Step into the Closing Meeting: Navigating an FDA Closeout and Beyond

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

May 30, 2024

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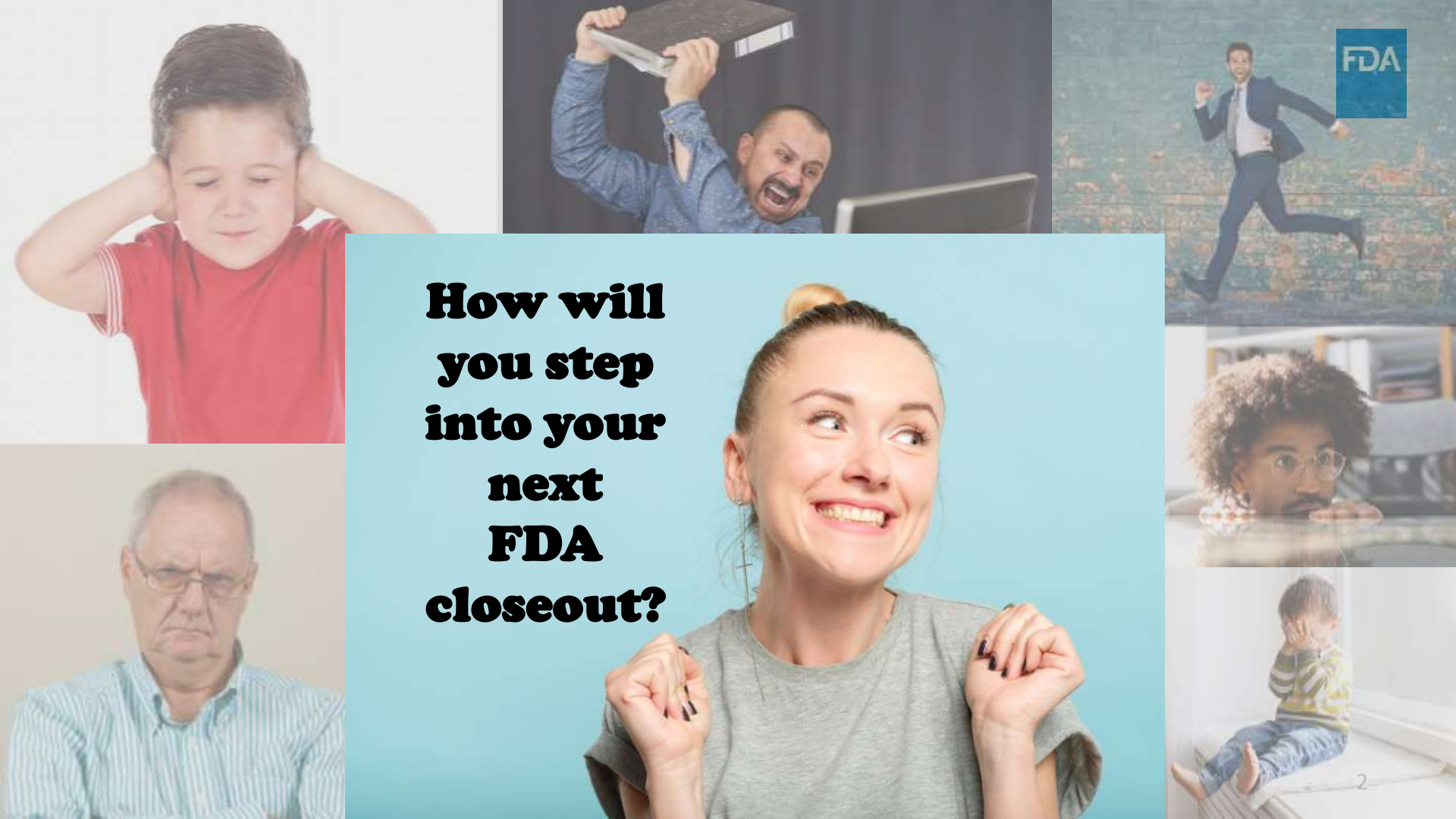

How will you step into your next FDA closeout?
FDA

Learning Objectives

- Identify typical activities conducted at the closing meeting
- Describe Agency's approach to classifying inspections and explain how written responses can affect final classification
- List most common 483 citations issued to medical device industry
- Describe common pitfalls with CAPA effectiveness checks and how these deficiencies can lead to 483 observations

CAPA = corrective and preventive actions

The Closeout

Potential Activities at the Closing Meeting

- **Issuance of Form FDA 483, Inspectional Observations**
  - Investigator's observations do not represent a final Agency determination regarding compliance
- **Discussion Items**
  - Additional issues of concern not included in 483
- **Issuance of Affidavit**
  - Statements to identify the interstate movement of product

Responding to the 483

- **Annotation**
  - Acknowledges management's response to an observation
    - Promise to Correct (optional timeframes)
    - Reported Corrected / Corrected and Verified
    - Under Consideration
    - Annotation Intentionally Left Blank
- **Written response**
  - Encouraged but not required to respond in writing
  - May affect the final classification of the inspection

Classifying Inspections

Classification of the Inspection

- **NAI (no action indicated)**
  - No objectionable conditions identified
- **VAI (voluntary action indicated)**
  - Objectionable conditions identified but agency not prepared to take administrative or regulatory action
- **OAI (official action indicated)**
  - Objectionable conditions identified + regulatory/administrative actions recommended

Post-inspectional Notification

FMD-145

- Correspondence sent to inspected firm within 45 calendar days after inspection is deemed closed/finalized
  - EIR released for OAI inspections when finalized and after confirmation that no further action is planned
- Receive redacted copy of narrative EIR

EIR = establishment inspection report

The Next FDA Inspection

- Investigator will verify corrections if a 483 was issued during the previous inspection
- Timing depends on previous inspection's classification, product risk, and signals received by the Agency

Most Common Citations Issued by Medical Device Investigators

Office of Medical Devices and Radiological Health Operations, FY2023

1,396
Medical Device Inspections

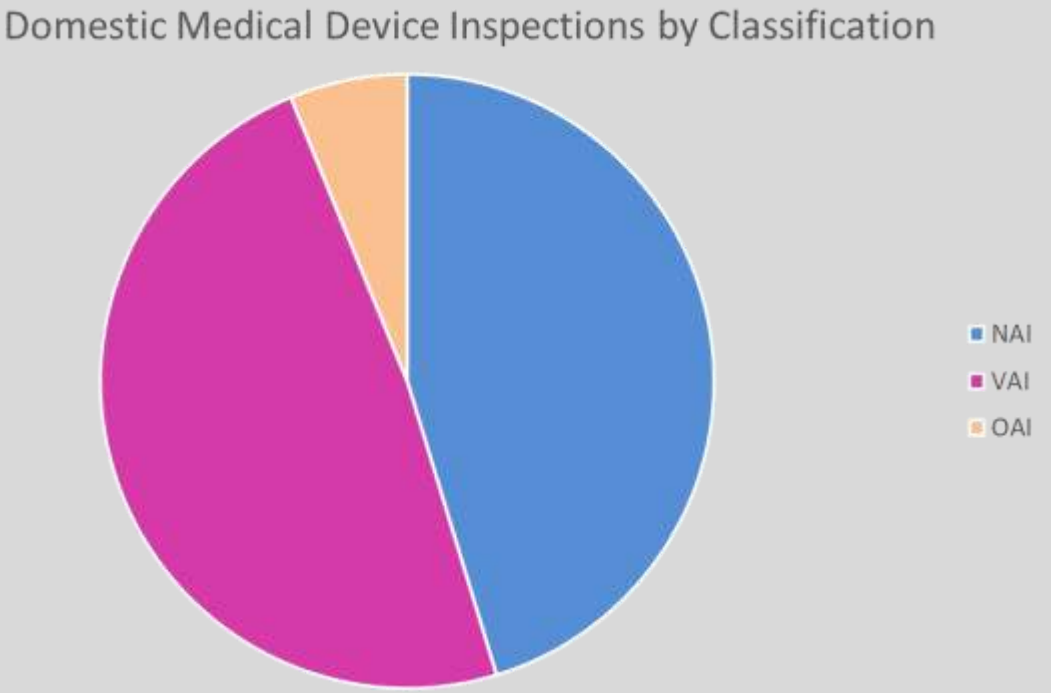
836
Mammography Inspections

70
Rad Health Inspections

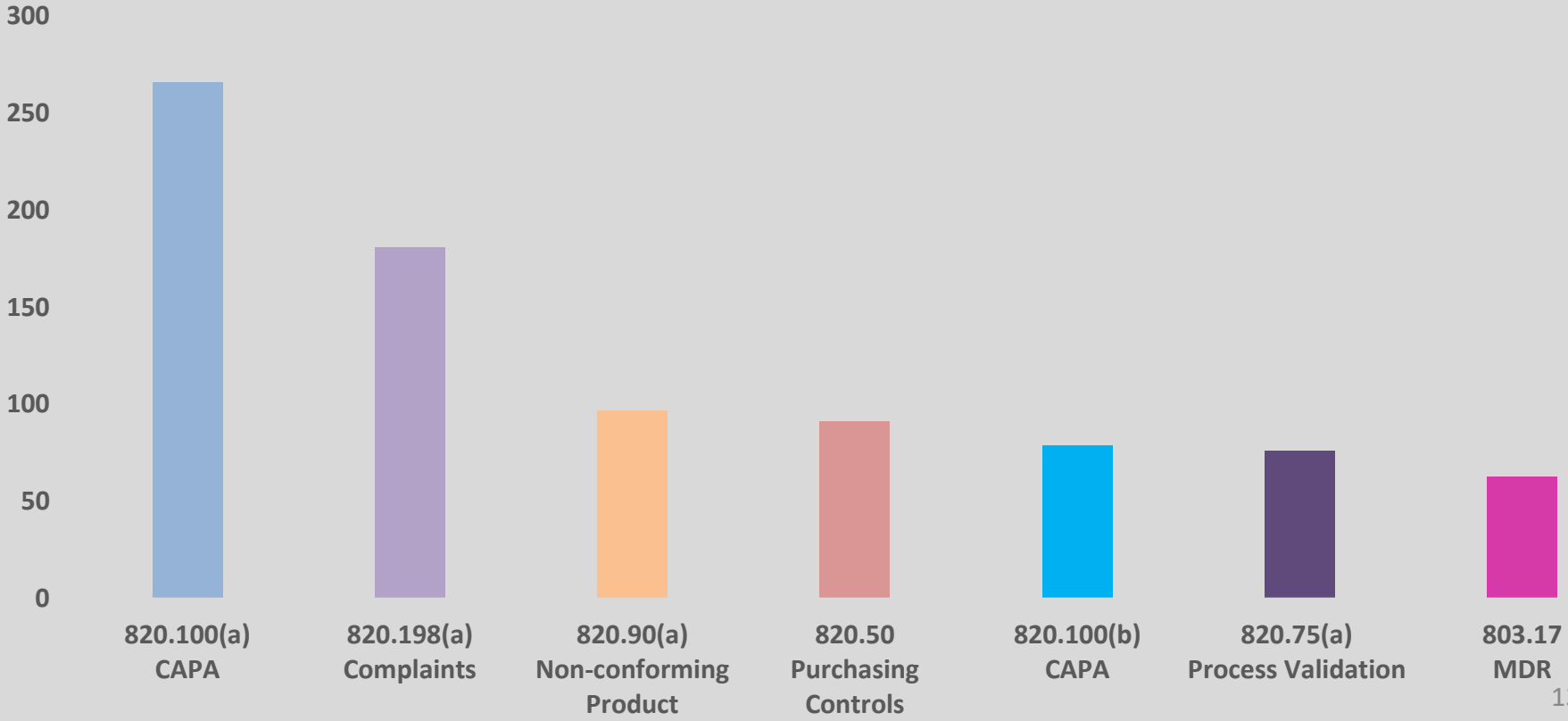
1,819
Domestic Inspections

442
Foreign Inspections

81
Unannounced Inspections



Most Frequent Citations Issued by Medical Device Investigators 2023



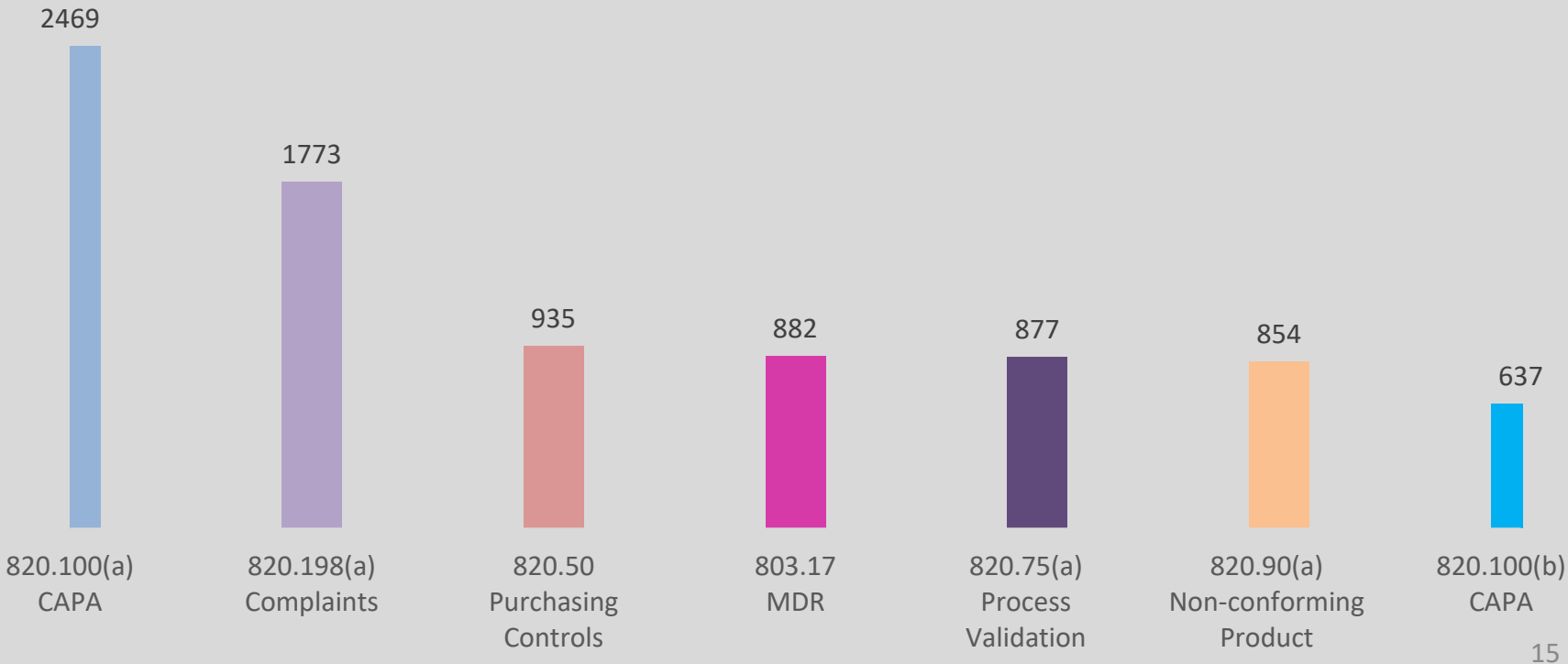
Comparison Between Selected Citations, Years 2022-2023

2022

2023

	2023	2022
Training	44	47
Design Change	41	51
MDR	63	58
Process Validation	76	79
CAPA Documentation	79	51
Purchasing Controls	91	75
Nonconforming Product	97	77
Complaints	181	152
CAPA	266	195

Most Frequent Citations Issued by Medical Device Investigators 2015 - 2023



Common Pitfalls with CAPA

Verification of Effectiveness

- Verify or validate corrective/preventive action
  - to ensure that it is effective and
  - to ensure it does not adversely affect finished device

Investigator's Record Review

(Based on true events)

- A firm opens a CAPA after receiving an observation for inadequate complaint investigations
  - — Corrective actions include SOP revision and employee training
  - —At next inspection, the Investigator reviews this CAPA's effectiveness check…

Documenting Effectiveness Checks

No plan or acceptance criteria

This firm is verifying implementation but not effectiveness of the corrective action

The Complaint Procedure has been revised to include information on investigating complaints. Training records attached. Therefore, this CAPA is effective and can be closed.

Observation for Inadequate Effectiveness Checks

(Also based on true events)

Procedures for corrective and preventive action have not been adequately established.

Specifically, the effectiveness check plan for CAPA-27, initiated to address lack of established acceptance criteria in validation plans and protocols, did not include clearly defined acceptance or sampling criteria, and only reviewed one design change without further justification for the sample size selected.

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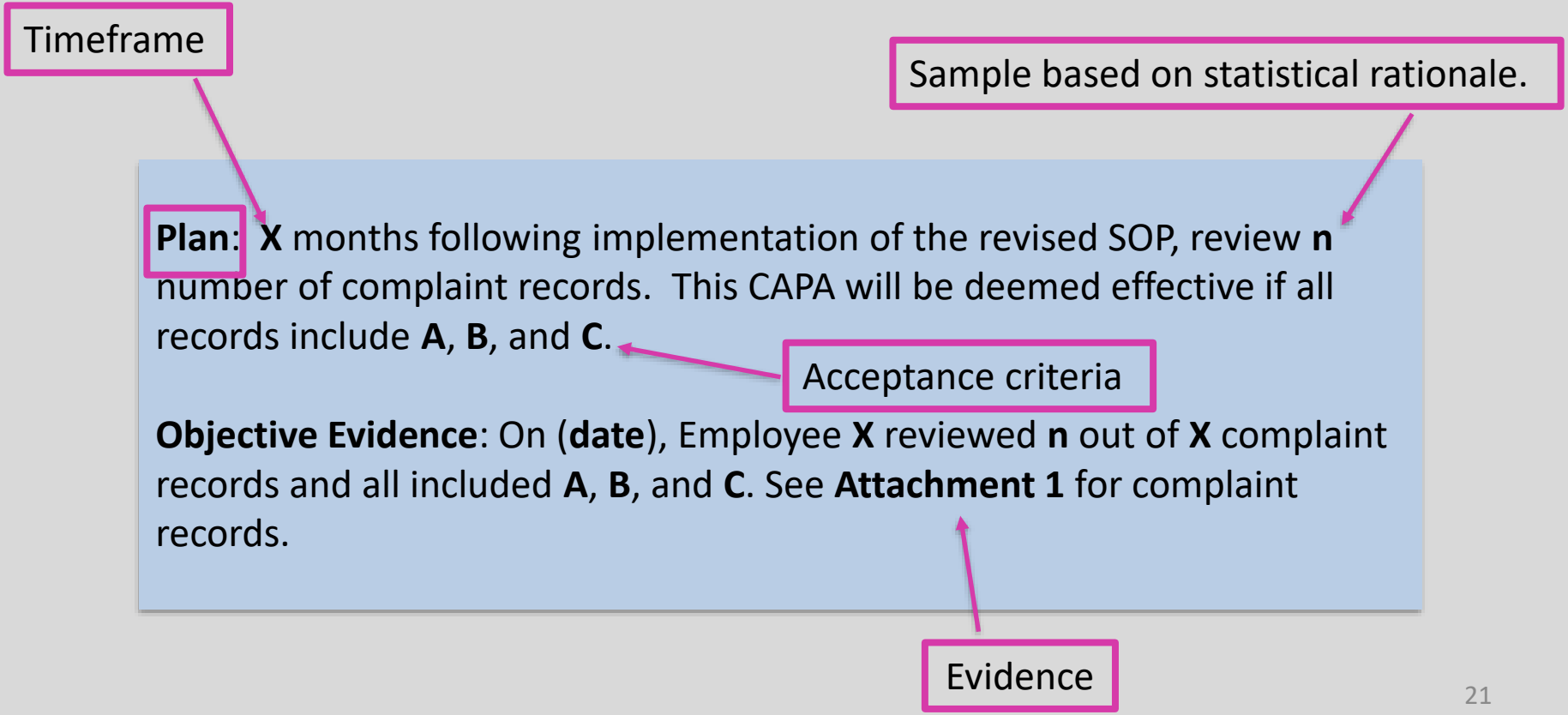
Documenting Effectiveness Checks



Knowledge Check

Which subsystem is most often cited by medical device investigators?

A. Production and Process Controls

B. CAPA

C. Design Controls

D. Management Controls

Knowledge Check

My firm will always receive a copy of the establishment inspection report (EIR) within 45 calendar days from the closeout meeting?

A. True

B. False

Resources

Slide Number	Cited Resource	URL
7	Inspectional Classifications	www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/inspection-classifications
12-14	Code of Federal Regulations, Title 21, Subchapter H (Medical Devices)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H
8	Field Management Directive (FMD-145): Release of the Establishment Inspection Report (EIR)	www.fda.gov/media/83055/download
15-19	Quality System Inspection Technique	www.fda.gov/files/Guide-to-Inspections-of-Quality-Systems.pdf
11	FDA Data Dashboard	datadashboard.fda.gov/ora/index.htm

Summary

- Medical device firms are most frequently cited for:
  - —Lack of/inadequate CAPA procedures
  - —Lack of/inadequate complaint handling procedures
- Annotating the 483 and/or responding in writing:
  - – Acknowledges your promise to correct deficiencies
  - – May affect the classification of the inspection

Questions

Your Call to Action

- Invite senior management, ask questions, and provide clarification at end-of-day summaries/wrap-ups so there are no surprises.
- Discuss your plans for correction with the Investigator during the closing and/or provide a written response.
- When completing CAPA effectiveness checks, ensure there is a plan with acceptance criteria based on statistical rationale and objective evidence.