FY 2024 Sponsor 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 in order to identify trends.

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

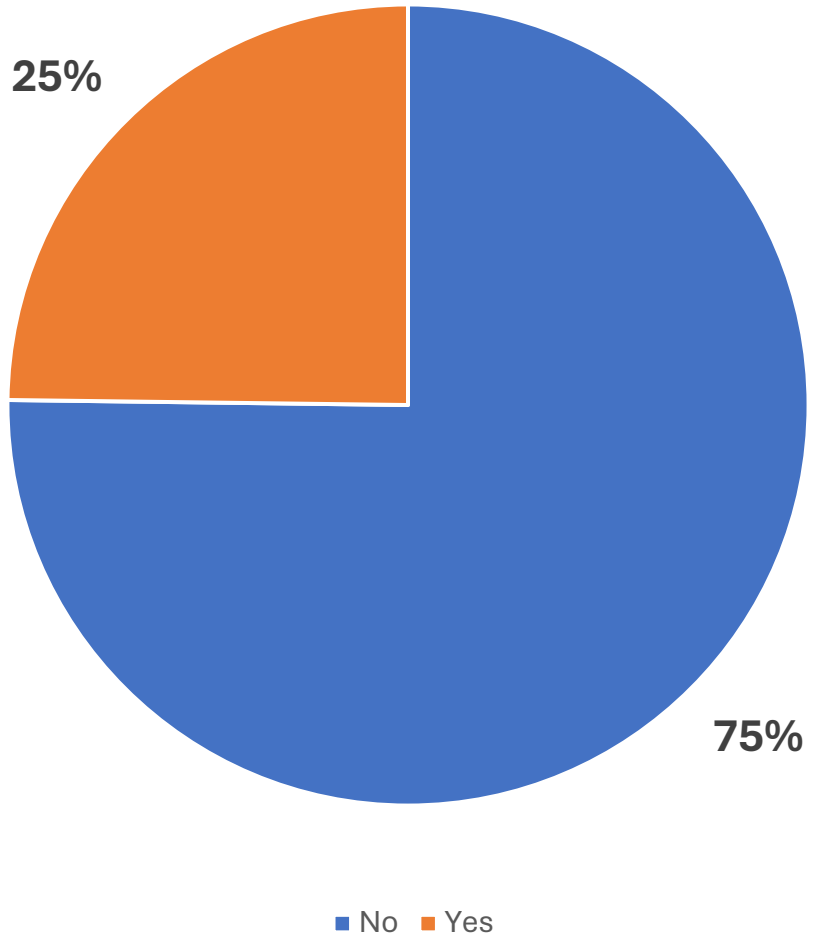
Acronyms

- FDA (Food and Drug Administration)
- ICF (Informed Consent Form)
- IND (Investigational New Drug)
- IRB (Institutional Review Board)
- PD (Protocol Deviation)
- IDE (Investigational Device Exemption)

FY 2024 Sponsor Inspections with an Issued 483

125 Inspections

No FDA 483 Issued – 94
FDA 483 Issued - 31



Trends and Themes Identified in FY 2024 Sponsor Data

- General Sponsor Responsibilities
- Failure to Secure Compliance
- Lack of IRB Approval
- Inadequate Annual Reporting
- Lack of adequate records for IP

Details for Themes

General Sponsor Responsibilities

- Inadequate monitoring of clinical sites
- monitoring plans were not followed
- Late safety reporting
- Inadequate validation of electronic systems used to maintain source records
- Protocols did not provide detail to clinical sites on how to report PDs
    - Late and under-reported PDs in progress reports
- Inadequate written procedures and case histories

Failure to Secure Compliance

- Terminated and serious non-compliant CIs were not reported to the FDA
- IRB approval for study conduct was not maintained
- IRB approved consent forms were not used
- Informed consent was not documented

Details for Themes

Lack of IRB Approval

- Sites did not maintain IRB approval while study was active
- Subjects were screened and enrolled under outdated protocol versions
    - Additional inclusion/exclusion criterion were not considered or reviewed
- Changes in research were not approved

Inadequate Annual Reporting

- IND annual reporting requirements were not followed
- Annual progress report to the FDA within 60 days of anniversary of IND timeframe not met
- Annual safety reports to investigator sites were not provided within the annual timeframe requirements

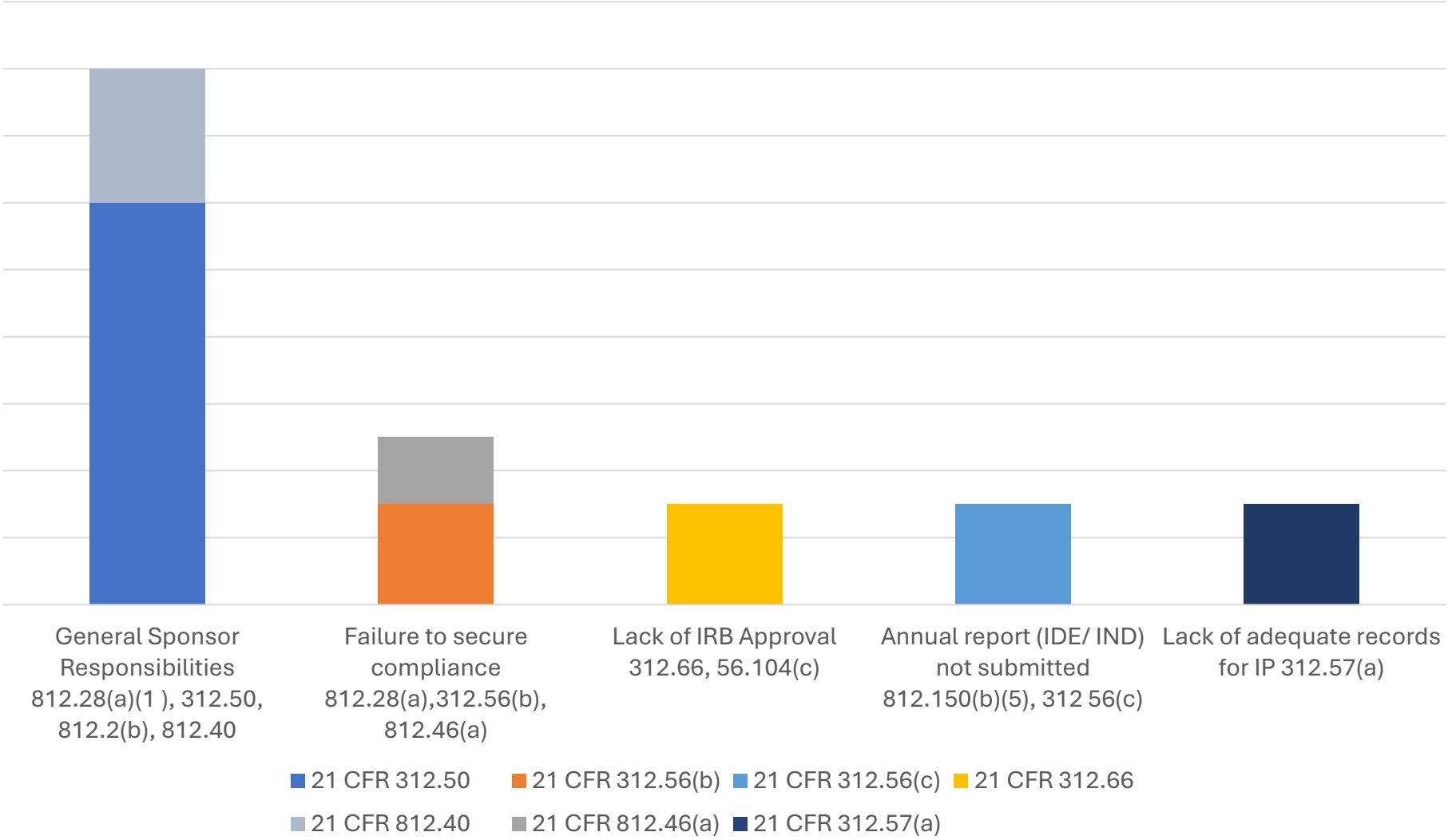
**(No IDE reporting requirements were cited)

Details for Themes, cont'd

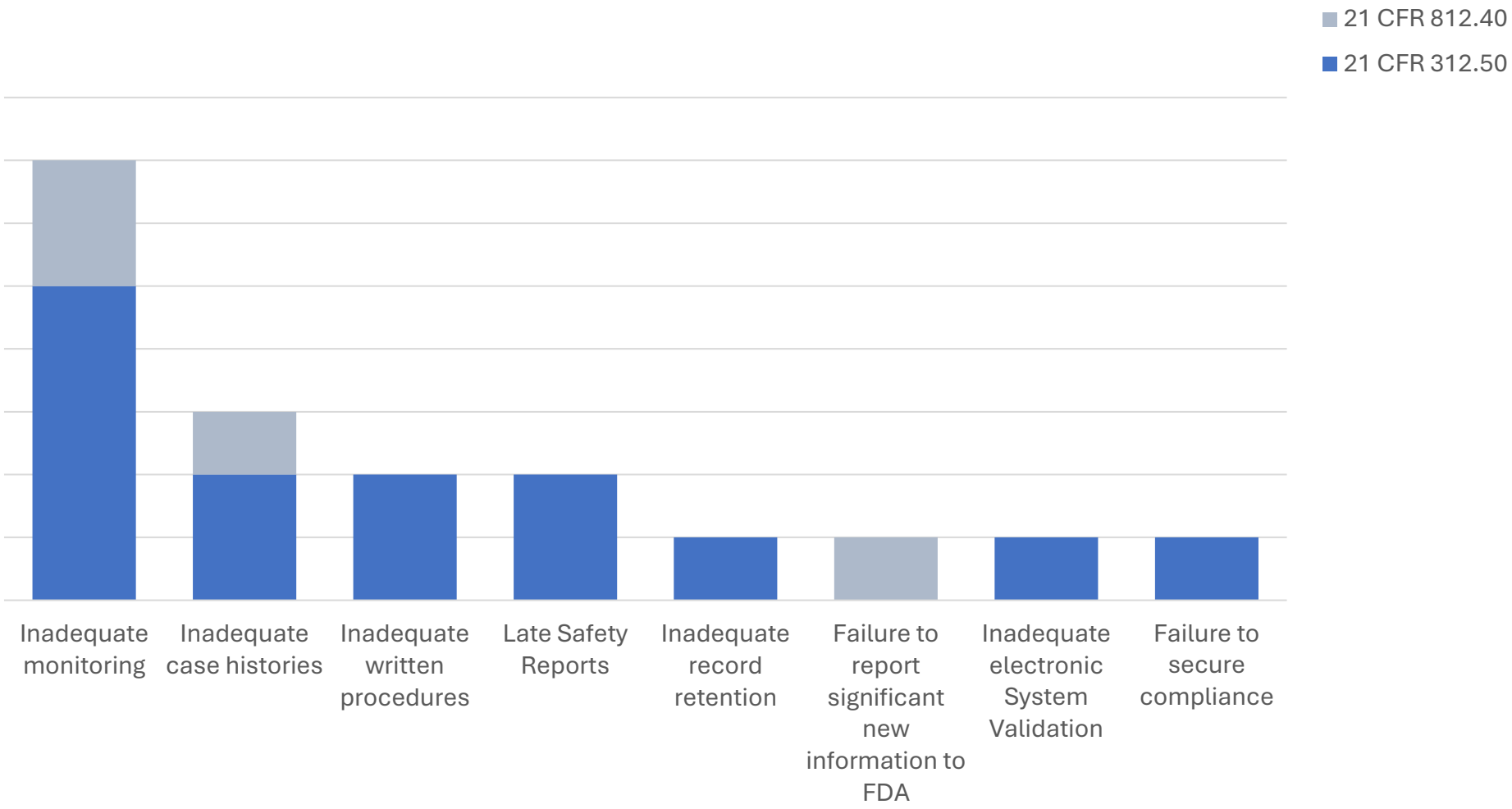
Lack of adequate records for IP

- Shipment, receipt and disposition records not maintained for IP
  - Only Sponsor-Investigators were cited
  - Only investigational drugs, no devices

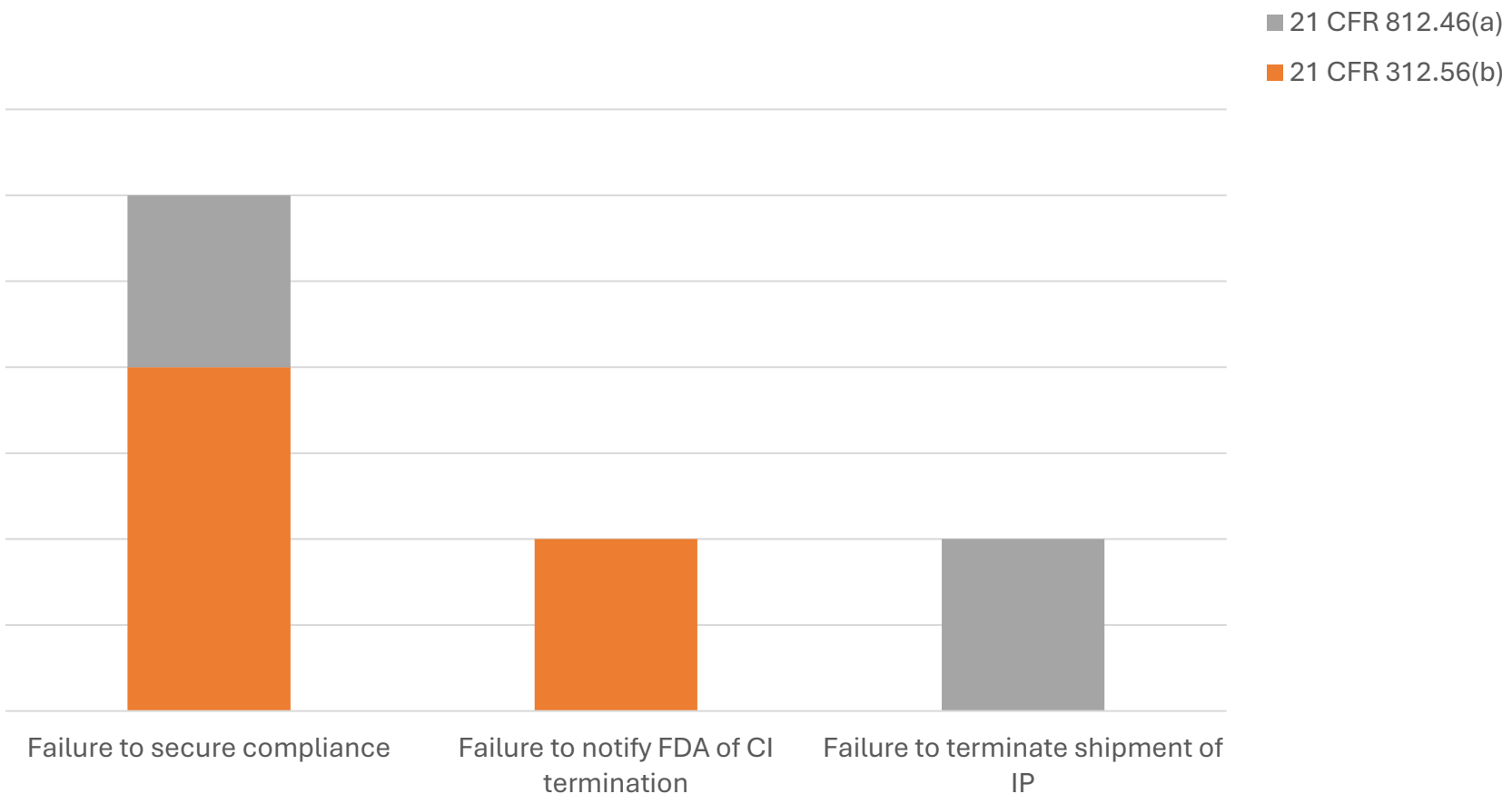
FY 2024 Sponsor Themes by Reference Number



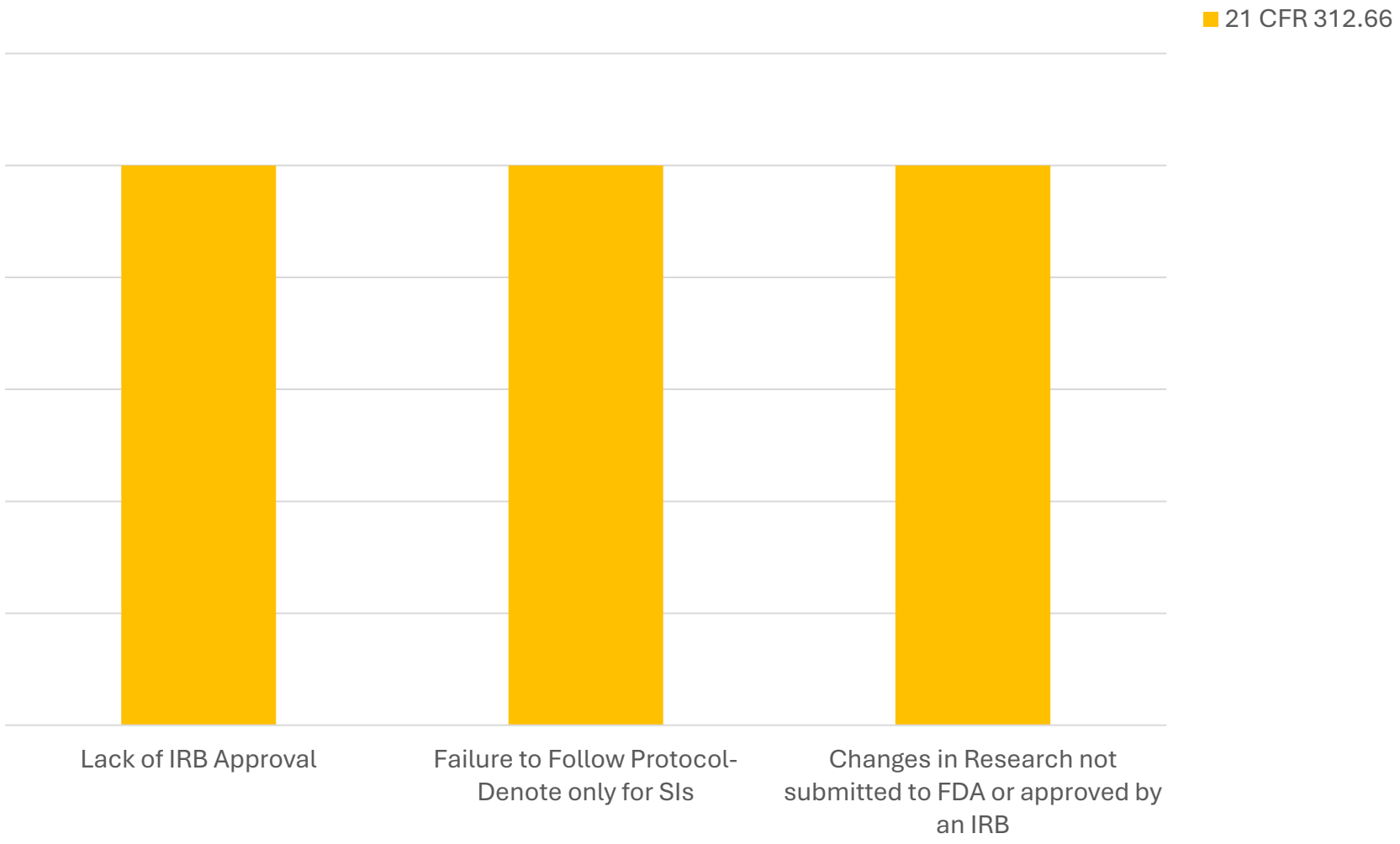
FY 2024 General Sponsor Responsibilities 812.28(a)(1), 312.50, 812.2(b), 812.40 Theme Details



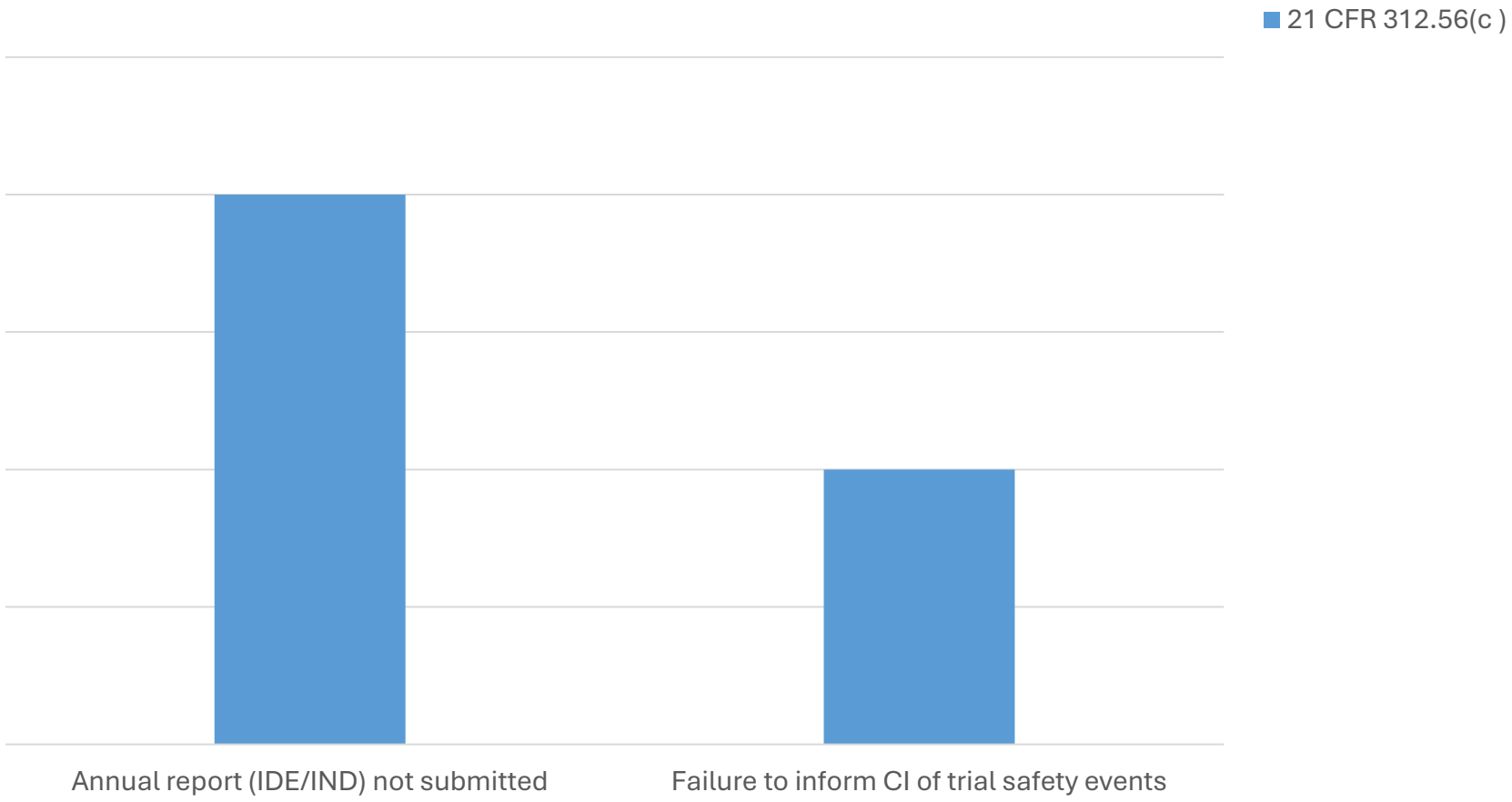
FY 2024 Failure to Secure Compliance 812.28(a),312.56(b), 812.46(a)Theme Details



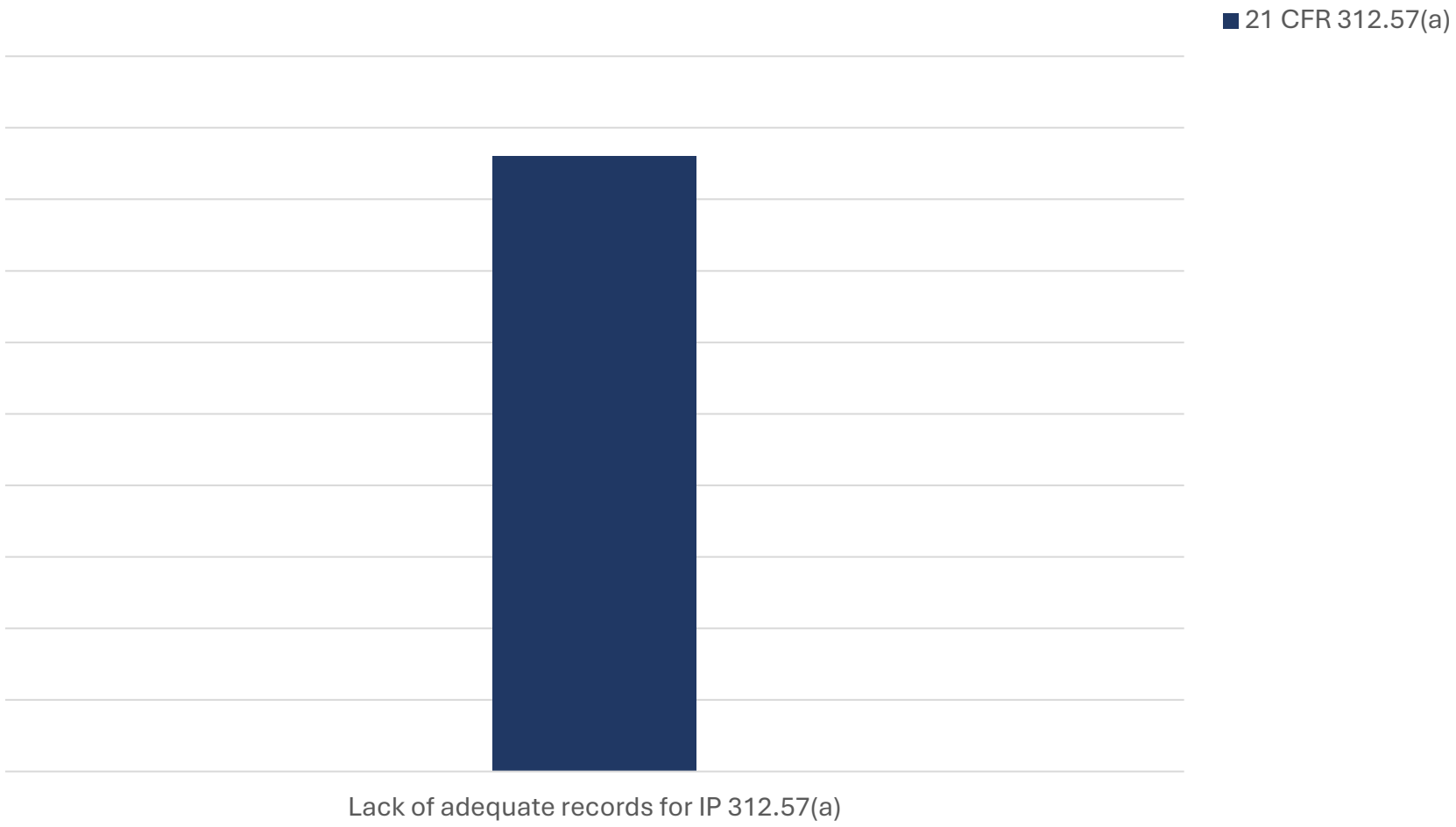
FY 2024 Lack of IRB Approval 312.66, 56.104(c) Theme Details



FY 2024 Annual report (IDE/ IND) not submitted 812.150(b)(5), 312 56(c)Theme Details



FY 2024 Lack of adequate records for IP 312.57(a) Theme Details

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