FY 2024 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)

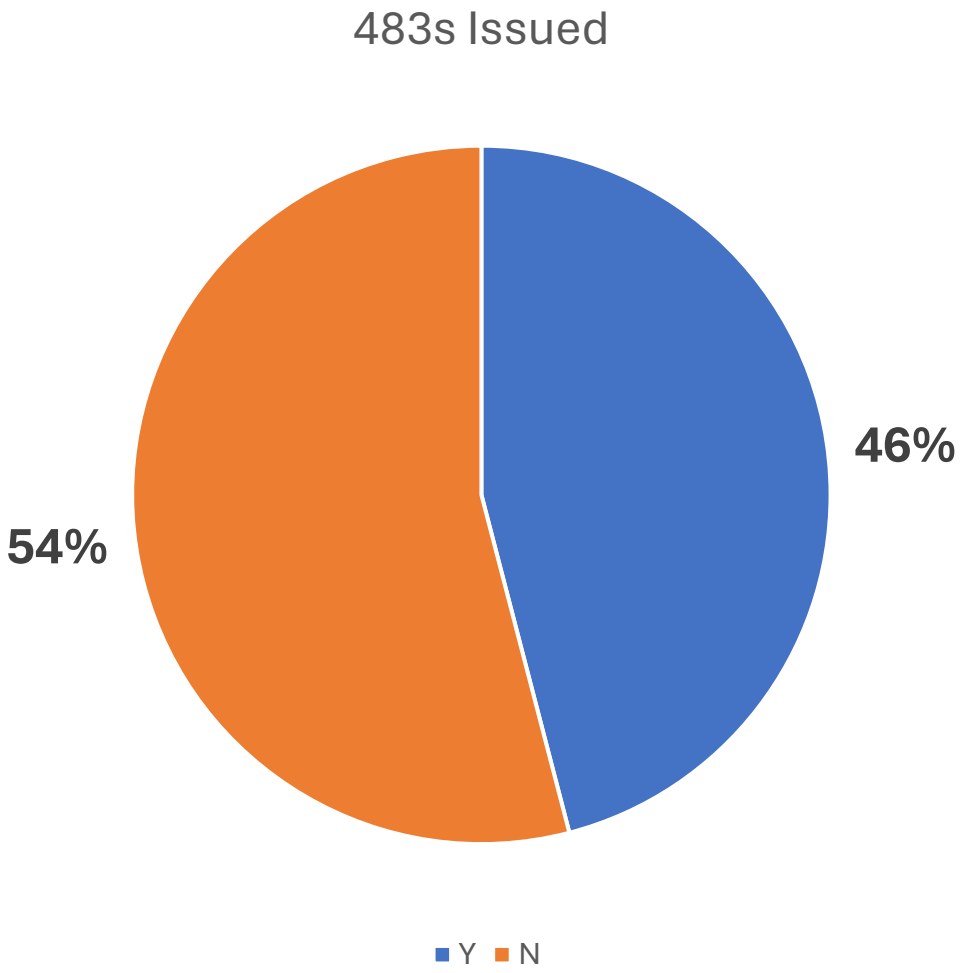
SOPs (Standard Operating Procedures)

FY 2024 GLP Firms Issued a 483

37 Inspections

No FDA 483 Issued – 20

FDA 483 Issued - 17



Trends and Themes Identified in FY 2024 GLP Data

- Testing Facility Management
- Study Director
- SOPs
- Training

Details for Themes

Testing Facility Management

- Failure to establish required SOPs
- Failure of the QAU to report problems noted during inspections to testing facility management and the study director
- Failure of the QAU to monitor critical phases of the study
- Failure to promptly replace the study director as necessary
- Failure to assure that personnel clearly understand the functions they are to perform
- Failure to assure that adequate resources are available as scheduled for nonclinical studies
- Failure to assure that deviations from the GLP regulations reported by the QAU were reported to the study director with corrective actions taken and documented

Study Director

- Failure to assure that protocol deviations are included in the final
- Failure to assure that all study data were accurately recorded and verified
- Failure to assure that unforeseen circumstances that might affect the quality and integrity of the nonclinical laboratory study were noted when they occurred and corrective action was taken and documented
- Failure to assure that all changes to the approved protocol were properly documented and maintained
- Failure to assure to that the nonclinical study was conducted in accordance with the protocol
- Failure of study director to have overall responsibility for the technical conduct of the study
- Not all protocols contained the type and frequency of tests, analyses, and measurements to be made.
- The final study report did not include a description of all circumstances that may have affected the quality or integrity of the data.
- Corrections or revisions to the study report were not made in the form of an amendment

Details for Themes

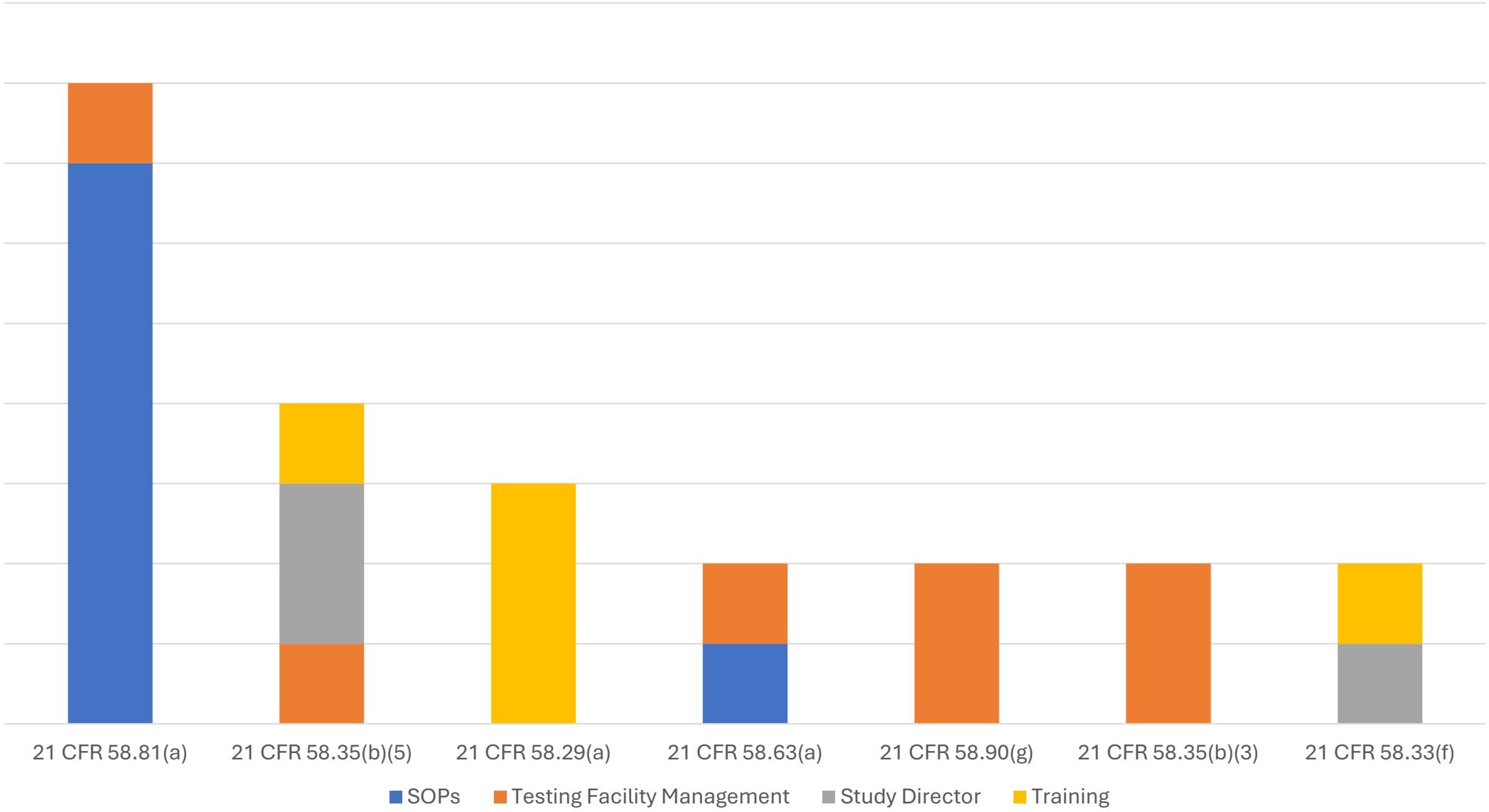
SOPs

- Failure to have SOPs that management is assured are adequate
- Changes or revisions to SOPs were not approved by management
- Not all deviations from SOPs were authorized by the study director and documented in the raw data

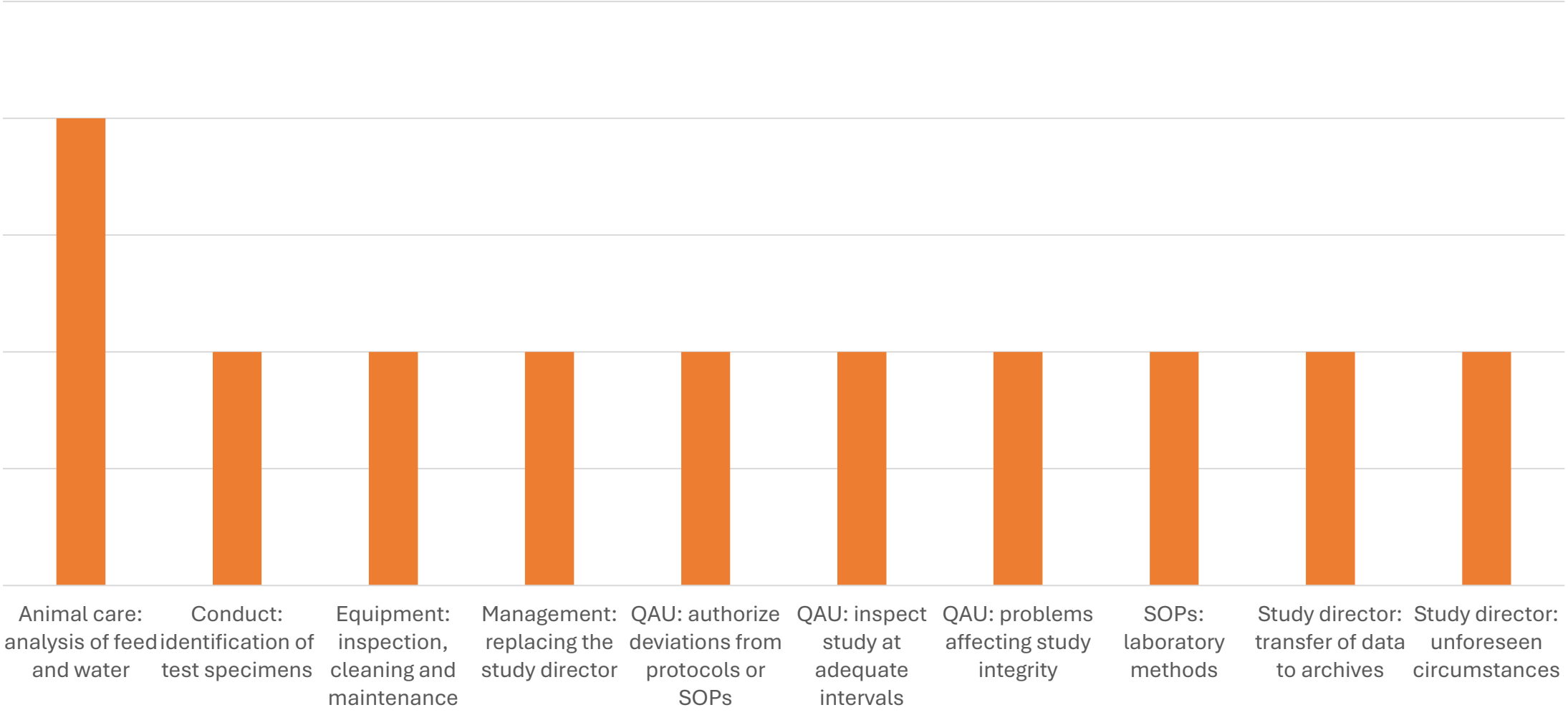
Training

- Failure to assure all study records and specimens are transferred to the archives
- Failure to properly identify all specimens
- Failure of the QAU to perform adequate study phase audits
- Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, to enable that individual to perform assigned functions

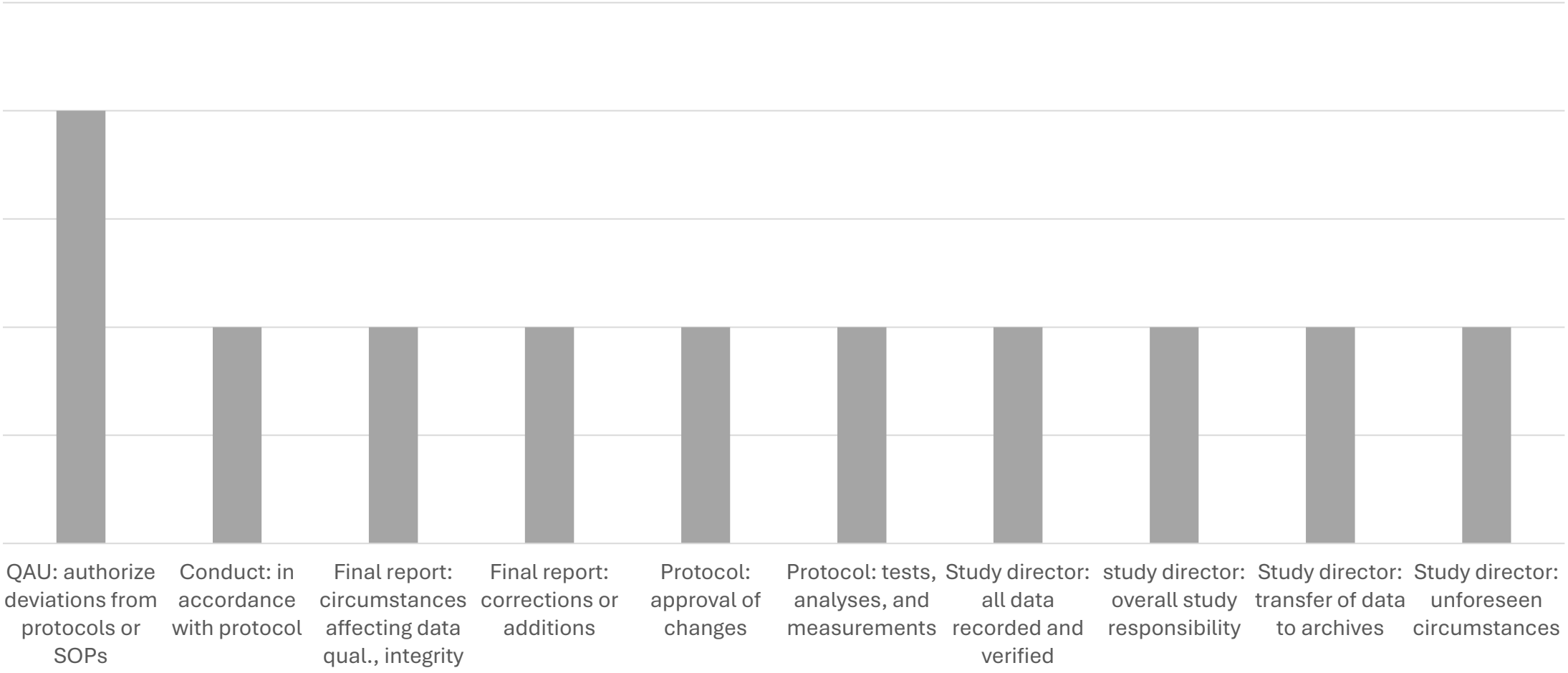
FY 2024 GLP Top Cites by Theme



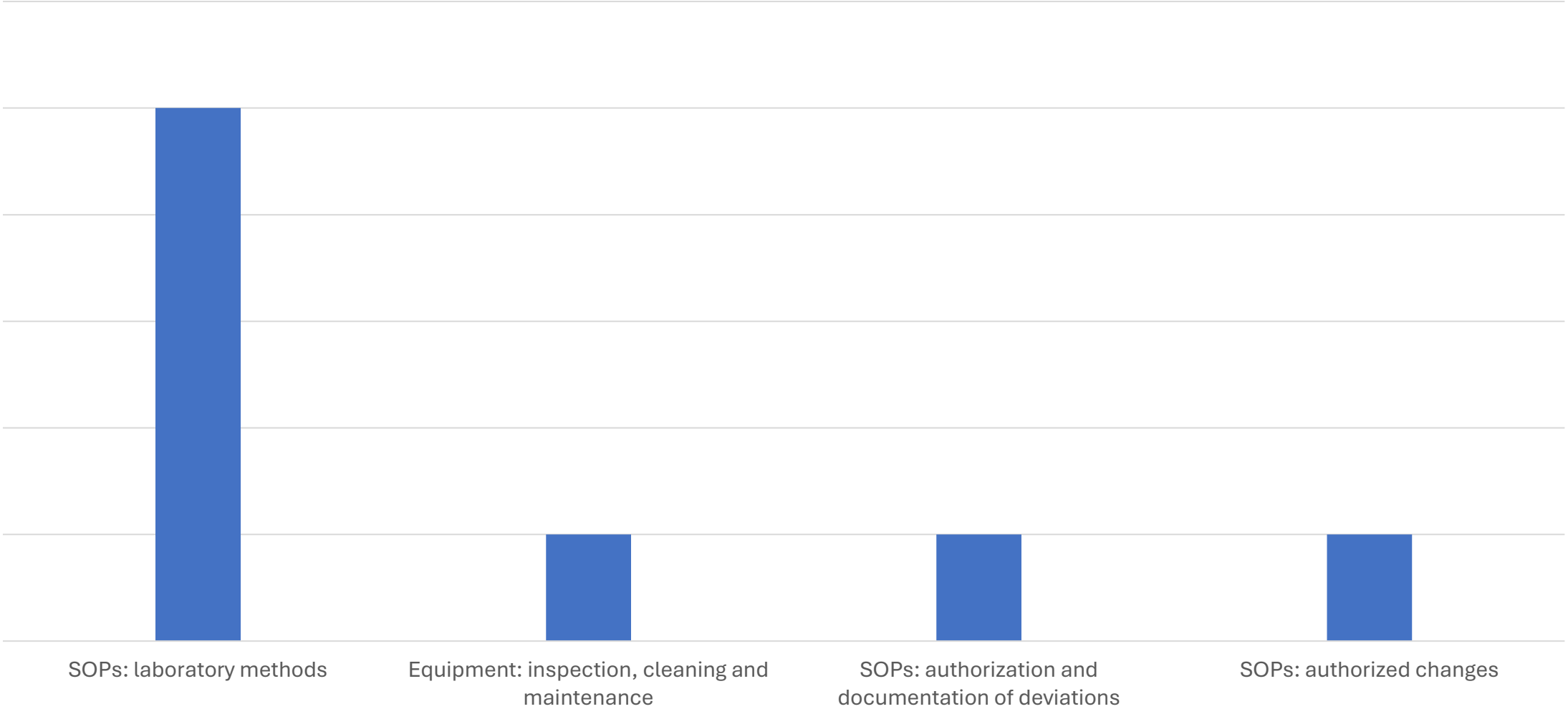
FY 2024 Theme Details for Testing Facility Management



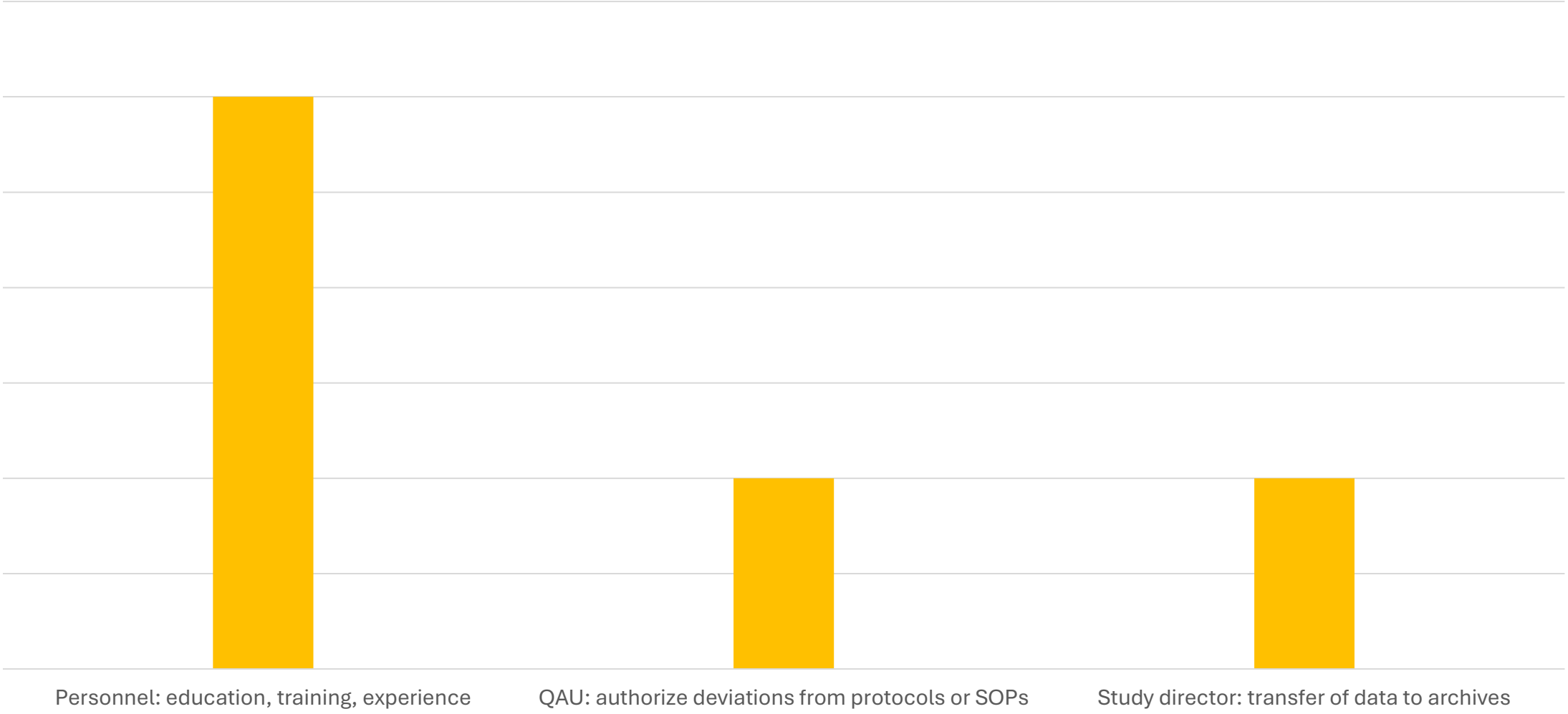
FY 2024 Theme Details for Study Director



FY 2024 Theme Details for SOPs



FY 2024 Theme Details for Training

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