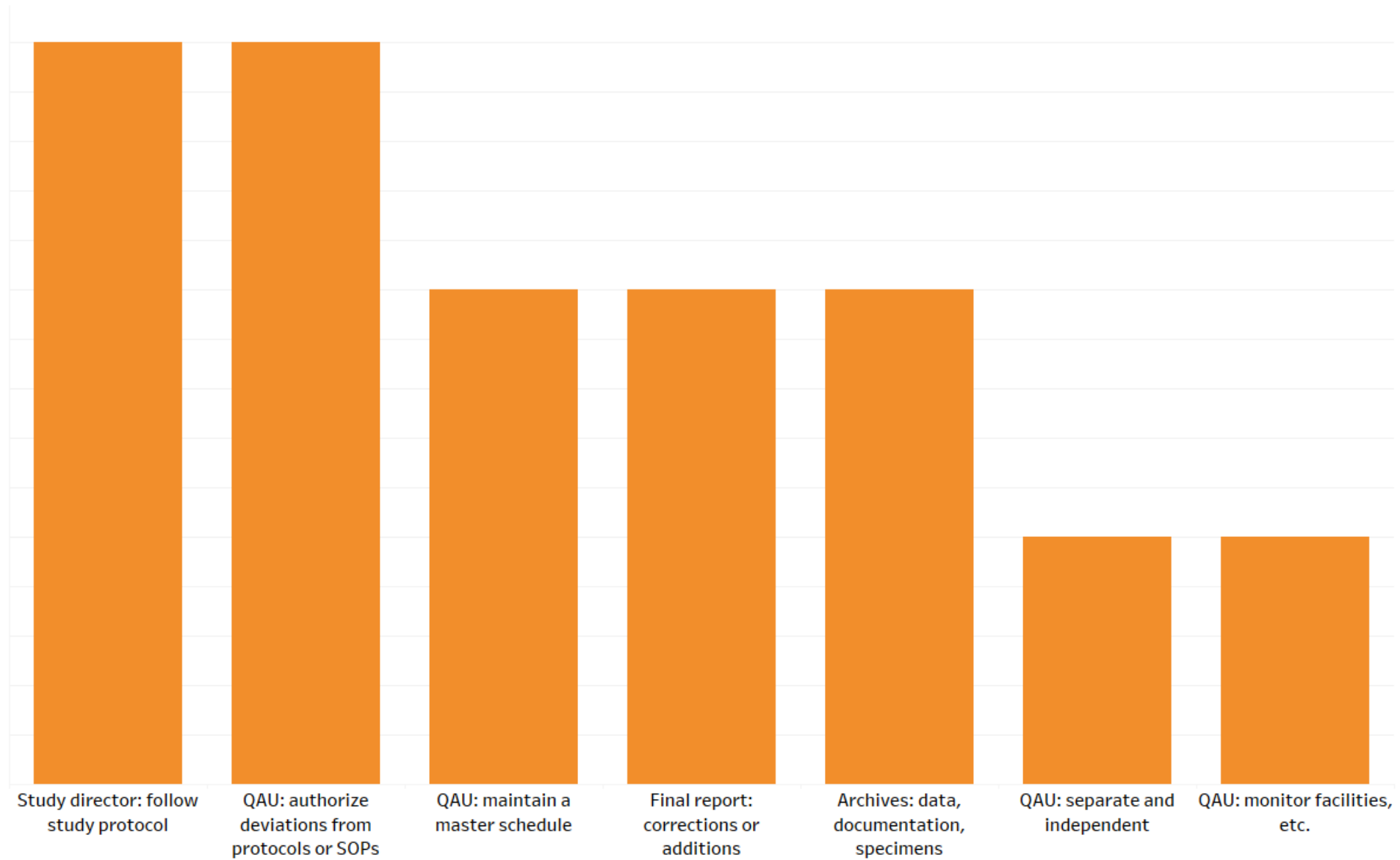
FY2023, significant observations were cited 29 times which could be attributed to lack of or inadequate training such as:

- 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
- Failure to ensure that all data are recorded and verified

FY 2023 GLP Top Cites by Theme



Training Details





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