

FY 2021 GOOD LABORATORY PRACTICE FDA 483 OBSERVATION TRENDS

Acronyms

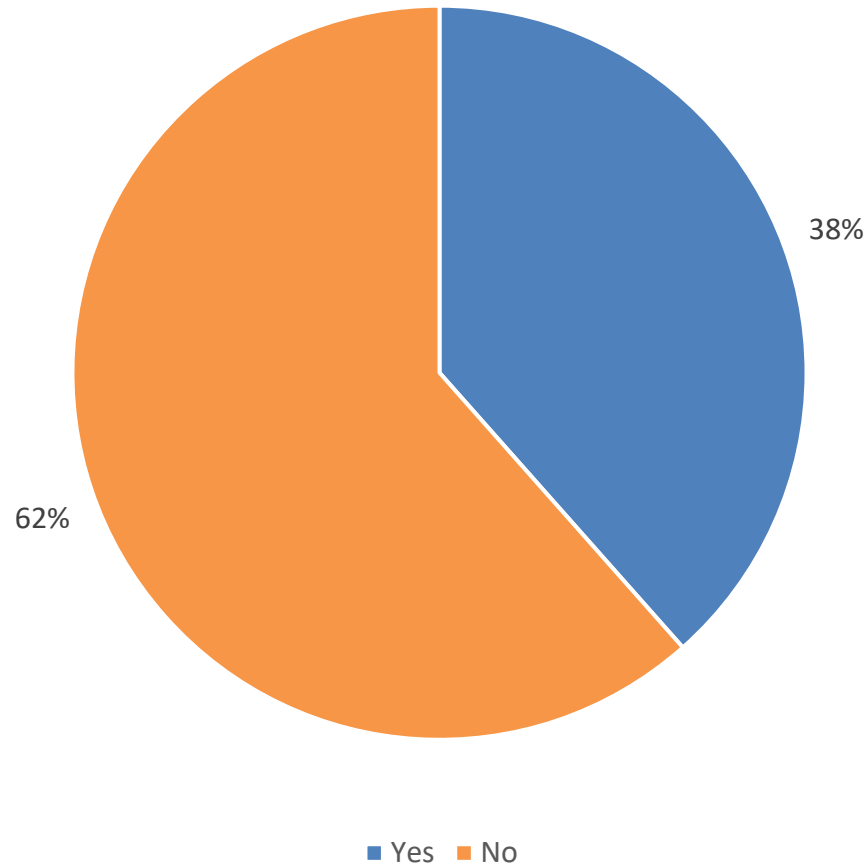
FDA (Food and Drug Administration)

GLP (Good Laboratory Practices)

QAU (Quality Assurance Unit)

SOPs (Standard Operating Procedures)

FY 2021 GLP Firms Issued a 483



FY 21 data from ORA's Online Reporting Analysis Decision Support System Query, Last updated 8/24/2022

Trends and
Themes
Identified in
FY 2021 GLP
Data

Test Facility Management

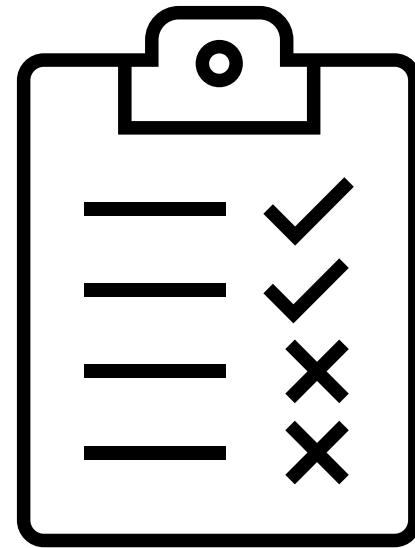
Training

Study Director

Details for Themes

Test Facility Management

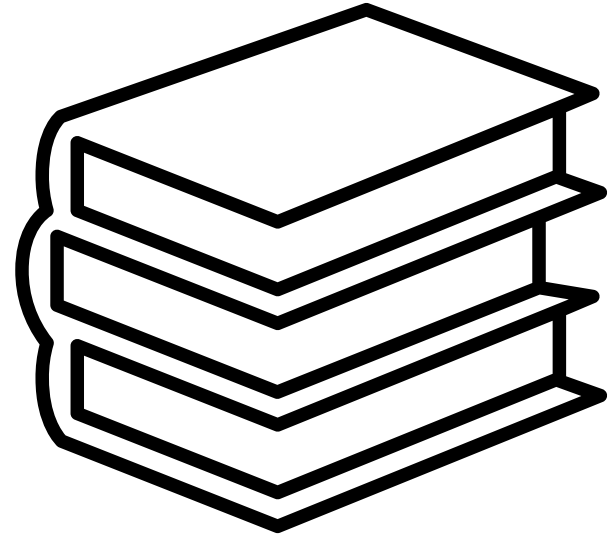
- Failure of testing facility management to assure that all personnel clearly understood the functions they were to perform.
- Testing facility management failed to assure that all personnel, resources, facilities, equipment, materials, and methodologies were available as scheduled.



Details for Themes

Training

- Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.

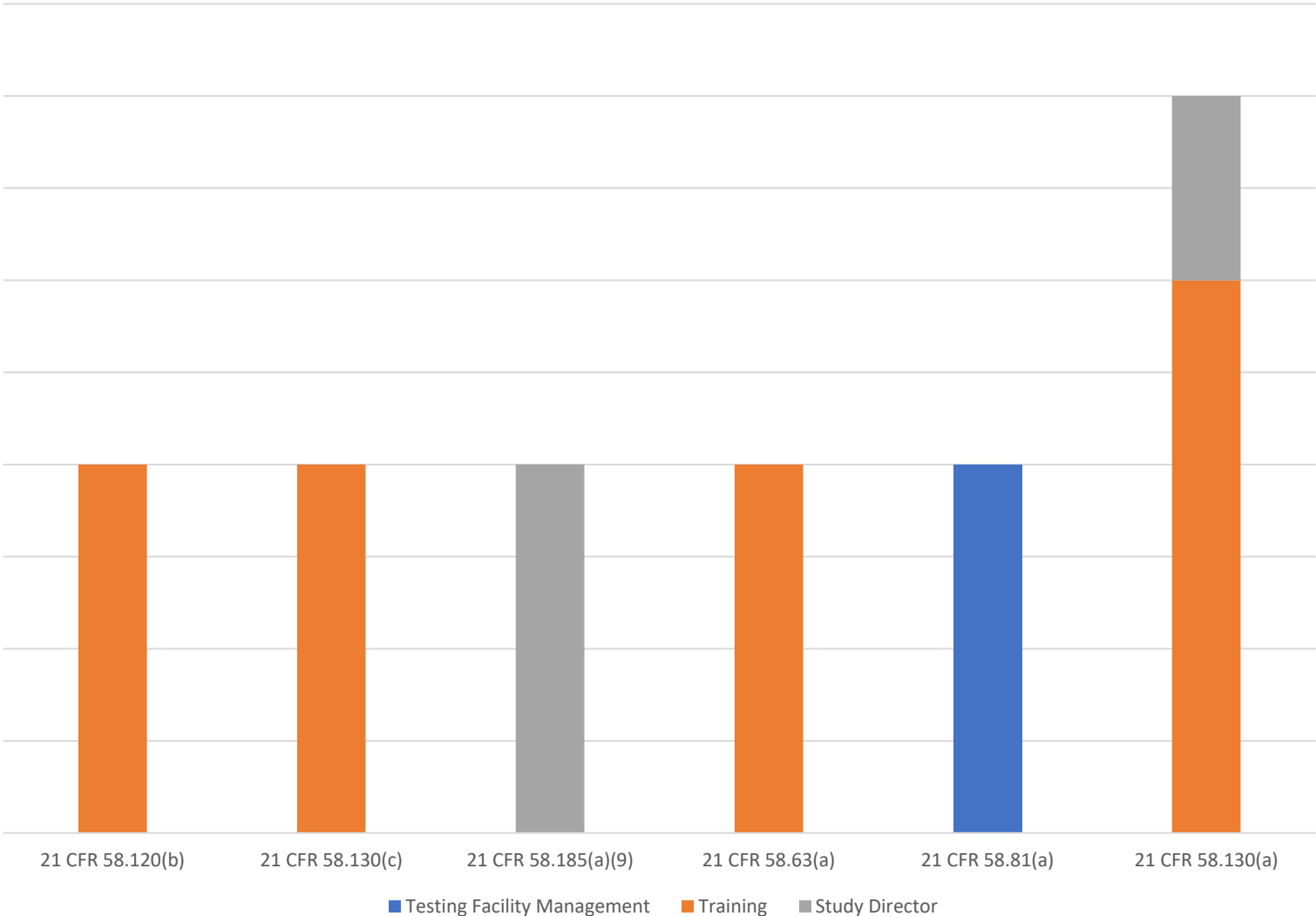


Details for Themes

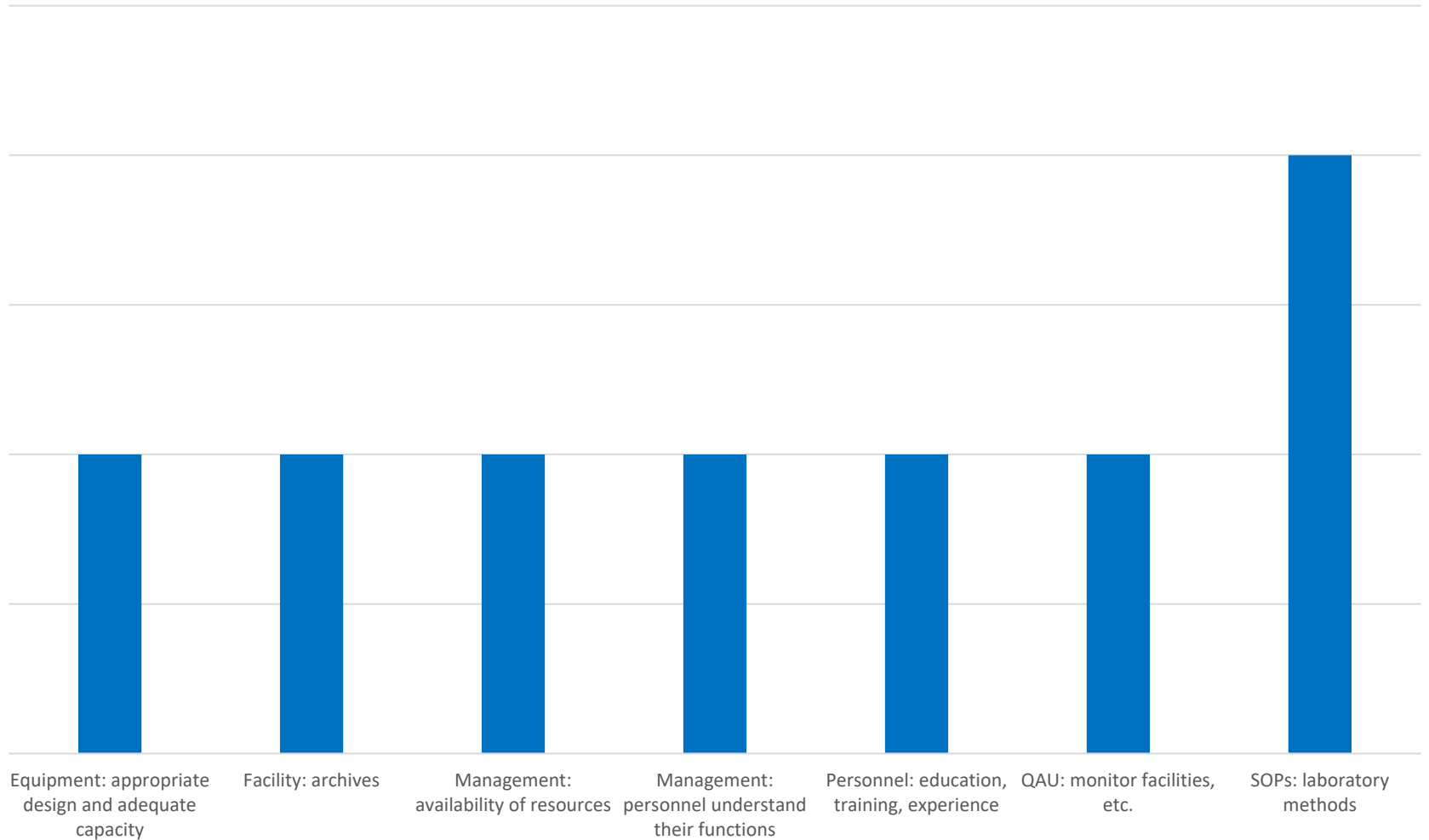
Study Director

- The study director failed 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.
- Not all changes in, or revisions of, an approved protocol and the reasons therefore were documented, signed by the study director, dated, and maintained with the protocol.
- The study director failed to assure that all raw data, documentation, protocols, specimens, and final reports were transferred to the archives during or at the close of the study.
- The study director failed to assure that the protocol, including any change, was approved and was followed.

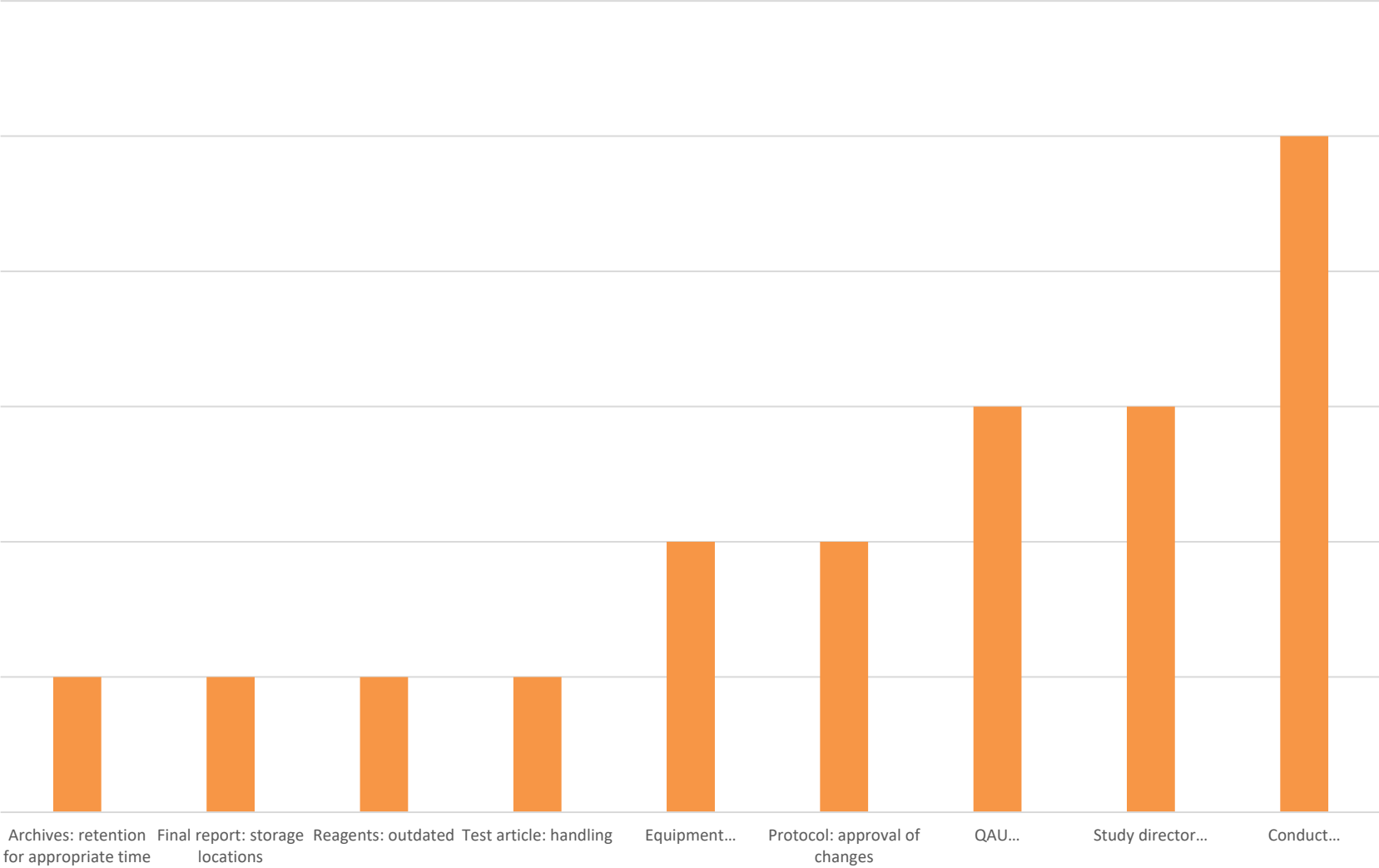
FY 2021 GLP 483 Observations Theme for Each Cite Reference Number



FY 2021 GLP 483 Observations by Testing Facility Management Details



FY 2021 GLP 483 Observations by Training Details



FY 2021 GLP 483 Observations by Study Director Details

